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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, 2020
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	87-0342734
(State or other jurisdiction of incorporation or organization)	(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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

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, 2020, the aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was **$297,619,813**.

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 25, 2021, common shares outstanding were 3,645,760.**

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 differentiated by safety and improved patient outcomes. 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, Australia and New Zealand, 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 230 distributors, 118 of which purchased at least five thousand dollars in UTMD medical devices during 2020.

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 $126 million in the form of share repurchases, and an additional $63 million 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 55% of UTMD's consolidated 2020 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 2017, UTMD's UK subsidiary began to distribute its devices directly to medical facilities in France. In early 2019, UTMD acquired the remaining life of Femcare's exclusive U.S. distribution agreement for the Filshie Clip System from CooperSurgical Inc. In late 2020, UTMD's Australia subsidiary incorporated a New Zealand subsidiary in order to distribute devices directly to medical facilities in New Zealand.

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

DELTRAN® PLUS

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

GESCO®

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

A class of catheters called umbilical vessel catheters (UVCs) are specially designed for administering vital medications and fluids immediately following birth through the infant's umbilical vessel into the inferior vena cava. Because of the neonate's small size and lack of vascular development, there is no better access to vital organs. The catheters are also called umbilical artery catheters (UACs) when placed in one of the umbilical arteries to measure blood pressure or monitor metabolic processes through blood analysis. In developing its UMBILI-CATH™ product line, Gesco pioneered the use of soft, biocompatible silicone catheters, helping to reduce the number of insertions required as well as other complications associated with invasive applications. UTMD has expanded the UVC product line to include catheters made from a proprietary thermosensitive polyurethane (Tecoflex®) that offers many of the flexibility and biocompatibility advantages of silicone after insertion, with the greater rigidity of polyurethane preferred by many clinicians for insertion. In addition, GESCO provides a convenient catheterization procedure tray of instruments and supplies necessary to place UVC catheters, as well as perform other similar procedures.

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

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

In 2000, UTMD gained FDA premarketing clearance of a PICC family of products specifically designed to minimize trauma to the critically ill neonate, named PICC-NATE®. The PICC-NATE product line was designed with the input of experienced neonatal medical practitioners for use as a long-term indwelling catheter system for single-use, therapeutic central venous infusion of drug solutions, blood products or other fluids and for blood sampling. The soft, strong silicone PICC-Nate comes in two diameter sizes, 1.9 Fr and 3.0 Fr, and two hub configurations. In early 2003, UTMD added Tecoflex polyurethane versions in the same sizes that offer many of the flexibility and biocompatibility advantages of silicone after insertion, with the greater rigidity of polyurethane preferred by many clinicians for insertion. In late 2020, UTMD added a tiny 1.1Fr Tecoflex PICC-Nate.

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 Epitome Scalpel. Whereas the Epitome 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 2020, sales of Filshie Clips, applicators and accessories represented 31% 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 38 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 throughout 2020 was sold OUS directly by UTMD to medical facilities in Canada, Ireland, France, the UK and Australia, and through specialty distributors in other countries. Beginning in 4Q 2020, UTMD began to distribute the Filshie Clip System directly to New Zealand medical facilities. In February 2019, UTMD purchased the remaining exclusive U.S. distribution rights of CooperSurgical Inc. (CSI), allowing the Company 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." (OUS) 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 must work 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 trusted 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, 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 2020, UTMD sold components and finished devices to 139 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 Mexico, 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 2020, as a percentage of consolidated total USD sales, represented 39% compared to 41% in 2019. The lower OUS share of total sales in 2020 was the result of more restrictions on medical procedures OUS, especially in Europe, due to the COVID-19 pandemic. In USD terms, 58% of 2020 OUS sales were 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 2020, UTMD distributed directly to OUS medical facilities in Canada, the UK, France, Ireland, Australia and New Zealand. In addition, the Company's devices are sold in other countries OUS through over 230 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 2020 comprised 9% of total domestic direct sales.

In the U.S., Canada, Ireland, France, the UK, New Zealand 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 employee sales force is comprised primarily of "inside" representatives who operate by telephone and email from corporate offices. The Company also utilizes independent sales representatives on a commission basis. 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, New Zealand and Australia, and in 2020 sold to over 230 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 77% of UTMD's indirect OUS sales in the years of 2018 - 2020.

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, 2020, the Company had 181 employees, eight regular consultants, 24 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, some 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 165 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 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 profit-sharing 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 eight 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-one 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 if 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 2020, royalties included in cost of goods sold were $138. 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 2020 the Company received $20 in royalty income compared to $6 in 2019 and $76 in 2018.

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 the 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 2020, 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 pandemic, 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 2020 trade revenues in USD terms from customers OUS were $16,312 (39% of total sales) compared to $19,411 (41% of total sales) in 2019 and $20,806 (50% of total sales) in 2018. OUS trade sales (U.S. exports) from the U.S. to OUS customers were $4,626 in 2020, $4,322 in 2019 and $5,427 in 2018. U.S. exports represented 28%, 22% and 26% of total OUS trade sales in 2020, 2019 and 2018, 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 $3,008 as of January 1, 2021, compared to $1,627 as of January 1, 2020 and $3,164 as of January 1, 2019.

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 42-year history of shipping 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-eight years, including the last ten years following the acquisition of the Filshie Clip System, was $22 per year, well below the deductible level of product liability insurance policies. In its 42 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-eight 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 $7 per year. There has never been an adverse judgement against Femcare in over 13 million Filshie Clip implantations over a period of 37 years.

Other than the three Filshie Clip System claims, there have been no product liability lawsuits for any other UTMD device during the last nine years.

In summary, since 1993 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 what they consider a nominal amount in lieu of potentially substantial defense costs of discovery and 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 interference in the United States renders 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. Restrictions on "nonessential" medical procedures during a pandemic reduce the demand for certain of UTMD's medical devices.

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.

Group Purchasing Organizations (GPOs) add non-productive costs, weaken the Company's marketing and sales efforts and cause lower revenues by restricting access:

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. Despite rhetoric otherwise, 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 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 pandemic 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.

UTMD owns all of its property and facilities with the exception of a long-term lease with 11 years remaining on one section of its Midvale parking lot. As of the beginning of 2021, 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.

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.

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:

	2020		2019	
	High	Low	High	Low
1st Quarter	$ 109.99	$ 75.33	$ 102.46	$ 80.22
2nd Quarter	109.00	77.27	96.16	76.60
3rd Quarter	93.82	77.22	102.44	82.62
4th Quarter	94.87	78.90	112.26	100.23

Stockholders.

The number of beneficial stockholders of UTMD's common stock as of March 6, 2021 was at least 2,500.

Dividends.

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

Record Date	Payable Date	Per Share Amount
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
December 13, 2019	January 3, 2020	0.280
March 13, 2020	April 2, 2020	0.280
June 17, 2020	July 3, 2020	0.280
September 15, 2020	October 5, 2020	0.280
2019 total cash dividends paid per share		$ 1.100
2020 total cash dividends paid per share		$ 1.120

Issuer Purchases of Equity Securities.

UTMD purchased 80,000 shares of its common stock for $6,426 including commissions and fees in March 2020 and 7,000 shares of its common stock for $551 including commissions and fees in September 2020. UTMD purchased 5,000 shares of its common stock for $398 including commissions and fees in May 2019.

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, 2020, 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				
	2020	2019	2018	2017	2016
Net Sales	$42,178	$46,904	$41,998	$41,414	$39,298
Net Income	10,798	14,727	18,555	8,505	12,128
Earnings Per Common Share (Diluted)	2.94	3.94	4.95	2.28	3.22
Total Assets	111,745	109,787	99,768	92,745	76,191
Working Capital	58,471	51,438	55,643	43,909	31,451
Long-term Debt	0	0	0	0	0
Cash Dividends Per Common Share	1.120	1.100	1.085	1.065	1.045

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 $), the Great Britain Pound (GBP or £), the Euro (EUR or €), the Australian Dollar (AUD or A$), the New Zealand Dollar (NZD) and the Canadian Dollar (CAD or C$).

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

Overview.

The final calendar quarter (4Q) of 2020 continued a trend of financial recovery from the "COVID-19 depression" in 2Q 2020 caused by government policies restricting medical procedures deemed nonessential, such as tubal ligation and loop excision of the transformation zone in which a significant portion of the products of Utah Medical Products, Inc. (Nasdaq: UTMD) are focused.

