

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, 2021

OR

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

For the transition period from _____ to _____

Commission File No. 001-12575

UTAH MEDICAL PRODUCTS INC

(Exact name of Registrant as specified in its charter)

Utah

(State or other jurisdiction of incorporation or organization)

87-0342734

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

7043 South 300 West

Midvale, Utah 84047

(Address of principal executive offices) (Zip Code)

(801) 566-1200

(Registrant's telephone number, including area code)

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

Title of each class:
Common stock, \$0.01 par value

Trading Symbol:
UTMD

Name of each exchange on which registered:
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

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

Indicate by check mark whether the registrant 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, 2021, the aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was **\$286,135,700**.

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 24, 2022, common shares outstanding are 3,654,987.**

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.

INDEX TO FORM 10-K

	<u>PAGE</u>
<u>PART I</u>	
<u>Item 1</u>	<u>Business</u> 1
<u>Item 1A</u>	<u>Risk Factors</u> 15
<u>Item 1B</u>	<u>Unresolved Staff Comments</u> 17
<u>Item 2</u>	<u>Properties</u> 17
<u>Item 3</u>	<u>Legal Proceedings</u> 17
<u>Item 4</u>	<u>Reserved</u> 17
<u>PART II</u>	
<u>Item 5</u>	<u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> 18
<u>Item 6</u>	<u>Selected Financial Data</u> 19
<u>Item 7</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> 20
<u>Item 7A</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 35
<u>Item 8</u>	<u>Financial Statements and Supplementary Data</u> 35
<u>Item 9</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u> 54
<u>Item 9A</u>	<u>Controls and Procedures</u> 54
<u>Item 9B</u>	<u>Other Information</u> 54
<u>PART III</u>	
<u>Item 10</u>	<u>Directors, Executive Officers and Corporate Governance</u> 55
<u>Item 11</u>	<u>Executive Compensation</u> 55
<u>Item 12</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> 55
<u>Item 13</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u> 55
<u>Item 14</u>	<u>Principal Accounting Fees and Services</u> 55
<u>PART IV</u>	
<u>Item 15</u>	<u>Exhibits, Financial Statement Schedules</u> 56
<u>Item 16</u>	<u>Form 10-K Summary</u> 56
<u>SIGNATURES</u>	57

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. Throughout this report, “the Company” refers jointly to Utah Medical Products, Inc. and all of its subsidiaries. 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) relationship 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 medical devices 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 (NZ), 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 220 distributors, 115 of which purchased at least five thousand dollars in UTMD medical devices during 2021.

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 \$125 million in the form of share repurchases, and an additional \$73 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 51% of UTMD's consolidated 2021 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. In 2021, due to BREXIT, Utah Medical Products Ltd in Ireland began distributing devices directly to medical facilities in France in lieu of the UK.

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 thirty years the most widely accepted transducer-tipped system. 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 pressure 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, introduced in 1991, 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. Subsequent enhancements to INTRAN PLUS included a viewport which allows physicians to observe amniotic fluid in a closed system along with alternative configurations for user preferences in tip size, zero switch/button location and amniotic fluid visualization.

In addition, adjunct tocodynamometer belts are provided by UTMD. Abcorp toco belts and straps for fetal monitoring by an external tocodynamometer are provided in latex-free form in several configurations. 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.

UTMD markets tocodynamometer belts, catheters and accessories, but does not market electronic monitors, the capital equipment that processes the electrical signals. UTMD continues to investigate the feasibility of tools that enhance fetal monitoring techniques.

Specialized Labor & Delivery Tools.

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.

The CVX-RIPE™ catheter is designed to mechanically improve the favorability of the cervix of pregnant patients at term gestation, for whom induction of labor is medically indicated. 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.

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 device 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.

Vacuum-Assisted Delivery (VAD) Systems.

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 about 3% 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.

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 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 venous 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.

[Table of Contents](#)

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.

PICC-NATE® is a percutaneous intraepithelial central venous catheter family of devices specifically designed to minimize trauma to the critically ill neonate. The 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 for securement. 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. Recently, UTMD also added a tiny 1.1Fr Tecoflex PICC-Nate.

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. UTMD added dispensing syringes with interlocking connectors to its NUTRI-CATH/NUTRI-LOK family of enteral feeding devices. UTMD further expanded the NUTRI-LOK system with specialty extension sets for GI tubes and for continuous connection to a fluid pump. In addition, 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 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. The 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. As a result, UTMD introduced an alternative enteral feeding family of devices incorporating ENFit™ ISO 80369-3 compliant connectors. These purple connectors are designed to replace Nutri-Lok connectors on catheters and extension sets. UTMD also distributes ENFit oral syringes.

UTMD replaced 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. A number of custom configurations of DIALY-NATE have been added to satisfy specific clinical preferences.

[Table of Contents](#)

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. UTMD also introduced a new filter and an improved blood bag spike for HEMO-NATE, and a needleless version.

UTMD expects to continue to enhance 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. Excising too little tissue can result in failure to remove the precancerous tissue. 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. 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, UTMD completed a significant redesign, and achieved certification to current 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.

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. OptiSpec® is 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. As part of its acquisition of Femcare, UTMD acquired 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

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 mammoplasty 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 later. 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.

UTMD introduced a product line of ultra-fine tipped microdissection needles, called OptiMicro™ Needles, to complement the Epite Scalpel. Whereas the Epite Scalpel has been particularly effective for large scale surgeries that entail a great amount of tissue cutting, the OptiMicro electrosurgical needles are particularly useful in small-scale plastic and reconstructive surgery applications where extreme precision and ideal cosmetic results are expected. 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 2021, sales of Filshie Clips, applicators and accessories represented 27% 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 39 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 2021 was sold OUS directly by UTMD and its subsidiaries to medical facilities in Canada, Ireland, France, the UK, Australia and New Zealand, and through specialty distributors in other countries. Femcare Australia began to distribute the Filshie Clip System directly to New Zealand medical facilities in 4Q 2020. In February 2019, UTMD purchased the remaining exclusive U.S. distribution rights of CooperSurgical Inc. (CSI), allowing the Company to directly distribute 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.

[Table of Contents](#)

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 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, of 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 still rare) Filshie Clip 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, requires 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 by patients or recommended by physicians.

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 symptoms. 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 an almost 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.”

Table of Contents

Unfortunately, in late 2021, after 25 years' use in the U.S., implanted in millions of women, a clip migration lawsuit was filed in Texas. Subsequently, plaintiffs' lawyers solicited and recruited claimants in five other states. There are presently a total of seven clip migration lawsuits filed in six states. In UTMD's view, the current lawsuits which have not been litigated yet are without merit, and should be resolved without a material impact on UTMD's consolidated performance. UTMD stockholders should be confident that Filshie Clips remain a very safe and effective method of tubal occlusion.

The U.S. FDA approved the Filshie Clip for marketing in the U.S. in 1996 after a PMA submission which included a prospective clinical trial involving 5,454 women implanted with Filshie Clips. As mandated by the FDA, Femcare, the developer and manufacturer of the Filshie Clip System, must submit an annual experience report for FDA's continual review and vigilance of the safety and effectiveness of the PMA device. 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.

Table of Contents

In 2021, UTMD sold components and finished devices to 155 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 2021, as a percentage of consolidated total USD sales, represented 38% compared to 39% in 2020 and 41% in 2019. The lower OUS share of total sales in 2021 was the result of more restrictions on medical procedures OUS, especially in Europe, due to the COVID-19 pandemic. In USD terms, 72% of 2021 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 2021, 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 220 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 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 2021 comprised 11% of total domestic direct sales (excluding domestic OEM 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 primarily on a growth 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.

Table of Contents

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 and its subsidiaries distribute directly to end-user facilities in Canada, the UK, France, Ireland, New Zealand and Australia, and in 2021 sold to over 220 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 2019 - 2021.

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, 2021, the Company worldwide had 178 full-time employees, 33 part-time employees, 7 regular consultants, 20 independent manufacturer's sales representatives and an additional 11 subcontract production employees in Utah. The Utah 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. In Ireland, the average tenure of full-time employees declined from 15 years to 10 years as a result of a significant increase in production employees in 2021. In the U.S., the average tenure of full-time employees increased from 15 years to 16 years. At the end of 2021, the average tenure with the Company of the combined 166 full-time employees in the U.S. and Ireland is now 14 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.

[Table of Contents](#)

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 2021, royalties included in cost of goods sold were \$137. 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 2021 the Company received \$15 in royalty income compared to \$20 in 2020 and \$6 in 2019.

GOVERNMENT REGULATION

UTMD and its subsidiaries' 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.

Table of Contents

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 and Femcare remain 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 available from a number of sources and 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 disruptions resulting from the COVID-19 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 2021 trade revenues in USD terms from customers OUS were \$18,395 (38% of total consolidated USD sales) compared to \$16,312 (39% of sales) in 2020 and \$19,411 (41% of total sales) in 2019. OUS trade sales (U.S. exports) from the U.S. to OUS customers were \$3,994 in 2021, \$4,626 in 2020 and \$4,322 in 2019. U.S. exports represented 22%, 28% and 22% of total OUS trade sales in 2021, 2020 and 2019, respectively. The U.S. export numbers exclude Utah intercompany sales of components and finished devices to UTMD foreign subsidiaries, which then distribute Utah-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 and 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 \$4,956 as of January 1, 2022 compared to \$3,008 as of January 1, 2021 and \$1,627 as of January 1, 2020.

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 44-year history of shipping many millions of devices.

UTMD is self-insured for product liability risk, and reserves funds against its current performance on an ongoing basis to provide for its costs of defense should any lawsuits be filed. UTMD was named as a defendant on six product liability lawsuits over the time span of the last twenty-nine years, excluding the Filshie Clip System acquired eleven years ago. Four of the six 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 a 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 a 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. The Company's average cost of defense of the six lawsuits was \$15/year, well below the deductible level of product liability insurance policies and hundreds of thousands of dollars less than product liability insurance premiums. In its 44 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.

Prior to late 2021, there were 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 all Filshie Clip System lawsuits since 2011 up to late 2021 was \$7 per year (less than \$25 per lawsuit to achieve resolution). In late 2021, Femcare was added as a defendant in a clip migration lawsuit in Texas, which now has expanded to five other states with a total of seven lawsuits as plaintiffs' lawyers have sought to solicit and recruit claimants in other states. As there is no basis for a claim of a poor device design which is approved by the U.S. FDA, no evidence of defective clips implanted in the patients and no lack of proper disclosure to physicians who have used Filshie Clips for decades in millions of patients, the current lawsuits, which are currently in the early stages of discovery and have not been litigated yet, are clearly without merit. Although the cost of defense will be higher than UTMD's historical average, the Company believes that they should be resolved without a material impact on UTMD's consolidated financial performance. There has never been an adverse judgment against Femcare in over 13 million Filshie Clip implantations over a period of 39 years.