UTMD management believes that the presentation of sequential 2020 quarterly comparisons provides meaningful supplemental information to both management and investors. Results for any given three month period in comparison with a previous year's same three month period may vary as a result of several factors: foreign currency exchange rates for sales invoiced in foreign currencies, uneven international distributor and OEM customer order patterns as a result of purchasing larger quantities of devices at a time, and the timing of ups and downs in government restrictions during the pandemic. The following table provides the sequential quarterly percentage changes in financial results for each income statement category, comparing the same periods in 2020 and 2019:

Consolidated Income Statement	1Q	2Q	3Q	4Q	Year
Worldwide Revenues	+ 1.6%	(25.8%)	(16.1%)	+ 1.5%	(10.1%)
Gross Profit	+ 0.9%	(34.0%)	(12.0%)	(7.0%)	(13.3%)
Operating Income	(5.8%)	(55.9%)	(17.9%)	(8.5%)	(22.3%)
Earnings Before Income Tax	(3.6%)	(56.7%)	(19.3%)	(9.5%)	(22.6%)
Net Income (US GAAP)	-	(62.8%)	(20.8%)	(21.7%)	(26.7%)
Earnings Per Share (US GAAP)	+ 0.4%	(62.0%)	(19.0%)	(19.8%)	(25.4%)

In summary, 4Q 2020 was UTMD's best revenue quarter of the year, almost 2% higher than the pre-pandemic 4Q 2019. Consolidated total worldwide revenues for the 2020 year were 10% lower than in 2019, after being down 26% in 2Q 2020. Direct to end user sales, which drive UTMD's overall profitability, were 14% lower for the 2020 year after being down 39% in the dismal 2Q 2020.

A comparison of 4Q and Year 2020 results with the results in the same periods of 2019, according to U.S. Generally Accepted Accounting Principles (US GAAP), is affected by some income tax provision adjustments not related to normal operations: 1) 4Q 2019 net income was increased $582 ($.156 increase in EPS) as a result of final adjustments made to state of Utah tax estimates following the December 2017 U.S. "Tax Cuts and Jobs Act" (TCJA), enacted in late 2017, and 2) 2Q 2020 net income was decreased $225 ($.061 decrease in EPS) by a long term deferred tax liability increase on the balance of Femcare intangible assets (the amortization of which is not tax-deductible in the UK) as a result of a change in the UK income tax rate. The $225 increase in deferred UK taxes over the next six years, according to US GAAP, must be booked in the quarter in which the tax law change was enacted. The UK decided to not reduce its corporate income tax rate from 19% to 17% beginning in 2Q 2020, as was previously enacted. UTMD management believes that the presentation of results excluding the unfavorable deferred tax liability adjustment to its 2Q 2020 net income and the favorable tax-related adjustments to 4Q 2019 net income provides meaningful supplemental information to both management and investors that is more clearly indicative of UTMD's operating results in 2020 compared to 2019. The non-US GAAP exclusion only affects Net Income and Earnings Per Share. All other income statement categories at and above the EBT line were unaffected by the tax provision adjustments.

Excluding the 2Q 2020 deferred tax liability increase and concomitant "one-time" income statement tax provision increase resulting from the enactment of the UK corporate income tax change, and favorable tax provision adjustments in 4Q 2019 related to the U.S. TCJA, UTMD's non-US GAAP Net Income and Earnings Per Share (EPS) quarterly percentage changes follow:

Consolidated Income Statement	1Q	2Q	3Q	4Q	Year
Net Income (Non-US GAAP)	-	(56.4%)	(20.8%)	(9.7%)	(22.1%)
EPS (Non-US GAAP)	+ 0.4%	(55.5%)	(19.0%)	(7.5%)	(20.7%)

In other words, ignoring the income tax provision adjustments in 4Q 2019 and 2Q 2020, all income statement categories improved sequentially during 2020 following the 2Q pandemic depression, compared to the same time periods in 2019.

Income statement results for the year 2020 compared to 2019 were as follows:

	2020	2019	Change
Net Sales	$42,178	$46,904	(10.1%)
Gross Profit (GP)	25,548	29,466	(13.3%)

Operating Income	13,708	17,632	(22.3%)
Income Before Tax (EBT)	13,840	17,884	(22.6%)
Net Income before tax adjustments	*11,023*	*14,145*	*(22.1%)*
Net Income per US GAAP	10,798	14,727	(26.7%)
EPS before tax adjustments	*3.002*	*3.784*	*(20.7%)*
Earnings per Share (EPS) per US GAAP	2.941	3.939	(25.4%)

Sales outside the U.S. (OUS) were more negatively affected by the reaction to the pandemic than inside the U.S., and have recovered more slowly. UTMD maintained its manufacturing operations in the U.S. and Ireland throughout the pandemic, without government assistance, in order to support important clinical needs of patients. Gross profit declined more than sales as a result of less absorption of fixed overheads and marginal costs associated with the pandemic including personal protective equipment for employees, cleaning supplies, extra pay to encourage employees to come to work, pay continuation beyond normal sick pay and accrued vacation pay for those quarantined with symptoms or exposed to someone with symptoms, lower productivity as a result of social distancing and higher costs levied by some suppliers and service providers.

The associated key 2020 profit margins (profits as a percentage of sales) compared to the 2019 calendar year follow:

	2020	2019
Gross Profit Margin (GPM)	60.6%	62.8%
Operating Income Margin	32.5%	37.6%
Income Before Tax Margin	32.8%	38.1%
Net Income Margin before TCJA tax adjusts	*26.1%*	*30.2%*
Net Income Margin per US GAAP	25.6%	31.4%

Operating Income, EBT and non-GAAP Net Income were leveraged further down from the lower GP due primarily to the fixed $6,470 noncash expense in 2020 resulting from amortizing Identifiable Intangible Assets (IIA) which resulted from the purchase of Femcare in 2011 and the remaining life of the U.S. exclusive distribution rights for the Filshie Clip System from CooperSurgical Inc. (CSI) in 2019. The IIA amortization expense in 2019 was only $6,089 because of a partial year of CSI IIA amortization and a stronger USD which reduced fixed GBP IIA amortization expense. Non-GAAP EPS declined less than Net Income due to share repurchases in 2020.

Net Income and EPS per U.S. Generally Accepted Accounting Principles (US GAAP) in both 2020 and 2019 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 2020 or 2019. Because of the tax estimate adjustments, in UTMD management's view, a comparison of US GAAP Net Income and EPS between 2020 and 2019 does not provide stockholders with meaningful insight about UTMD's financial performance. The non-GAAP results presented above eliminate the tax estimate adjustments from Net Income and EPS.

Measures of the Company's liquidity and overall financial condition improved as of the end of 2020 compared to the end of 2019 as the result of continued strong positive cash flow from normal operations, despite the negative performance comparison with the prior year. The Company's continued excellent positive cash flow in 2020 allowed it to increase cash dividends paid to stockholders, repurchase 87,000 UTMD shares in the open market and use $860 in cash to invest in new manufacturing equipment for a future need in addition to maintaining Property, Plant and Equipment (PP&E) in good working order.

In spite of a combined $11,952 in share repurchases, stockholder dividends and capital expenditures, UTMD's cash equivalent balances at the end of 2020 increased $8,804 to $51,590 from $42,787 at the end of 2019. Working capital increased $7,034 to $58,471at the end of 2020 from $51,438 at the end of 2019. Total liabilities increased $229. The Company remained without debt. UTMD's total debt ratio (total liabilities to total assets) was 8% at the end of both 2020 and 2019. Stockholders' Equity increased to $102,822 from $101,092 at the end of 2019, despite the $4,116 in 2020 cash dividends to stockholders and use of $6,976 for 2020 share repurchases, both of which reduce Stockholders' Equity.

Productivity of Fixed Assets and Working Capital Assets.
Assets.

Year-end 2020 total consolidated assets were $111,745 comprised of $62,262 in current assets, $11,326 in consolidated net PP&E and $38,157 in net intangible assets. This compares to $109,787 total assets at the end of 2019 comprised of $54,885 in current assets, $10,728 in consolidated net PP&E and $44,173 in net intangible assets. Total asset turns (total consolidated sales divided by average total assets for the year) in 2020 were 38% compared to 45% in 2019, as sales declined while assets increased.

Current assets increased $7,377 due to an $8,804 increase in year-end cash and investments, offset by $638 lower accounts and other receivables and $691 lower year-end inventories. Year-end 2020 and 2019 cash and investment balances were $51,590 and $42,787, representing 46% and 39% of total assets, respectively. Net (after allowance for doubtful accounts) year-end trade accounts receivable (A/R) balances were $592 lower at the end of 2020 compared to 2019. This was in spite of the fact that 4Q 2020 sales were higher than in 4Q 2019. Average days in A/R from date of invoice on December 31, 2020 was 31 compared to 36 days at December 31, 2019, based on 4Q 2020 and 4Q 2019 shipments respectively. A/R over 90 days from invoice date declined to less than 2% of total A/R at the end of 2020 from 3% at the end of 2019. The Company believes any older A/R will be collected or are within its reserve balances for uncollectible amounts. Although reducing inventories is difficult with a sudden decline in sales, UTMD was able to reduce its 2020 year-end inventories by 10% from the end of 2019, keeping pace with the 10.1% decline in annual sales.

Working capital (current assets minus current liabilities) at year-end 2020 was 14% higher at $58,471 compared to $51,438 at year-end 2019. Consistent with Federal and State rules, the TCJA repatriation tax current liability was only $80 at the end of 2020. The end of 2020 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, as well as continued payment of stockholder dividends and repurchase of UTMD shares.

December 31, 2020 net $11.3 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 $22 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 2020 net consolidated PP&E (depreciated book value of all fixed assets) increased $598 as a result of the combination of capital expenditures of $860, depreciation of $655 and the effect of FX rates on year-end foreign subsidiary asset balances.