Other than Filshie Clip System claims, there have been no product liability lawsuits for any UTMD device during the last ten years. Except for the six non-Filshie Clip System lawsuits described above, there have been no other product liability claims filed over the last 29 years after distribution and use of over 20 million critical care and surgical finished devices.

In summary, since 1993, during which time over one hundred million finished devices and OEM components were manufactured and distributed by UTMD and its subsidiaries, there have been no adverse judgments resulting from a claim of defect in UTMD's or its subsidiaries' designs or manufacture of products, or a fault in informational materials. In the current tort system, particularly 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) in the U.S. 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 their administrative fees.

The Company’s business strategy may not be successful in the future:

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

As the healthcare industry becomes increasingly bureaucratic it puts smaller companies like UTMD at a competitive disadvantage:

An aging population is placing greater burdens on healthcare systems, particularly hospitals. The length of time and number of administrative steps required in adopting new products for use in hospitals has grown substantially in recent years. Smaller companies like UTMD typically do not have the administrative resources to deal with broad new administrative requirements, resulting in either loss of revenue or increased costs. As UTMD introduces new products it believes are safer and more effective, it may find itself excluded from certain clinical users because of the existence of long term supply agreements for preexisting products, particularly from competitors which offer hospitals a broader range of products and services. Restrictions used by hospital administrators to limit clinician involvement in device purchasing decisions makes communicating UTMD’s clinical advantages 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 COVID-19 pandemic could continue to disrupt UTMD's supply chain or interfere with normal business operations due to the loss of employee availability and rapidly rising input costs.

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 10 years remaining on one section of its Midvale parking lot. As of the beginning of 2022, 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.

ITEM 3 - LEGAL PROCEEDINGS

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

ITEM 4 - RESERVED

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

Market Information.

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

	2021		2020	
	High	Low	High	Low
1st Quarter	\$ 95.64	\$ 82.18	\$ 109.99	\$ 75.33
2nd Quarter	90.46	81.01	109.00	77.27
3rd Quarter	97.79	84.60	93.82	77.22
4th Quarter	133.87	88.29	94.87	78.90

Stockholders.

The number of beneficial stockholders of UTMD's common stock as of March 6, 2022 was at least 2,000.

Dividends.

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

Record Date	Payable Date	Per Share Amount
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
December 15, 2020	January 5, 2021	0.285
March 17, 2021	April 2, 2021	0.285
June 15, 2021	July 6, 2021	0.285
September 16, 2021	October 5, 2021	0.285
December 15, 2021	December 29, 2021	2.000
	2020 total cash dividends paid per share	\$ 1.120
	2021 total cash dividends paid per share	\$ 3.140

Issuer Purchases of Equity Securities.

UTMD did not purchase any of its own securities in 2021. 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.

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, 2021, 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.

	<u>Year Ended December 31</u>				
	<u>2021</u>	<u>2020</u>	<u>2019</u>	<u>2018</u>	<u>2017</u>
Net Sales	\$49,054	\$42,178	\$46,904	\$41,998	\$41,414
Net Income	14,788	10,798	14,727	18,555	8,505
Earnings Per Common Share (Diluted)	4.04	2.94	3.94	4.95	2.28
Total Assets	115,636	111,745	109,787	99,768	92,745
Working Capital	69,412	58,471	51,438	55,643	43,909
Long-term Debt	0	0	0	0	0
Cash Dividends Per Common Share	3.140	1.120	1.100	1.085	1.065

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 2021 year financial results demonstrate Utah Medical Products, Inc.'s (Nasdaq: UTMD's) continuing performance improvement despite many challenges related to the COVID-19 pandemic including on-again/off-again restrictions on so-called nonessential medical procedures, supply chain disruption, high inflation on raw materials, freight and labor costs as well as a continued shortage of labor from higher employee turnover. Because of UTMD's unusual dip in 2020 financial performance, UTMD continues to report its income statement results compared to the same periods not only for 2021 compared to 2020, but also for 2021 compared to the pre-pandemic year of 2019. In that regard, the Company exceeded its stated objective for 2021 to try to fully recover back to its 2019 financial performance.

UTMD management believes that the presentation of three years of annual income statement comparisons provides meaningful supplemental information to both management and investors due to the impact of several factors related to the COVID-19 pandemic including economic variations affecting foreign currency exchange rates for sales invoiced in foreign currencies, uneven customer demand from the timing of ups and downs in government restrictions on "nonessential" medical procedures, supply disruptions and inflation in input costs.

Consolidated Income Statement	2021	2021 Compared to 2020	2020	2021 Compared to 2019	2019
Worldwide Revenues	\$ 49,054	+16.3%	\$ 42,178	+ 4.6%	\$ 46,904
Gross Profit	30,917	+21.0%	25,548	+ 4.9%	29,466
Operating Income	18,880	+37.7%	13,708	+ 7.1%	17,633
Earnings Before Income Tax	19,061	+37.7%	13,840	+ 6.6%	17,884
Net Income (US GAAP)	14,788	+37.0%	10,798	+ 0.4%	14,727
Earnings Per Share (US GAAP)	\$ 4.041	+37.4%	\$ 2.941	+ 2.6%	\$ 3.939

For perspective, as stockholders may recall, total worldwide revenues for the 2020 pandemic year were 10% lower than in pre-pandemic 2019. Sales outside the U.S. (OUS) were more negatively affected by the reaction to the pandemic than inside the U.S., and recovered more slowly in 2021. Direct to end-user sales, which drive UTMD's overall profitability, were 14% lower for the 2020 pandemic year. Operating Income in 2020 was 22% lower than in pre-pandemic 2019. 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. During the pandemic, UTMD protected its critical mass of overhead resources and did not adjust relative to the decline in sales, which proved to be a good decision given 2021 results and future resource needs.

A comparison of 2021 bottom line results with the results of 2020 and 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) in 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; 2) in 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 delay in the enacted UK income tax rate reduction, and 3) in 2Q 2021, net income was decreased \$390 (\$.107 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 an enacted increase in the UK income tax rate effective in 2023. The 2020 \$225 increase in deferred UK taxes over the following six years, and the 2021 \$390 increase in deferred UK taxes from 2023 through 2026, 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, and then in 2Q 2021 decided to increase its corporate income rate to 25% as of April 1, 2023. UTMD management believes that the presentation of results excluding the unfavorable deferred tax liability adjustment to its 2020 and 2021 net income and the favorable U.S. tax-related adjustment to 2019 net income provides meaningful supplemental information to both management and investors that is more clearly indicative of UTMD's operating results in 2021 compared to 2020 and 2019. Please note that the non-US GAAP exclusions only affects Net Income and Earnings Per Share. All other income statement categories at and above the EBT line were unaffected by the UK tax rate adjustments.

Excluding the 2021 and 2020 deferred tax liability increases and concomitant "one-time" income statement tax provision increase resulting from the enactment of the UK corporate income tax changes, and favorable tax provision adjustment in 2019 related to the U.S. TCJA, UTMD's non-US GAAP Net Income and Earnings Per Share (EPS) percentage changes follow:

Consolidated Income Statement	2021	2021 Compared to 2020	2020	2021 Compared to 2019	2019
Net Income (Non-US GAAP)	\$15,178	+37.7%	\$11,023	+ 7.3%	\$14,145
EPS (Non-US GAAP)	\$4.147	+38.2%	\$3.002	+ 9.6%	\$3.784

Key profit margins (profits as a percentage of sales) in 2021 compared to 2020 and 2019 calendar years follow:

	2021	2020	2019
Gross Profit Margin (GPM)	63.0%	60.6%	62.8%
Operating Income Margin	38.5%	32.5%	37.6%
Income Before Tax Margin	38.9%	32.8%	38.1%
Net Income Margin before tax adjusts	30.9%	26.1%	30.2%
Net Income Margin per US GAAP	30.1%	25.6%	31.4%

Profit margins in 2021 recovered to be consistent with UTMD's pre-pandemic performance. In 2020, 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. In contrast and despite higher variable costs in 2021, UTMD's 2021 Gross Profit increased more than Sales due to lower U.S. employee medical plan costs and improved labor productivity, in addition to better absorption of fixed manufacturing overhead expenses.

In 2020, Operating Income was leveraged down from lower GP compared to 2019 primarily due to the fixed \$6,470 noncash expense 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. Also, the CSI IIA amortization expense in 2019 was only \$6,089 because of a partial year of amortization plus a stronger USD in 2019 which reduced fixed GBP Femcare IIA amortization expense in USD terms. In contrast, the fixed IIA amortization expenses, which are included in General & Administrative (G&A) operating expense, were diluted by substantially higher sales in 2021 than in 2020 and a 6.6% stronger GBP in 2021 relative to the 2020 USD, which reduced the USD value of the fixed GBP Femcare IIA amortization expense.

Non-US GAAP Net Income and EPS increased the same as Operating Income in 2021 compared to 2020 because the consolidated total income tax rate prior to US GAAP tax adjustments was the same in both years at 20.4%.

Measures of the Company's liquidity and overall financial condition improved as of the end of 2021 compared to the end of 2020 with year-end working capital up 19% and Stockholders' Equity up 4% despite a \$7,309 special dividend paid to stockholders near the end of 2021 which reduced both cash and Stockholders' Equity by that same amount. The improvement was the result of continued strong positive cash flow from normal operations. In total, UTMD paid \$11,465 in stockholder cash dividends in 2021 compared to \$4,116 in 2020. In 2020, the Company also used \$6,976 of its cash to repurchase its shares. UTMD did not repurchase shares in 2021. The Company also used \$552 in cash in 2021 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 the combined \$12,017 use of cash for stockholder dividends and capital expenditures, UTMD's cash equivalent balances at the end of 2021 increased \$9,384 to \$60,974 from \$51,590 at the end of 2020. Working capital increased \$10,941 to \$69,412 at the end of 2021 from \$58,471 at the end of 2020. Total liabilities declined \$425. The Company remained without debt. UTMD's total debt ratio (total liabilities to total assets) was 7% at the end of 2021 compared to 8% at the end of 2020. Stockholders' Equity at the end of 2021 increased to \$107,138 from \$102,822 at the end of 2020, despite the \$11,465 in 2021 cash dividends to stockholders which reduce Stockholders' Equity.