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

	12-31-20	12-31-19
EUR	1.2228	1.1227

GBP	1.3663	1.3268
AUD	0.7708	0.7030
CAD	0.7841	0.7715

The year-end 2020 net book value (after accumulated depreciation) of consolidated PP&E was 33% of purchase cost. End-of-year PP&E turns (Net Sales divided by Net PP&E) was 3.7 in 2020 compared to 4.4 in 2019 due to 10% lower 2020 sales, higher USD asset values of foreign subsidiaries and investment in new PP&E assets needed for the future which are not in use yet. A future leverage in productivity of fixed assets which will not have to be further 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 $38,157 (34% of total assets) at the end of 2020 compared to $44,173 (40% of total assets) at the end of 2019. 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 2020 were net IIA of $11,410 and goodwill of $6,972. The accumulated amortization of Femcare IIA as of December 31, 2020 since the March 18, 2011 acquisition was $21,494. The remaining Femcare IIA will be fully amortized in 5 more years. The goodwill portion of intangible assets resulting from the Femcare acquisition, which is not amortized, increased $202 due to a stronger GBP at year-end. The GBP FX rate at December 31, 2020 increased 3.0% from December 31, 2019. In early 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 $8,474 has been amortized through year-end 2020. The remaining CSI IIA will be fully amortized in less than 3 more years. UTMD's goodwill balance from prior acquisitions including Femcare, Columbia Medical, Gesco and ABCorp was $14,163 at the end of 2020, 37% 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 2021. Amortization of IIA was $6,515 in 2020 compared to $6,144 in 2019. The difference was essentially a full year of amortization of the $21,000 IIA resulting from the acquisition of CSI remaining Filshie Clip System exclusive U.S. distribution rights compared to 11 months of amortization in 2019. The 2020 non-cash amortization expense of Femcare IIA was $2,049 (£1,595) compared to $2,037 (£1,595) in 2019. The Femcare IIA amortization USD difference was again due to the change in USD/GBP FX rate. The 2021 non-cash amortization expense (included as part of consolidated G&A operating expenses) of Femcare IIA will be £1,591, or $2,147 if the USD/GBP average FX rate is 1.35. In other words, the 2021 Femcare IIA amortization expense, despite a slightly lower GBP amount, will be about $100 higher because of a projected stronger GBP relative to the USD. The 2020 non-cash amortization expense of CSI IIA was $4,421 compared to $4,053 in 2019. The 2021 operating expense resulting from amortization of CSI IIA will again be $4,421.

Liabilities.

The remaining $2,074 balance of UTMD's $2,792 total repatriation tax liability from the TCJA is 74% instead of 76% (after the allowed 24% in the first three 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 final 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 2020 current liabilities were $343 higher than at the end of 2019. Ending accrued liabilities were $653 higher due to higher taxes payable and higher customer deposits. Total liabilities were $229 higher at the end of 2020 compared to the end of 2019. The resulting 2020 year-end total debt ratio at 8% was the same as at the end of 2019 because total assets in 2020 were proportionately higher.

The year-end 2020 DTL balance created as a result of the fifteen-year deferred tax consequence of the amortization of Femcare's IIA was $2,151, down from $2,239 at the end of 2019. The relatively small decline in this DTL considering the $2,049 in 2020 amortization of IIA was due to a 3% stronger GBP compared to the USD at the end of 2020 and the UK tax law change in 2Q 2020 which increased the remaining DTL $225. In addition to liabilities stated on the balance sheet, UTMD has operating lease and purchase obligations described in Note 14 and Note 12, respectively, to the financial statements.

Results of Operations.

a) Revenues.

Under accounting standards applicable for 2020, 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 medical facilities are substantially the same in the U.S., Canada, Ireland, UK, France, Australia and New Zealand.

UTMD may allow 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 2020 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. OUS sales are export sales from UTMD in the U.S. to customers outside the U.S. invoiced in USD, and sales from UTMD subsidiaries in Ireland, Canada, Australia and the UK which may be invoiced in EUR, GBP, CAD, AUD, NZD or USD. The term "trade" means sales to customers which are not part of UTMD. Each UTMD entity had 2020 intercompany sales of components and/or finished devices to other UTMD entities.

The following table shows the percent changes in 2020 quarterly revenues by sales channel compared to the same periods of time in 2019. Australia domestic sales included sales directly to New Zealand medical facilities beginning in 4Q 2020:

Revenues [USD denominated]	1Q	2Q	3Q	4Q	Year
U.S. domestic (excluding OEM)	+ 14.5%	(29.1%)	(8.0%)	(2.7%)	(7.5%)
Canada domestic	(21.7%)	(62.9%)	(5.6%)	(23.0%)	(29.7%)
Ireland domestic	(26.2%)	(48.6%)	(18.1%)	(31.3%)	(31.0%)
UK domestic	(11.2%)	(72.8%)	(34.4%)	(29.5%)	(36.2%)
France domestic	(11.8%)	(72.1%)	(12.3%)	(22.5%)	(29.8%)
Australia domestic	(8.6%)	(43.0%)	(13.6%)	(1.2%)	(16.7%)
Subtotal, Direct to End-User:	+4.2%	(39.1%)	(11.1%)	(8.8%)	(14.3%)
All Other OUS (Sales to Int'l Distributors)	(5.2%)	(4.5%)	(34.7%)	+ 39.9%	(3.4%)
U.S. OEM Sales	+ 0.7%	+ 9.5%	(8.9%)	(1.3%)	(0.8%)
Worldwide Revenues	+ 1.6%	(25.8%)	(16.1%)	+ 1.5%	(10.1%)

Global consolidated trade sales in 2020 were $42,178 compared to $46,904 in 2019 and $41,998 in 2018. The $4,726 (10.1%) lower sales in 2020 were primarily the result of restrictions on medical procedures that government officials worldwide deemed nonessential during the COVID-19 pandemic, presumably to conserve medical facility capacity. Total U.S. domestic sales were down $1,627 (5.9%) in 2020, at $25,866 compared to $27,493 in 2019. OUS sales were down $3,099 (16.0%) at $16,312 compared to $19,411 in 2019.

Domestic Sales.

U.S. domestic sales in 2020 were $25,866 (61% of total sales) compared to $27,493 (59% of total sales) in 2019. The components of the $1,627 lower 2020 domestic sales were $484 (7.1%) lower sales of the Filshie Clip System devices in the U.S., $51 (0.8%) lower sales of components and finished devices used in other companies' products (OEM customers), and $1,092 (7.7%) lower direct sales of all other UTMD non-Filshie finished devices to domestic end-users. Domestic sales in 2018 were $21,192.

Domestic Filshie Clip System sales in 2020 were 24% of total U.S. domestic sales compared to 25% in 2019. The month of April during 2Q 2020 had dramatically the lowest sales after the initial pandemic scare. The last seven months of 2020 were more consistent with 2019 monthly sales except for the month of October, at which time another scare seemed to occur. Looking forward to 2021, UTMD expects U.S. Filshie device sales will recover to an amount greater than in 2019, as only 11 months out of twelve in 2019 were direct to end-user sales. Unfortunately, a third scare seemed to occur in January as January 2021 sales took a dip lower than in any prior month in 2020 except for April and May.

Domestic OEM sales in 2020 were 25% of total U.S. domestic sales compared to 24% in 2019. UTMD sold components and finished devices to 139 different U.S. companies in 2020 compared to 147 companies in 2019 for use in their product offerings. Sales to UTMD's largest OEM customer represented 75% of total domestic OEM sales in both 2020 and 2019, with the slightly lower sales UTMD projected at the beginning of 2020 due to the customer's inventory build-up in 2019. Looking forward based on early fixed orders, UTMD expects that a substantial OEM sales increase will lead its domestic rebound in 2021.

Domestic direct (end-user) sales excluding the Filshie Clip System were about 51% of total U.S. domestic sales in both 2020 and 2019. Of UTMD's three main domestic direct product categories, neonatal products were $4,379 (6% lower), labor & delivery (L&D) products were $3,677 (9% lower), and gynecology/ electrosurgery/ urology products excluding the Filshie Clip System were $4,304 (11% lower).

OUS Sales.

Sales OUS in 2020 were $16,312 (16.0% lower) compared to $19,411 in 2019. OUS sales were $20,806 in 2018. Europe was particularly affected by government restrictions. In the UK, the region with the greatest decline in sales for the 2020 year, citizens are individually being told by government officials when they can leave their homes.

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. Although in recent years a stronger USD was responsible for lower OUS sales, the FX rate impact in 2020 was not a significant factor compared to the impact of the pandemic. UTMD's FX rates for income statement purposes are transaction-weighted averages. The average rates from the applicable foreign currency to USD during 2020 compared to 2019 follow:

	2020	2019	Change
GBP	1.291	1.277	+1.1%
EUR	1.146	1.119	+2.4%
AUD	0.692	0.696	(0.6%)
CAD	0.751	0.754	(0.3%)
	Sales weighted FX rate average change:		+0.2%

Consolidated sales in 2020 increased $99 due to the FX rate change.

Fifty-eight percent of (USD denominated) 2020 OUS sales were invoiced in foreign currencies compared to 66% in 2019. As a portion of total USD consolidated sales, 22% of UTMD's USD-equivalent sales were invoiced in foreign currencies in 2020 compared to 27% in 2019. The GBP, EUR, AUD and CAD converted sales represented 6%, 10%, 3% and 3% of total 2020 USD sales, respectively. This compares to 8% GBP, 11% EUR, 4% AUD and 4% CAD of total 2019 USD sales.

USD-denominated trade (excludes intercompany) sales of devices to OUS customers by UTMD's Ireland facility (UTMD Ltd) were $5,347 in 2020 (9% lower) compared to $5,894 in 2019. As the EUR was 2.4% higher relative to the USD in 2020, the FX impact added $67 to Ireland 2020 sales. In other words, constant currency sales were $5,279 (10% lower).

In 2020, UTMD's UK subsidiary, Femcare Ltd., had $3,437 trade sales of devices to domestic UK, domestic France and international distributor customers, down 36% compared to $5,382 in 2019. The FX impact added $47 in USD terms.

USD-denominated sales of devices to end-users in Australia by Femcare's Australia distribution subsidiary (Femcare Australia Pty Ltd) were 17% lower in 2020 compared to 2019. With a slightly weaker AUD (0.6%) in 2020, constant currency sales were down 16%.

USD-denominated sales of devices to end-users in Canada by UTMD's Canada distribution subsidiary (Utah Medical Products Canada, Inc.) were 30% lower in 2020 compared to 2019. The CAD was also only slightly weaker (0.3%) in 2020, so that constant currency sales were 29% lower.

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:

	2020	%	2019	%	2018	%
Obstetrics	$4,523	11	$5,000	11	$4,447	11
Gynecology/ Electrosurgery/ Urology	20,552	49	25,354	54	23,167	55
Neonatal	5,870	14	6,066	13	6,436	15
Blood Pressure Monitoring and Accessories*	11,233	26	10,484	22	7,948	19
Total:	$42,178	100	$46,904	100	$41,998	100

OUS revenues by product category:

	2020	%	2019	%	2018	%
Obstetrics	$ 846	5	$ 947	5	$ 698	3
Gynecology/ Electrosurgery/ Urology	9,934	61	13,731	71	15,022	72
Neonatal	1,490	9	1,412	7	2,252	11
Blood Pressure Monitoring and Accessories*	4,042	25	3,321	17	2,834	14
Total:	$ 16,312	100	$ 19,411	100	$20,806	100

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

Looking forward to 2021, the ability for medical facilities to return to more normal "nonessential" procedure rates remains highly uncertain due to ever changing government policies in combating a continuing coronavirus pandemic. After recovering well during the last seven months of 2020, U.S. Filshie device sales had another significant dip in January 2021. UTMD expects that, except for Canada, higher 2021 FX rates for its subsidiaries' foreign currency (GBP, EUR, AUD) sales will increase foreign currency sales in USD terms by about 4%. U.S. OEM sales, which have longer lead times due to less frequent larger orders, are more predictable and appear likely to be at least 10% higher in 2021. Although OUS distributor order patterns vary, UTMD's largest OUS distributor has placed its 2021 order for BPM devices that is $325 higher than in 2020. In summary, although UTMD has the capacity and is hoping to return to its $46.9 million consolidated revenue level realized in 2019, management's best estimate at this time is 2021 consolidated revenues between $45 and $46 million (compared to $42.2 million in 2020).

b) Gross Profit (GP).

UTMD's 2020 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 $25,548 (60.6% of sales) compared to $29,466 in 2019 (62.8% of sales) and $26,306 (62.6% of sales) in 2018. GP in 2020 declined $3,918 (13.3%) with a 10.1% decline in revenues.

The greater decline in GP than in sales was a result of UTMD's decision to not cut important manufacturing overhead resources in the same proportion as the decline in sales, which would sacrifice future capabilities just to maintain a short term GP margin (GPM). GPM = GP divided by sales. Although lower, the 60.6% GPM in 2020 margin remains healthy. With higher sales in 2021 and fewer costs associated with the pandemic, UTMD expects its consolidated 2021 GPM to improve to closer to that of 2019 and 2018.

In addition to the lower absorption of fixed manufacturing overhead costs in 2020, there were two other categories of increased costs that reduced the 2020 GPM by more than one percentage point: 1) marginal costs associated with the coronavirus pandemic including personal protective equipment for employees, cleaning supplies, extra pay to encourage employees to come to work, pay continuation beyond normal sick pay and accrued vacation pay for those quarantined with symptoms or exposed to someone with symptoms, lower productivity as a result of social distancing and higher prices levied by some suppliers and service providers, and 2) an unusually unfavorable year for UTMD's self-insured health care plan in the U.S.

UTMD's Ireland subsidiary's (UTMD Ltd's) GP was EUR 4,198 in 2020 compared to EUR 2,908 in 2019 and EUR 3,606 in 2018. The associated GPMs were 54.4% in 2020, 43.1% in 2019 and 49.8% in 2018. Femcare UK GP was GBP 1,495 in 2020 compared to GBP 3,884 in 2019 and GBP 5,010 in 2018. The UK 2020 GPM was 56.0% compared to 70.2% in 2019 and 71.7% in 2018. Femcare Australia and Femcare Canada are purely distribution facilities for UTMD finished devices in their respective countries. GP is the result of subtracting intercompany purchase prices of devices from sales. Australia GP was AUD 1,194 in 2020 (58.1% of sales) compared to AUD 1,415 in 2019 (57.7% of sales) and AUD 1,526 in 2018 (58.7% of sales). Canada GP was CAD 1,128 in 2020 (57.2% of sales), CAD 1,670 in 2019 (54.5% of sales) and CAD 1,999 in 2018 (60.0% of sales). In the U.S., GP was $17,043 in 2020, $19,180 in 2019 and $13,065 in 2018. UTMD U.S. GPMs were 54.2% in 2020, 57.1% in 2019 and 54.1% in 2018. A summation of the above GP of each subsidiary will not yield UTMD's consolidated total GP because of elimination of profit in inventory of intercompany goods.

c) Operating Income.

Operating Income results from subtracting operating expenses from GP. Operating Income in 2020 was $13,708 (32.5% of sales) compared to $17,632 (37.6% of sales) in 2019 and $18,697 (44.5% of sales) in 2018. On top of a lower GPM, the lower 2020 Operating Income margin additionally primarily reflected IIA amortization expense, included in General and Administrative (G&A) operating expenses, which was 15.3% of sales in 2020 compared to 13.0% in 2019. Excluding the non-cash Femcare and CSI IIA amortization expenses, UTMD consolidated operating expenses were $5,370 (12.7% of sales) in 2020 compared to $5,744 (12.2% of sales) in 2019 and $5,478 (13.0% of sales) in 2018. Even though UTMD was able to reduce 2020 operating expenses (excluding the IIA amortization) substantially, the lower operating expenses still diluted UTMD's Operating Income Margin slightly as they did not decline as much as sales declined.

The UTMD Ltd (Ireland) Operating Income margin in 2020 was 50.5% compared to 38.5% in 2019 and 45.9% in 2018. Femcare UK's 2020 Operating Income margin per US GAAP, which includes the IIA amortization expense of the 2011 acquisition, was negative compared to 27.8% in 2019 and 38.1% in 2018. Femcare Australia's 2020 Operating Income margin was 41.7% compared to 38.6% in 2019 and 45.4% in 2018. Femcare Canada's 2020 Operating Income margin was 40.7% compared to 41.9% in 2019 and 49.1% in 2018. UTMD's 2020 Operating Income margin in the U.S. was 28.5% compared to 33.7% in 2019 and 39.1% in 2018. For clarity, the CSI IIA amortization expense hit the U.S. Operating Income margin, and the Femcare IIA amortization expense hit the Femcare UK Operating Income margin.

Operating expenses include sales and marketing (S&M) expenses, product development (R&D) expenses and G&A expenses. Consolidated operating expenses were $11,840 (28.1% of sales) in 2020, $11,834 (25.2% of sales) in 2019 and $7,608 (18.1% of sales) in 2018. The following table provides a comparison of operating expense categories, as well as further segmentation of G&A expenses, for the last three years.

	2020	2019	2018
S&M expenses	$ 1,554	$ 1,738	$ 1,708
R&D expenses	486	483	454
G&A expenses:			
a) litigation expense provision	-	16	(8)
b) corporate legal	14	32	32
c) outside directors fees	116	118	109
d) stock option compensation	160	113	64
e) management bonus accrual	587	653	639
f) outside accounting audit/tax	223	216	238
g)Femcare IIA amortization	2,049	2,037	2,131
h) CSI IIA amortization	4,421	4,053	-
i) property & liability insurance premiums	95	91	126
j) all other G&A expenses	2,135	2,284	2,116
G&A expenses – total	9,800	9,613	5,447
Total Consolidated Operating Expense:	$ 11,840	$ 11,834	$ 7,608
Percent of sales:	28.1%	25.2%	18.1%

Description of Operating Expense Categories:

i) S&M expenses:

S&M expenses in 2020 were $1,554 (3.7% of 2020 sales) compared to $1,738 in 2019 (3.7% of 2019 sales) and $1,708 in 2018 (4.1% of 2018 sales). Due to social distancing, UTMD's trade show and associated travel expenses were $140 lower in 2020 than in 2019.