Productivity of Fixed Assets and Working Capital Assets.

Assets.

Year-end 2021 total consolidated assets were \$115,636 comprised of \$73,158 in current assets, \$11,067 in consolidated net PP&E and \$31,412 in net intangible assets. This compares to \$111,745 total assets at the end of 2020 comprised of \$62,262 in current assets, \$11,326 in consolidated net PP&E and \$38,157 in net intangible assets. Total asset turns (total consolidated sales divided by average total assets for the year) in 2021 were 43% compared to 38% in 2020, as sales increased faster than the increase in average assets.

Current assets increased \$10,896 due to the \$9,384 increase in year-end cash and investments, \$1,028 higher accounts and other receivables, \$374 higher year-end inventories and \$110 higher other current assets, all due to the higher sales activity. Year-end 2021 and 2020 cash and investment balances were \$60,974 and \$51,590, representing 53% and 46% of total assets, respectively. Net (after allowance for doubtful accounts) year-end trade accounts receivable (A/R) balances were \$1,025 higher at the end of 2021 compared to 2020. This due to 4Q 2021 sales \$903 higher than in 4Q 2020, and average days in A/R of 36 days based on 4Q trade sales instead of 31 days at the end of 2020. Average days in A/R from date of invoice of 36 days is well within UTMD's objective. A/R over 90 days from invoice date rose from 1.7% of total A/R at the end of 2020 to 2.4% at the end of 2021. The Company believes any older A/R will be collected or are within its reserve balances for uncollectible amounts. Inventories at 2021 year-end were only 6% higher from the end of 2020, despite a 16% increase in annual shipments.

Working capital (current assets minus current liabilities) at year-end 2021 was 19% higher at \$69,412 compared to \$58,471 at year-end 2020. Consistent with Federal and State rules, the TCJA repatriation tax current liability at the end of 2021 was \$220 compared to \$80 at the end of 2020. The end of 2021 working capital exceeds UTMD's needs for normal operations in an uncertain economic environment, funding of 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. Despite a negative impact on Return on Stockholders' Equity of retaining a high cash balance, UTMD believes that in times of high economic uncertainty and change, maintaining substantial cash balances increases its likelihood of being able to take advantage of opportunities that will benefit stockholders in the longer term, and retain key resources that will help ensure continued excellent long term performance.

December 31, 2021 net \$11,067 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 \$25 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 2021 net consolidated PP&E (depreciated book value of all fixed assets) declined \$259 as a result of the combination of capital expenditures of \$552, depreciation of \$636 and the effect of foreign currency exchange (FX) rates on year-end foreign subsidiary asset balances.

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

	12-31-21	12-31-20
EUR	1.1377	1.2228
GBP	1.3536	1.3663
AUD	0.7268	0.7708
CAD	0.7902	0.7841

The year-end 2021 net book value (after accumulated depreciation) of consolidated PP&E was 33% of purchase cost. End-of-year PP&E turns (Net Sales divided by Net PP&E) was 4.4 in 2021 compared to 3.7 in 2020 due to 16% higher 2021 sales and lower USD asset values of foreign subsidiaries, offset by 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 continued incremental profitability.

Table of Contents

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 \$31,412 (27% of total assets) at the end of 2021 compared to \$38,157 (34% of total assets) at the end of 2020. 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. Those two categories of Femcare intangibles at year-end 2021 were net IIA of \$9,064 and goodwill of \$6,907. The accumulated amortization of Femcare IIA as of December 31, 2021 since the March 18, 2011 acquisition was \$23,419. The remaining Femcare IIA will be fully amortized in 4 more years. The goodwill portion of intangible assets resulting from the Femcare acquisition, which is not amortized, declined \$65 due to a weaker GBP at year-end, i.e. the different FX rate on fixed goodwill in GBP terms. 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 \$12,895 has been amortized through year-end 2021. The remaining CSI IIA will be fully amortized in less than 2 more years. UTMD's goodwill balance from prior acquisitions including Femcare, Columbia Medical, Gesco and Abcorp was \$14,098 at the end of 2021.

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 2022. Amortization of IIA was \$6,645 in 2021 compared to \$6,515 in 2020. The difference was due to £5 lower Femcare IIA amortization and the GBP FX difference on all Femcare IIA amortization. Specifically, the 2021 non-cash amortization expense of Femcare IIA was \$2,189 (£1,590) compared to \$2,049 (£1,595) in 2020. The 2022 non-cash amortization expense (included as part of consolidated G&A operating expenses) of Femcare IIA will be £1,589, or \$2,161 if the USD/GBP average FX rate is 1.36. In other words, the 2022 Femcare IIA amortization expense is expected to be about \$28 lower because of a slightly lower GBP amount and a projected weaker GBP relative to the USD. Both the 2021 and 2020 non-cash amortization expense of CSI IIA was \$4,421. The 2022 operating expense resulting from amortization of CSI IIA will again be \$4,421.

Liabilities.

As a reminder, payments for the Federal and State repatriation (REPAT) tax liability which resulted from the U.S. TCJA enacted in 2017 is 8% of the respective 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. Calendar year 2022 represents the fifth year, but the \$220 current liability is somewhat less than 8% of UTMD's \$2,792 total REPAT tax liability due to earlier overpayment because earlier 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 long term \$1,675 REPAT tax liability, to be paid in years 2023-2025, represents 60% of the total liability.