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 2018-2020 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 $486 (1.2% of sales) in 2020 compared to $483 (1.0% of sales) in 2019 and $454 (1.1% of sales) in 2018. 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 2020, 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 2020 were $9,800 (23.2% of sales) compared to $9,613 (20.5% of sales) in 2019 and $5,447 (13.0% of sales) in 2018. 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 identify certain specific categories of G&A expenses which might be of interest to stockholders. The management bonus expense in 2020 also included accruals for special bonuses paid during the year related to the COVID-19 pandemic, particularly to encourage employees to come to work in early 2020 when government incentives and media pressure was high for employees to stay at home. Actual management bonuses paid at the end of the year were on the average 25% lower than in 2019, which reflected a 23% lower consolidated EBT.

Amortization of the 2011 acquired Femcare IIA is part of G&A expenses. Although the IIA GBP amortization expense in 2020 was the same as in 2019, because of a slightly stronger GBP for the year as a whole, the USD 2020 IIA amortization expense was $12 higher than in 2019. The main impact was less absorption of the fixed GBP expense because of 10% lower sales in 2020. The resulting G&A noncash amortization expense of Femcare IIA was 4.9% of 2020 total consolidated sales compared to 4.3% of total consolidated 2019 sales and 5.1% of total 2018 sales. The Femcare IIA amortization expense will continue until March 2026 (or until the value of any remaining IIA becomes impaired). UTMD estimates that the Femcare IIA amortization expense in 2021 may be as much as $100 higher due to a stronger GBP.

The early 2019 $21,000 purchase of CSI exclusive Filshie Clip System U.S. distribution rights also represents an IIA which is being amortized on a straight line basis over the remaining life of the Femcare distribution agreement with CSI which would have been through 3Q 2023. This CSI IIA amortization expense is included in U.S. G&A expenses. In 2020, the CSI IIA amortization expense was $4,421 (10.5% of sales) compared to $4,053 in 2019 (8.6% of total sales), lowering UTMD's Operating Income margin by almost two full percentage points. This was the result of 10% lower sales in 2020 and one month less amortization expense in 2019. In 2021, the CSI IIA amortization expense will again be $4,421, but hopefully diluted by higher sales.

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 $132 in 2020 compared to $252 in 2019 and $761 in 2018. The non-operating income in 2018 included a $450 gain from the sales of assets which did not recur in 2019 or 2020. The lower non-operating income in 2020 compared to 2019 was essentially due to lower interest rates on UTMD's cash balances. A description of components of UTMD's non-operating income or expense follows:

1) Interest Expense. There was no interest expense in 2018-2020. Absent an acquisition or large repurchase of shares that requires new borrowing, UTMD does not expect any interest expense in 2021.
2) Investment of excess cash. Consolidated investment income (including gains and losses on sales of investments) was $64 in 2020 compared to $255 in 2019 and $248 in 2018. Interest rates in 2020 were practically zero. UTMD is not expecting this to change much in 2021.
3) Royalties. Royalties in 2020 were $20 compared to $5 in 2019 and $76 in 2018. 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 which was terminated in 2019. UTMD did not receive any royalty in 2019 after January because of the purchase of the CSI distribution agreement. Presently, there is one other arrangement which began in 2020 under which UTMD is receiving royalties on its technology.
4) Gains/ losses from remeasured currency in bank accounts. UTMD recognized $45 non-operating income in 2020 compared to an expense of $76 in 2019 and income of $13 in 2018 from gains or losses 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.
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 $10 in 2020 compared to $85 in 2019 and $3 in 2018.

EBT results from adding net non-operating income or subtracting net non-operating expense from Operating Income. Consolidated EBT was $13,840 (32.8% of sales) in 2020 compared to $17,884 (38.1% of sales) in 2019 and $19,458 (46.3% of sales) in 2018. The 2020 EBT of UTMD Ltd. (Ireland) was €3,728 (48.3% of sales) compared to €2,577 (38.2% of sales) in 2019 and €3,144 (43.4% of sales) in 2018. Femcare UK's 2020 EBT was (£593) compared to £1,566 (28.3% of sales) in 2019 and £2,896 (41.5% of sales) in 2018. Femcare AUS's 2020 EBT was AUD 857 (41.8% of sales) compared to AUD 952 (38.8% of sales) in 2019 and AUD 1,183 (45.5% of sales) in 2018. Femcare Canada's 2020 EBT was CAD 798 (40.5% of sales) compared to CAD 1,280 (41.8% of sales) in 2019 and CAD 1,632 (49.0% of sales) in 2018.

As a side note for clarity of financial results, UTMD's EBT, as well as all other income statement measures above the EBT line in the Income Statements, were unaffected by 2018 and 2019 adjustments to tax estimates of the repatriation tax and associated GILTI tax and FDII tax credit, all of which resulted from the TCJA enacted in December 2017, or the income tax rate change in the UK enacted in 2Q 2020 which increased UTMD's long term deferred tax liability.

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:

	2020	2019	2018
EBT	$13,840	$17,884	$19,458
Depreciation Expense	655	700	765
Femcare IIA Amortization Expense	2,049	2,037	2,130
CSI IIA Amortization Expense	4,421	4,053	0
Other Non-Cash Amortization Expense	45	54	60
Stock Option Compensation Expense	160	113	64
Remeasured Foreign Currency Balances	(45)	76	(13)
UTMD non-US GAAP EBITDA:	$21,125	$24,917	$22,464

In summary, UTMD's 2020 non-US GAAP EBITDA declined 15.2% compared to 2019, more in line with the change in GP than with the change in Operating Income or Net Income. This metric will also grow faster than an increase in sales in 2021.

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 2020 was $10,798 (25.6% of sales) compared to $14,727 (31.4% of sales) in 2019 and $18,555 (44.2% of sales) in 2018. Because of changes in tax estimates for the years 2018-2019 due to the TCJA enacted in December 2017, as well as an UK income tax change enacted in 2020, 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 income tax adjustments, 2020 non-US GAAP Net Income was $11,023 (26.1% of sales) compared to $14,145 (30.2% of sales) in 2019 and $15,504 (36.9% of sales) in 2018. Please see the table below which presents Net Income both according to US GAAP and also prior to recognition of the various tax estimate adjustments.

The US GAAP consolidated income tax provision rate for 2020 was 22.0% compared to 17.7% of EBT in 2019 and 4.6% of EBT in 2018. The non-US GAAP consolidated combined income tax provision rate for 2020 was 20.4% compared to 20.9% of EBT in 2019 and 20.3% of EBT in 2018. For clarity, the UK income tax rate change in 2020 from 17% to 19% added $225 to UTMD's 2020 income tax provision, representing the increased tax which will be due over the remaining life of amortization of Femcare's IIA, which is not a tax deductible expense in the UK. The income tax adjustment in 2019 subtracted $582 from UTMD's 2019 income tax provision, and the tax adjustment in 2018 subtracted $3,051from UTMD's 2018 income tax provision. As described in more detail in last year's SEC Form 10-K, the favorable 2018 and 2019 adjustments were due to UTMD's initial estimates of the income tax impact of the TCJA which were too high.

More normally and 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. For the three years 2018-2020, the non-US GAAP combined income tax rates ranged from 20.3% to 20.9%.

The UK had an income tax rate of 19% for all three years 2018-2020. The UK also allowed a tax deduction for sales of UK patented products which varied from year-to-year based on somewhat complicated rules which are sorted out for UTMD by independent UK tax specialists. The income tax rate for AUS was 30% for all three years. The income tax rate for Canada was about 26% for the three years. Profits of the Ireland subsidiary were 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 remember, in the U.S. the Federal income tax rate was changed after 2017 to 21% 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 a GILTI tax related to foreign income and FDII tax credit related to profits on export sales. The State income tax rate declined to 4.95% from 5% prior to the TCJA, and the State enacted income apportionment rules that provide for additional tax relief.

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 2020 per US GAAP were $2.941 ($3.002 prior to the UK deferred tax liability adjustment) compared to $3.939 ($3.784 prior to the State TCJA tax correction) in 2019 and $4.950 ($4.136 prior to the TCJA tax corrections) in 2018. Due to the COVID-19 pandemic, the 2020 non-US GAAP EPS result did not meet management's projection at the beginning of the year.

The 2020-ending weighted average number of diluted common shares (the number used to calculate diluted EPS) was 3,672 (in thousands) compared to 3,739 in 2019 and 3,749 in 2018. Dilution for "in the money" unexercised options for the year 2020 was 14 (in thousands) compared to18 shares in both 2019 and 2018. Actual outstanding common shares as of December 31, 2020 were 3,643.

UTMD management believes the presentation of Net Income and EPS results excluding the tax liability estimate adjustments in 2020, 2019 and 2018 provides meaningful supplemental information to both management and investors that is more clearly indicative of UTMD's bottom line results for comparison purposes.