Year-end 2021 current liabilities were \$45 lower than at the end of 2020. Ending accrued liabilities were \$159 lower due primarily to \$585 higher OEM customer deposits and \$279 higher accrued payroll and bonuses offset by \$1,038 lower dividends payable. The \$1,038 stockholder dividend declared in 4Q 2020 was paid in January 2021, whereas the \$7,309 dividend declared in 4Q 2021 was paid in December 2021. Total liabilities were \$425 lower at the end of 2021 compared to the end of 2020. The resulting 2021 year-end total debt ratio was 7% compared to 8% at the end of 2020.

The year-end 2021 DTL balance created as a result of the fifteen-year deferred tax consequence of the amortization of Femcare's IIA was \$2,105, down from \$2,151 at the end of 2020. The relatively small \$47 decline in this DTL considering the \$2,189 in 2021 amortization of IIA was due to the UK tax law change in 2Q 2021 which increased the DTL \$390, together with a difference in GBP FX rate at the end of 2021. Without the tax law change, the theoretical tax effect at the 2021 19% tax rate for the 2021 IIA amortization expense would have been \$416. 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 2021, 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 collectability 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.

[Table of Contents](#)

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.

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 11% 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. 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 2021 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 2021 intercompany sales of components and/or finished devices to other UTMD entities.

The following table shows the 2021 USD denominated revenues by sales channel compared to 2020 and 2019. Australia domestic sales included sales directly to New Zealand medical facilities beginning in 4Q 2020:

Revenue [USD denominated]	2021	2021 Compared to 2020	2020	2021 Compared to 2019	2019
U.S. domestic (excluding OEM)	\$21,096	+ 8.9%	\$19,373	+ 0.7%	\$20,949
Canada domestic	1,382	(6.7%)	1,481	(34.4%)	2,107
Ireland domestic	446	+17.7%	379	(18.8%)	549
UK domestic	2,388	+18.1%	2,023	(24.7%)	3,171
France domestic	1,424	+13.6%	1,253	(20.2%)	1,785
Australia domestic	1,705	+20.0%	1,421	(0.1%)	1,706
Subtotal, Direct to End-User:	\$28,441	+ 9.7%	\$25,930	(6.0%)	\$30,267
All Other OUS (Sales to Int'l Distributors)	11,050	+13.3%	9,753	+ 9.5%	10,092
U.S. OEM Sales	9,563	+47.3%	6,495	+ 46.1%	6,545
Worldwide Revenues	\$49,054	+16.3%	\$42,178	+ 4.6%	\$46,904

Except for Canada, sales in all channel categories rebounded well from 2020. Whereas UTMD total consolidated sales in 2021 were almost 5% higher than in the pre-pandemic year of 2019, direct sales in Europe and Canada remained 20-30% lower than in 2019, indicating a slower recovery from the pandemic in those regions. Global consolidated trade sales in 2021 were \$49,054 compared to \$42,178 in 2020 and \$46,904 in 2019. The \$4,726 (10.1%) lower sales in 2020 from 2019 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 including OEM were up \$4,793 (+18.5%) in 2021, at \$30,659 compared to \$25,866 in 2020, and \$27,493 in 2019. OUS sales were up \$2,083 (+12.8%) at \$18,395 compared to \$16,312 in 2020, and \$19,411 in 2019.

Domestic Sales.

U.S. domestic sales in 2021 were \$30,659 (63% of total sales) compared to \$25,866 (61% of total sales) in 2020, and \$27,493 (59% of total sales) in 2019. The components of the \$4,793 higher 2021 domestic sales were \$209 (3.3%) lower sales of the Filshie Clip System devices in the U.S., \$3,069 (+47.3%) higher sales of components and finished devices used in other companies' products (OEM customers), and \$1,933 (+14.8%) higher direct sales of all other UTMD (non-Filshie) finished devices to domestic end-users. Domestic sales in 2019 were \$27,493.

[Table of Contents](#)

Domestic Filshie Clip System sales in 2021 were 20% of total U.S. domestic sales compared to 24% in 2020 and 25% in 2019. Filshie sales did not recover as well as the other domestic sales categories. Looking forward to 2022, despite a continued recovery in overall surgical sterilization procedures including laparoscopic interval procedures, as there is a medical procedure trend in the U.S. to choose salpingectomy versus tubal ligation for permanent contraception post C-Section, UTMD expects U.S. Filshie device sales in 2022 will remain about the same as in 2021.

Domestic OEM sales in 2021 were 31% of total U.S. domestic sales compared to 25% in 2020 and 24% in 2019. UTMD sold components and finished devices to 155 different U.S. companies in 2021, compared to 139 different companies in 2020 and 147 companies in 2019, for use in their product offerings. Sales to UTMD's largest OEM customer represented 82% of total domestic OEM sales in 2021 compared to 75% of total domestic OEM sales in both 2020 and 2019. UTMD's largest OEM customer markets biopharmaceutical manufacturing control systems which exclusively utilize UTMD's pressure monitoring technology, and for which demand is booming. If UTMD had had the manufacturing capacity primarily in terms of assembly operators in 2021, OEM sales would have been much higher. Looking forward to 2022, UTMD again expects substantial growth in OEM sales as engineering projects for manufacturing expansion come to fruition.