US GAAP:

	2020	2019	2018
Net Income	$10,798	$14,727	$18,555
Net Income Margin	25.6%	31.4%	44.2%
EPS	$ 2.941	$ 3.939	$ 4.950

Non-US GAAP (excluding 2020 UK DTL change and TCJA tax adjustments in 2019 and 2018):

	2020	2019	2018
Net Income	$11,023	$14,145	$15,504
Net Income Margin	26.1%	30.2%	36.9%
EPS	$ 3.002	$ 3.784	$ 4.136

Please 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 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 2020 financial results, UTMD realized a substantial decline in revenues due to government restrictions of medical procedures in which UTMD's devices are used, particularly OUS. UTMD remained operating throughout the pandemic in 2020, without government subsidies (except in the UK), while incurring significant marginal expenses. Management decided to not cut overhead expenses in proportion to (what it has perceived as a relative short-term) decline in 2020 sales in order to protect the longer term interests of employees, suppliers, customers and stockholders.

Looking forward to 2021, because the COVID-19 and its variants do not recognize time periods, a significant lack of predictability of demand for UTMD's medical devices remains. Nevertheless, management believes that 2021 sales are likely to be higher than in 2020 but probably not as high as in 2019. Higher sales will allow an expansion of UTMD's GPM, and better absorption of the fixed IIA amortization expenses, giving leverage to profits. For the sake of specificity and as an example, UTMD estimates that an 8% increase in sales in 2021 will yield an 18% increase in EBT compared to 2020 results.

ROE

Maintaining a high ROE remains 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. The income tax estimate adjustments in all three years had an impact on the overall ROE ratios using US GAAP Net Income. UTMD's 2020 ROE before stockholder dividends (with US GAAP Net Income) was 10.6%. In comparison, 2019 ROE was 15.5% and 2018 ROE was 22.2%.

Before dividends, UTMD's 2020 ROE (using non-US GAAP Net Income) was 10.8% compared to 14.9% in 2019 and 18.6% in 2018, excluding the effect of the tax adjustments on Net Income. The lower 2020 ROE was the result of 22.1% lower non-US GAAP Net Income and 7.3% higher average Stockholders' Equity. Average Stockholders' Equity was $101,957 in 2020 compared to $95,042 in 2019 and $83,557 in 2018. UTMD's Stockholders' Equity has tripled over the last ten years despite being reduced by $37 million in dividends and $14 million in share repurchases over that same period of time.

Maintaining a high ROE with the dilutive effect of rapidly growing Average Stockholders' Equity (despite reductions from dividends and stock repurchases), while maintaining excellent Net Income results, suggests an excellent increase in stockholder value. UTMD's average ROE over the last 28 years was 25%.

Liquidity and Capital Resources

Cash Flows.

Although Net Profit was $3,930 lower in 2020 compared to 2019, net cash provided by operating activities in 2020, 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, was $3,080 higher than in 2019. Net cash provided by operating activities totaled $20,136 in 2020 compared to $17,056 in 2019 and $16,834 in 2018. Changes in 2020 cash from operating activities compared to 2019 changes (second order derivative) were largely related to the lower business activity resulting from restrictions on nonessential medical procedures during the pandemics, i.e. 1) a $1,354 higher amount of cash provided in 2020 compared to 2019 as a result of reducing trade accounts receivable (A/R) $617 instead of the $737 increase in 2019, and 2) a $2,609 higher amount of cash provided as a result of reducing inventories $923 instead of the $1,686 increase in 2019. Also related to less business activity, but offsetting cash provided by lower inventories and A/R, was a $422 reduction in cash provided as a result of a $308 decline in accounts payable instead of a $114 increase in 2019. Other activities which provided more cash in 2020 than in 2019 were 1) $371 higher noncash amortization expense, 2) $369 less reduction of deferred income taxes, 3) a $330 smaller reduction in the long term repatriation tax payable, and 4) $47 higher noncash stock-based compensation expense. A $607 increase in accrued expenses at the end of 2020 instead of a $1,651 decrease in 2019 also helped provide $2,259 more cash than in 2019.

In investing activities, during 2020 UTMD used $860 to purchase new molds and manufacturing equipment for new capabilities as well as to maintain and improve existing operating capabilities, compared to using $540 in 2019. On the other hand, in 2019 UTMD used $21,000 to purchase the remaining life of CSI's exclusive U.S. distribution rights for the Filshie Clip System. There was no similar acquisition in 2020.

In 2020 UTMD received $358 and issued 8,278 shares of stock upon the exercise of employee and director stock options. Option exercises in 2020 were at an average price of $43.26 per share. The Company received a $7 tax benefit from option exercises in 2020. UTMD repurchased 87,000 shares of its stock in the open market during 2020 at an average cost of $80.19 per share.

In comparison, 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. UTMD repurchased 5,000 shares of its stock in the open market during 2019 at an average cost of $79.52 per share.

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.

UTMD did not borrow in any of the three years 2018-2020. Cash dividends paid to stockholders were $4,116 in 2020 compared to $4,096 in 2019 and $4,026 in 2018.

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 2021 capital expenditures for ongoing operations are expected to be about the same in magnitude as depreciation of PP&E.

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

Management's Outlook.

UTMD remains relatively small compared to many other companies, 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 2021, 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 2020, the value of UTMD's stock declined 22%, ending the year at $84.30/ share, while $1.12 in cash dividends/ share were paid. In comparison, the DJIA, S&P 500 and NASDAQ (where UTMD is traded) indices were up 7%, 16% and 44% respectively in 2020.

In comparison, 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. The DJIA, S&P 500 and NASDAQ indices were up 22%, 29% and 35% respectively in 2019.

The UTMD stock price has declined during a calendar year only 5 other times in the last 22 years. The average compounded appreciation in UTMD stock value for the last 22 years, including the 2020 decline, was 12.3% per year, outpacing all of the major indices. Adding dividends, UTMD stockholder value increased at an annually compounded rate of 13.2% over the last 22 years.

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, 2020:

Contractual Obligations and Commitments	Total	2021	2022- 2023	2024-2025	2026 and thereafter
Long-term debt obligations	$ -	$ -	$ -	$ -	$ -
Operating lease obligations	497	62	90	90	255
Purchase obligations	2,794	2,755	39	-	-
Total	$ 3,291	$ 2,817	$ 129	$ 90	$ 255

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 .8178, .8907 and .8729 EUR per USD as of December 31, 2020, 2019 and 2018, respectively. Exchange rates were .7319, .7537 and .7837 GBP per USD as of December 31, 2020, 2019 and 2018, respectively. Exchange rates were 1.2974, 1.4226 and 1.4193 AUD per USD on December 31, 2020, 2019 and 2018, respectively. Exchange rates were 1.2754, 1.2962 and 1.3644 CAD per USD on December 31, 2020, 2019, and 2018, 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, 2020. 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, 2020.

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.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Utah Medical Products, Inc. (the Company) as of December 31, 2020 and 2019, 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, 2020, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements 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 for Femcare Group Limited, a wholly owned subsidiary. The portions not audited by us include assets of $28,666,000 and $40,845,000 as of December 31, 2020 and 2019, respectively and total revenues of $4,871,000 and $8,768,000 for the years ended December 31, 2020 and 2019, respectively. Those portions of the consolidated financial statements 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 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Evaluation of revenue recognition

Description of the Matter:

As discussed in Notes 1 to the consolidated financial statements, the Company is party to contractual performance obligations which include sales to domestic and foreign countries. Auditing management's assessment and recognition of revenue can be complex, involves judgment, and is based on a thorough understanding of the Company's contracts.

How We Addressed the Matter in Our Audit:

We evaluated the design and implementation of certain internal controls over the Company's estimation of the costs to be incurred in satisfying performance obligations including walkthroughs of the key controls. We selected certain performance obligations and read the underlying contract with the customer, evaluated the determination of the method for measuring revenue, confirmed certain foreign transactions with customers and agreed recorded amounts of revenue to shipping documents, invoices and where collection has occurred, to cash receipts.

/s/ Haynie & Company

Haynie & Company
Salt Lake City, Utah
March 26, 2021

We have served as the Company's auditor since 2018.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the consolidated balance sheets of Femcare Group Limited (the Company), including its subsidiaries, as of December 31, 2020 and 2019, and the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

The accounting policy in respect of revenue is that revenue is recognised to the extent that it is probable that the economic benefits will flow to the Company and the revenue can be reliably measured. Revenue is measured as the fair value of the consideration received or receivable, excluding discounts, rebates, value added tax and other sales taxes.

We identified the assessment of the revenue as a critical audit matter due to its inherent risk of understatement.
The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's process for dispatching goods and raising invoices to customers. We tested a sample of orders during the year to establish that these were dispatched and invoiced. We evaluated the Company's determination of the recoverability of any unpaid receivables at 31 December 2020.

We also identified the assessment of the valuation of intangible assets as a critical audit matter. Intangible assets are valued at cost and amortised using the straight-line method over the useful economic life of the asset. Goodwill is carried at cost and tested for impairment annually. We identified the valuation of intangible assets and goodwill as a critical audit matter due to their materiality to the financial statements. We reviewed and tested the Company's calculations in respect of amortisation and evaluated the Company's determination of the carrying value as at 31 December 2020.

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

Reading, United Kingdom
March 26, 2021

UTAH MEDICAL PRODUCTS, INC.
CONSOLIDATED BALANCE SHEETS AS OF
DECEMBER 31, 2020 AND 2019
(in thousands)

	2020	2019
ASSETS		
Current assets:		
Cash	$ 51,590	$ 42,787
Accounts & other receivables, net (note 2)	4,104	4,742
Inventories (note 2)	6,222	6,914
Prepaid expenses and other current assets	346	443
Total current assets	62,262	54,886
Property and equipment, net (notes 4 and 10)	11,326	10,728
Goodwill	14,164	13,961
Other intangible assets (note 2)	56,159	55,205
Other intangible assets - accumulated amortization	(32,166)	(24,993)
Other intangible assets, net (note 2)	23,993	30,212
Total assets	$ 111,745	$ 109,787
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 788	$ 1,098
Accrued expenses (note 2)	3,003	2,350
Total current liabilities	3,791	3,448
Long term lease liability	335	376
Long term income tax payable (REPAT tax) (note 7)	1,995	2,110
Deferred tax liability - intangible assets	2,151	2,239
Deferred income taxes (note 7)	651	521
Total liabilities	8,923	8,694
Commitments and contingencies (note 6 and 12)	0	0
Stockholders' equity:		
Common stock, $0.01 par value; 50,000 shares authorized, 3,643 shares issued and outstanding in 2020 and 3,722 shares in 2019	36	37
Accumulated other comprehensive loss	(8,281)	(9,782)
Additional paid-in capital	115	18
Retained earnings	110,952	110,820
Total stockholders' equity	102,822	101,093
Total liabilities and stockholders' equity	$ 111,745	$ 109,787

See accompanying notes to financial statements.

UTAH MEDICAL PRODUCTS, INC.
CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME FOR THE YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018
(In thousands, except per share amounts)

	2020	2019	2018
Sales, net (notes 1, 3, 9 and 11)	$ 42,178	$ 46,904	$ 41,998
Cost of goods sold	16,630	17,438	15,692
Gross profit	25,548	29,466	26,306
Operating expense:			
Sales and marketing	1,554	1,738	1,708
Research and development	486	483	454
General and administrative	9,800	9,613	5,447
Operating income	13,708	17,632	18,697
Other income (expense):			
Dividend and interest income	112	254	217
Gains on investments	-	-	32
Royalty income (note 12)	20	6	76
Other, net	-	(8)	437
Income before provision for income taxes	13,840	17,884	19,459
Provision for income taxes (note 7)	3,042	3,157	904
Net income	$ 10,798	$ 14,727	$ 18,555
Earnings per common share (basic) (note 1)	$ 2.95	$ 3.96	$ 4.97
Earnings per common share (diluted) (note 1)	$ 2.94	$ 3.94	$ 4.95
Other comprehensive income (loss):			
Foreign currency translation net of taxes of $0 in all periods	$ 1,502	$ 1,507	$ (2,949)
Total comprehensive income	$ 12,300	$ 16,234	$ 15,606

See accompanying notes to financial statements.

UTAH MEDICAL PRODUCTS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOW FOR THE
YEAR ENDED DECEMBER 31, 2020, 2019 AND 2018
(In thousands)

	2020	2019	2018
Cash flows from operating activities:			
Net income	$ 10,798	$ 14,727	$ 18,555
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	655	700	765
Amortization	6,515	6,144	2,191
Gain on investments	-	-	(32)
Provision for losses on accounts receivable	(5)	14	20
Amortization of operating lease assets	39	38	-
Loss/(Gain) on disposal of assets	1	16	(410)
Deferred income taxes	(26)	(396)	(326)
Stock-based compensation expense	160	113	64
Tax benefit attributable to exercise of stock options	7	23	49
(Increase) decrease in:			
Accounts receivable	617	(738)	(496)
Other receivables	45	(16)	-
Inventories	924	(1,686)	(244)
Prepaid expenses and other current assets	108	(16)	(68)
Increase (decrease) in:			
Accounts payable	(308)	114	52
Accrued expenses	607	(1,651)	(558)
Long-term repatriation tax payable	-	(330)	(2,728)
Net cash provided by operating activities	20,137	17,056	16,834
Cash flows from investing activities:			
Capital expenditures for:			
Property and equipment	(860)	(540)	(402)
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	(860)	(21,540)	534
Cash flows from financing activities:			
Proceeds from issuance of common stock - options	358	283	454
Common stock purchased and retired	(6,976)	(398)	(1,205)
Dividends paid	(4,116)	(4,112)	(4,026)
Net cash (used in) financing activities	(10,734)	(4,227)	(4,777)
Effect of exchange rate changes on cash	260	386	(1,354)

Net increase (decrease) in cash and cash equivalents	8,803	(8,325)	11,237
Cash at beginning of year	42,787	51,112	39,875
Cash at end of year	$ 51,590	$ 42,787	$ 51,112
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the period for income taxes	$ 3,186	$ 5,304	$ 4,851
Cash paid during the period for interest	-	-	-

See accompanying notes to financial statements.

UTAH MEDICAL PRODUCTS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018
(In thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Retained	Total Stockholders'
	Shares	Amount	Capital	Income	Earnings	Equity
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
Shares issued upon exercise of employee stock options for cash	8	-	358	-	-	358
Stock option compensation expense	-	-	160	-	-	160
Common stock purchased and retired	(87)	(1)	(421)	-	(6,555)	(6,976)
Foreign currency translation adjustment	-	-	-	1,502	-	1,502
Common stock dividends	-	-	-	-	(4,112)	(4,112)

Net income	-	-	-	-	10,798	10,798
Balance at December 31, 2020	3,643	$ 36	$ 115	$ (8,280)	$ 110,951	$ 102,822

See accompanying notes to financial statements.

Utah Medical Products, Inc.
Notes to Consolidated Financial Statements
Years Ended December 31, 2020, 2019 and 2018

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, 2020 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, 2020 except under an extreme global financial crisis.

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, 2020, using the 2020 year-end 1.3663 USD/GBP and0.7708 USD/AUD currency exchange rates, is about $6,544 in 2021, $6,542 in 2022, $5,805 in 2023, $2,121 in 2024, and $2,121 in 2025 (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 2021-2022, and $3,684 in 2023 (see note 15).

Stock-Based Compensation

At December 31, 2020, 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 2020, the Company recognized $160 in stock-based compensation cost compared to $113 in 2019 and $64 in 2018.

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.

The Company accounts for deferred taxes under ASU 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes, which requires that all deferred income taxes are classified as noncurrent in a classified statement of financial position.

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, 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.

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 two years 2018 through 2019. In 2020 the Company paid tax penalties of $4.

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, 2020 and 2019 was $113 and $113, 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:

	2020	2019	2018
Weighted average number of shares outstanding – basic	3,658	3,721	3,730
Dilutive effect of stock options	14	18	18
Weighted average number of shares outstanding, assuming dilution	3,672	3,739	3,748

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 2020 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.

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Note 2 – Detail of Certain Balance Sheet Accounts

	December 31, 2020	December 31, 2019
Accounts and other receivables:		
Accounts receivable	$ 4,224	$ 4,835
Accrued interest and other	14	43
Less allowance for doubtful accounts	(134)	(136)
Total accounts and other receivables	$ 4,104	$ 4,742
Inventories:	.	
Finished products	$ 1,363	$ 1,708
Work-in-process	1,375	1,023
Raw materials	3,484	4,183
Total inventories	$ 6,222	$ 6,914
Goodwill:		
Balance as of January 1	$ 13,961	$ 13,703
Effect of foreign exchange	203	258
Subtractions as a result of impairment	-	-
Total Goodwill as of December 31	$ 14,164	$ 13,961
Other identifiable intangible assets:		
Patents	$ 2,201	$ 2,194
Non-compete agreements	137	133
Trademarks & trade names	10,021	9,738
Customer relationships	9,769	9,486
Distribution agreements	21,000	21,000
Regulatory approvals & product certifications	13,031	12,654
Total Other Identifiable Intangible Assets	56,159	55,205
Accumulated amortization	(32,166)	(24,993)
Other Identifiable Intangible Assets, Net	$ 23,993	$ 30,212
Accrued expenses:		
Income taxes payable	$ 3	$ 453
Payroll and payroll taxes	946	1,032
Reserve for litigation costs	113	113
Other	1,941	752
Total accrued expenses	$ 3,003	$ 2,350

Note 3 – Quarterly Results of Operations (Unaudited)

	Unaudited Quarterly Data for 2020			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net Sales	$ 10,902	$ 8,787	$ 10,479	$ 12,010
Gross Profit	6,836	4,950	6,497	7,265
Net Income	3,140	1,313	2,933	3,412
Earnings Per Common Share (Diluted)	0.84	0.36	0.80	0.94

	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)	0.84	0.94	0.99	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	0.91

Note 4 – Property and Equipment

Property and equipment consists of the following:

	December 31,	
	2020	2019
Land	$ 1,725	$ 1,671
Buildings and improvements	14,531	13,887
Furniture, equipment and tooling	16,750	16,254
Right of Use Asset	377	414
Construction-in-progress	527	372
Total	33,910	32,598
Accumulated depreciation	(22,584)	(21,870)
Property and equipment, net	$ 11,326	$ 10,728

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, 2020			
	U.S. & Canada	England & Australia	Ireland	Total
Land	$ 621	$ 684	$ 420	$ 1,725
Buildings and improvements	6,523	3,443	4,565	14,531
Furniture, equipment and tooling	14,632	761	1,357	16,750
Right of Use Asset	361	-	16	377
Construction-in-progress	36	-	491	527
Total	22,173	4,888	6,849	33,910
Accumulated depreciation	(17,934)	(974)	(3,676)	(22,584)
Property and equipment, net	$ 4,239	$ 3,914	$ 3,173	$ 11,326

	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	$ 4,104	$ 3,984	$ 2,640	$ 10,728

Note 5 – Long-term Debt

None in 2019 and 2020.

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, 2020 or December 31, 2019.

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.

Note 7 – Income Taxes

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

	December 31,		
	2020	2019	2018
Inventory write-downs and differences due to UNICAP	$ 86	$ 84	$ 60
Allowance for doubtful accounts	32	33	18
Accrued liabilities and reserves	68	55	62
Depreciation and amortization	(3,034)	(2,933)	(3,216)
Deferred income taxes, net	$ (2,848)	$ (2,761)	$ (3,076)

The components of income tax expense are as follows:

	Years ended December 31,		
	2020	2019	2018
Current	$ 3,253	$ 3,467	$ 1,386
Deferred	(211)	(310)	(482)
Total	$ 3,042	$ 3,157	$ 904

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

	Years ended December 31,		
	2020	2019	2018
Federal income tax expense at the statutory rate	$ 1,915	$ 2,512	$ 2,127
State income taxes	369	(124)	365
Foreign income taxes (blended rate)	550	985	1,607
ETI, manufacturing deduction and tax credits	(7)	(9)	(146)
Deemed repatriation transition tax	263	(266)	(3,230)
US Taxes on foreign income	(35)	59	179
Other	(13)	-	2
Total	$ 3,042	$ 3,157	$ 904

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

	Years ended December 31,		
	2020	2019	2018
Domestic	$ 9,031	$ 11,549	$ 10,130
Foreign	4,809	6,335	9,329
Total	$ 13,840	$ 17,884	$ 19,459

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 426 thousand shares of common stock, of which 69 thousand are outstanding as of December 31, 2020. 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
2020		
Granted	26	$ 77.05 - 77.05
Expired or canceled	1	58.50 - 77.05
Exercised	8	26.52 - 74.64
Total outstanding at December 31	69	26.52 - 77.05
Total exercisable at December 31	33	26.52 - 74.64

	Shares (000's)	Price Range Per Share
2019		
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

	Shares (000's)	Price Range Per Share
2018		
Granted	22	$ 74.64 - 74.64
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

For the years ended December 31, 2020, 2019 and 2018, the Company reduced current income taxes payable by $7, $23 and $49, 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 2020, the Company recognized $160 in equity compensation cost, compared to $113 in 2019 and $64 in 2018.

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,		
	2020	2019	2018
Expected dividend amount per quarter	$ 0.2943	$ -	$ 0.2875
Expected stock price volatility	27.5%	-	27.5%
Risk-free interest rate	0.56%	-	2.57%
Expected life of options	5.3 years	-	4.9 years

The per share weighted average fair value of options granted during 2020 is $16.17and in 2018 is $15.77. No options were granted in 2019.

All UTMD options vest over a four-year service period. At December 31, 2020 there was $432 total unrecognized compensation expense related to non-vested stock options under the plans. A $164 portion of the cost is expected to be recognized over the next twelve months, and the remaining $267 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, 2020:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 26.52 - 58.50	23,270	4.07	$ 49.99	23,270	$ 49.99
74.64 - 77.05	45,766	8.68	76.00	9,516	74.64
$ 26.52 - 77.05	69,036	7.13	$ 67.23	32,786	$ 57.15

	2020	2019	2018
Intrinsic Value of Stock Options Exercised	$ 371	$ 354	$ 812
Intrinsic Value of Stock Options Outstanding	$ 1,178	$ 2,553	$ 1,605

Note 9 – Geographic Information

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

	2020	2019	2018
United States	$ 25,866	$ 27,493	$ 21,192
Europe	6,399	8,906	9,160
Other	9,913	10,505	11,646

Note 10 – Long-lived Assets by Geographic Area

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

	2020	2019	2018
United States	$ 23,327	$ 27,605	$ 10,309
England	21,871	23,548	24,892
Ireland	3,173	2,639	2,543
Australia	440	423	447
Canada	672	686	676

Note 11 – Revenues by Product Category and Geographic Region

Global revenues by product category:

	2020	2019	2018
Obstetrics	$ 4,523	$ 5,000	$ 4,447
Gynecology/ Electrosurgery/ Urology	20,552	25,354	23,167
Neonatal	5,870	6,066	6,436
Blood Pressure Monitoring and Accessories	11,233	10,484	7,948
Total:	$ 42,178	$ 46,904	$ 41,998

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

	2020	2019	2018
Obstetrics	$ 846	$ 947	$ 698
Gynecology/ Electrosurgery/ Urology	9,934	13,731	15,022
Neonatal	1,490	1,412	2,252
Blood Pressure Monitoring and Accessories	4,042	3,321	2,834
Total:	$ 16,312	$ 19,411	$ 20,806

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 2020, 2019 and 2018, UTMD received royalties of $20, $6 and $76, respectively, for the use of intellectual property.

UTMD had $3,286 in operating lease and purchase commitments as of December 31, 2020.

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 $167, $171 and $160 for the years ended December 31, 2020, 2019 and 2018, respectively.

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 11 years and on the automobile it is 12 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, 2020
Operating Lease Cost (*in thousands*)	$61
Right of Use Assets obtained in exchange for new operating lease obligations	$0

Other Information	As of December 31, 2020
Weighted Average Remaining Lease Term - Operating Leases	10 years
Weighted Average Discount Rate – Operating Leases	5.4%

Operating lease liabilities/ payments (*in thousands*)

Operating lease payments, 2021	$60
Operating lease payments, 2022	$45
Operating lease payments, 2023	$45
Operating lease payments, 2024	$45
Operating lease payments, 2025	$45
Thereafter	$254

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

Total operating lease liabilities/ payments	$494
Operating lease liabilities – current (included in Accrued Expenses)	$41
Operating lease liabilities – long term	$335
Present value adjustment	$118

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

Year ending December 31,	
2021	$41
2022	$27
2023	$29
2024	$30
2025	$32
Thereafter	$218

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.

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 2020.

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

	2020	2019	2018
Numerator *(in thousands)*			
Net income	10,798	14,727	18,555
Denominator			
Weighted average shares, basic	3,658	3,721	3,730
Dilutive effect of stock options	14	18	18
Diluted shares	3,672	3,739	3,748
Earnings per share, basic	2.95	3.96	4.97
Earnings per share, diluted	2.94	3.94	4.95

Note 17 – Recent Accounting Pronouncements

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.

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, 2020 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 2020, 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, 2020, 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, 2020. Management's report appears on page 36 of this Form 10-K under the caption "Management's Report on Internal Control Over Financial Reporting" and is 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, 2020, 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 2021 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: 2020 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. 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 2021 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 2021 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 2021 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 2021 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 2021 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 #	Title of Document	Location
3.1	Articles of Restatement of the Articles of Incorporation	Incorporated by Reference (1)
3.2	Articles of Correction to the Restated Articles of Incorporation	Incorporated by Reference (1)
3.3	Bylaws	Incorporated by Reference (2)
10.1	Employment Agreement dated December 21, 1992 with Kevin L. Cornwell*	Incorporated by Reference (6)
10.2	Amendment, effective May 15, 1998, to Employment Agreement dated December 21, 1992 with Kevin L. Cornwell*	Incorporated by Reference (6)
10.3	Utah Medical Products, Inc., 2003 Employees' and Directors' Incentive Plan*	Incorporated by Reference (7)
10.4	Utah Medical Products, Inc., 2013 Employees' and Directors' Incentive Plan*	Incorporated by Reference (8)
10.5	Summary of Officer and Director Compensation	This filing
21	Subsidiaries of Utah Medical Products, Inc.	This filing
23.1	Consent of Haynie & Company, UTMD's independent auditors for the years ended December 31, 2020 and December 31, 2019	This filing
23.2	Consent of Nortons Assurance Limited, Femcare Group Limited's independent auditors for the years ended December 31, 2020 and December 31, 2019	This filing
31.1	Certification of CEO pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	This Filing
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	This Filing
32.1	Certification of CEO pursuant to 18 U.S.C. §1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	This Filing
32.2	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	This Filing
101	The following financial information from the Utah Medical Products, Inc. Annual Report on Form 10-K for the fiscal year ended December 31, 2020, formatted in Inline Extensible Business Reporting Language (iXBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income and Comprehensive Income, (iii) Consolidated Statements of Cash Flow, (iv) Consolidated Statements of Stockholders' Equity, and (v) related Notes to the Consolidated Financial Statements, tagged in detail.	This Filing
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL 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 annual report on form 10-K filed with the Commission for the year ended December 31, 2003.
(4) Incorporated by reference from the Company's 2003 definitive proxy statement on form DEF 14A filed with the Commission on March 27, 2003.
(5) 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 26th day of March 2021.

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 26th day of March 2021.

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

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