Domestic direct end-user sales excluding the Filshie Clip System were 49% of total U.S. domestic sales in 2021 compared to 51% in both 2020 and 2019. Of UTMD's four domestic direct product categories, neonatal products were \$5,343 (22% higher), labor & delivery (L&D) products were \$3,940 (7% higher), gynecology/ electrosurgery/ urology products excluding the Filshie Clip System were \$4,837 (12% higher), and blood pressure monitoring devices were \$873 (25% higher).

OUS Sales.

Sales OUS in 2021 were \$18,395 (12.8% higher) compared to \$16,312 in 2020. OUS sales were \$19,411 in 2019. Europe and Canada were particularly affected by government restrictions during the pandemic.

Because a significant portion of UTMD's OUS sales are invoiced in foreign currencies, changes in FX rates can potentially have a material effect on period-to-period USD-denominated sales. Although a weaker USD in the first half of the year helped increase foreign currency sales in USD terms, the FX rate impact for the year 2021 was a minor factor compared to the negative impact of the pandemic on OUS sales. UTMD's FX rates for income statement purposes are transaction-weighted averages. The average rates from the applicable foreign currency to USD during 2021 compared to 2020 follow. The average FX rates for 2019 are also listed for reference:

	<u>2021</u>	<u>Change</u>	<u>2020</u>	<u>2019</u>
GBP	1.376	+6.6%	1.291	1.277
EUR	1.183	+3.2%	1.146	1.119
AUD	0.751	+8.6%	0.692	0.696
CAD	0.798	+6.2%	0.751	0.754

The sales weighted FX rate change in 2021 compared to 2020 was +4.9%. In other words, consolidated USD sales in 2021 were increased \$619 from what they would have been using the prior year's FX rates.

Seventy-two percent of (USD denominated) 2021 OUS sales were invoiced in foreign currencies compared to 58% in 2020 and 66% in 2019. As a portion of total USD consolidated sales, 27% of UTMD's USD-equivalent sales were invoiced in foreign currencies in 2021 compared to 22% in 2020 and 27% in 2019. The GBP, EUR, AUD and CAD converted sales represented 6%, 15%, 3% and 3% of total 2021 USD sales, respectively. This compares to 6%, 10%, 3% and 3% of total 2020 USD sales, and 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 (excluding France) by UTMD's Ireland facility (UTMD Ltd) were \$7,439 in 2021 (39% higher) compared to \$5,347 in 2020, and were \$5,894 in 2019. In addition, UTMD Ltd also sold devices that it had manufactured directly to France in 2021 due to BREXIT, which in prior years were sold to Femcare Ltd in the UK on an intercompany basis and then sold by Femcare Ltd directly to French medical facilities. USD-denominated sales to France in 2021 were \$1,424 (14% higher) compared to \$1,253 in 2020, and were \$1,785 in 2019. Some sales, mostly to Northern Ireland, were invoiced in GBP which was up 6.6% in 2021 compared to the 2020 USD. In addition, as the 2021 EUR was 3.2% higher relative to the 2020 USD, the total FX impact added \$226 to Ireland's total 2021 sales.

In 2021, UTMD's UK subsidiary, Femcare Ltd., had \$2,451 trade sales of devices to domestic UK and certain international distributor customers, up 12% compared to \$2,183 in 2020. The total FX impact added \$170 in USD terms. Femcare USD-denominated sales excluding France in 2019 were \$3,596.

[Table of Contents](#)

USD-denominated sales of devices to end-users in Australia by Femcare’s Australia distribution subsidiary (Femcare Australia Pty Ltd) were \$1,705 (20% higher) in 2021 compared to \$1,421 in 2020. In 4Q 2020, UTMD converted from selling devices by Femcare in the UK to a third party distributor in New Zealand (NZ) to distributing devices directly to NZ medical facilities from Femcare Australia. In addition, an 8.6% stronger AUD in 2021 added \$135 in USD-denominated sales. Femcare Australia sales in 2019, which did not include sales to NZ, were \$1,706.

UTMD’s Canada distribution subsidiary (Utah Medical Products Canada, Inc.) had the weakest sales results of UTMD’s OUS subsidiaries. USD-denominated sales of devices to end-users in Canada were \$1,382 (7% lower) than \$1,481 in 2020 despite a CAD which was 6.2% stronger than in the prior year. The stronger CAD added \$88, so 2021 sales were \$1,294 (13% lower) in constant currency terms. Canada sales were \$2,107 in 2019.

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:

	<u>2021</u>	<u>%</u>	<u>2020</u>	<u>%</u>	<u>2019</u>	<u>%</u>
Obstetrics	\$4,675	9	\$4,523	11	\$5,000	11
Gynecology/ Electrosurgery/ Urology	21,973	45	20,552	49	25,354	54
Neonatal	6,691	14	5,870	14	6,066	13
Blood Pressure Monitoring and Accessories*	<u>15,715</u>	<u>32</u>	<u>11,233</u>	<u>26</u>	<u>10,484</u>	<u>22</u>
Total:	\$49,054	100	\$42,178	100	\$46,904	100

OUS revenues by product category:

	<u>2021</u>	<u>%</u>	<u>2020</u>	<u>%</u>	<u>2019</u>	<u>%</u>
Obstetrics	\$ 735	4	\$ 846	5	\$ 947	5
Gynecology/ Electrosurgery/ Urology	11,053	60	9,934	61	13,731	71
Neonatal	1,347	7	1,490	9	1,412	7
Blood Pressure Monitoring and Accessories*	<u>5,260</u>	<u>29</u>	<u>4,042</u>	<u>25</u>	<u>3,321</u>	<u>17</u>
Total:	\$ 18,395	100	\$ 16,312	100	\$ 19,411	100

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

Looking forward to 2022, continuing government restrictions on so-called “non-essential” medical procedures seems unlikely. Although there remains much room for pandemic recovery in UTMD’s direct distribution OUS, UTMD projects a 3-4% stronger USD on the average which will offset the unit growth in direct foreign currency sales in USD terms. OUS distributor order patterns vary and are less predictable, but UTMD’s largest OUS distributor has placed a fixed 2022 order for BPM devices that is \$550 higher than in 2021 based on an average EUR FX rate of 1.13 in 2022. Domestically, OEM sales are projected to be over \$700 higher with projected capacity limits, but could be even higher if production worker hiring constraints in Utah become less severe. A key to sales results will be retaining U.S. Filshie device sales at a similar level as in 2021. Except for Filshie devices in the U.S., UTMD raised product prices across the board an average of about 5% in late 4Q 2021, which will benefit 2022 sales in comparison to 2021 assuming customer demand remains relatively inelastic. In summary, management’s best estimate at this time is that 2022 revenues will be up in the range of mid-single digit percentage growth.

b) Gross Profit (GP).

UTMD's 2021 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 \$30,917 (63.0% of sales) compared to \$25,548 (60.6% of sales) in 2020 and \$29,466 in 2019 (62.8% of sales). GP in 2021 increased \$5,369 (+21.0%) with a 16.3% increase in revenues.

The Gross Profit Margin (GPM), which is GP divided by sales, expanded primarily due to the fact that a large portion of UTMD's manufacturing expenses were fixed compared to the prior year. Another way to say this is that in 2020, a 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 GPM. 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 compared to 62.8% in 2019: 1) marginal costs associated with the COVID-19 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. Self-insured health care plan costs in 2021 returned to be more consistent with prior years' levels. Despite higher variable costs in 2021, particularly freight on incoming materials and a cost of living adjustment for Utah and Ireland production workers, the GPM in 2021 recovered to be consistent with the pre-pandemic year of 2019.

In 2022, UTMD plans to help manage inflationary manufacturing cost pressures with administering higher prices for its devices, as and when necessary. Nevertheless, management expects that manufacturing costs in 2022 will increase faster than revenues resulting in a lower GPM. However, UTMD also expects that GP will still be higher than in 2021. If sales increase as a mid-single digit percentage, then GP are projected to increase as a low single-digit percentage.

UTMD's Ireland subsidiary's (UTMD Ltd's) GP was EUR 6,788 compared to EUR 4,198 in 2020 and EUR 2,908 in 2019. The associated GPMs were 61.2% in 2021, 54.4% in 2020 and 43.1% in 2019. Femcare UK 2021 GP was GBP 913 compared to GBP 1,495 in 2020 and GBP 3,884 in 2019. The UK 2021 GPM was 46.3% compared to 56.0% in 2020 and 70.2% in 2019. The transfer from the UK to Ireland of direct sales to France primarily explains the GP changes for both Ireland and the UK. Femcare Australia and Femcare Canada are simply distribution facilities for UTMD finished devices in their respective countries. GP is the result of subtracting intercompany purchase prices of devices plus freight from sales. Australia GP was AUD 1,399 (61.6% of sales) compared to AUD 1,194 (58.1% of sales) in 2020 and AUD 1,415 (57.7% of sales) in 2019. Canada GP was CAD 907 (52.4% of sales) in 2021 compared to CAD 1,128 (57.2% of sales) in 2020 and CAD 1,670 (54.5% of sales) in 2019. In the U.S., GP was \$20,100 in 2021, \$17,043 in 2020 and \$19,180 in 2019. UTMD U.S. GPMs were 55.8% in 2021, 54.2% in 2020 and 57.1% in 2019. 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.

[Table of Contents](#)

c) Operating Income.

Operating Income results from subtracting operating expenses from GP. Operating Income in 2021 was \$18,880 (38.5% of sales) compared to \$13,708 (32.5% of sales) in 2020 and \$17,632 (37.6% of sales) in 2019. On top of benefitting from a higher GPM, the higher 2021 Operating Income margin (Operating Income divided by sales) additionally reflected better absorption of relatively fixed IIA amortization expense, included in General and Administrative (G&A) operating expenses, which was 13.5% of sales in 2021 compared to 15.3% of sales in 2020 and 13.0% of sales in 2019. Excluding the non-cash Femcare and CSI IIA amortization expenses, UTMD consolidated operating expenses were \$5,427 (11.1% of sales) compared to \$5,370 (12.7% of sales) in 2020 and \$5,744 (12.2% of sales) in 2019. In other words, holding operating expense (excluding the IIA amortization expense) growth to 1% while sales increased 16% and GP increased 21%, leveraged the overall growth in Operating Income to almost 38% compared to 2020.

The UTMD Ltd (Ireland) Operating Income margin in 2021 was 57.8% compared to 50.5% in 2020 and 38.5% in 2019. Femcare UK's Operating Income margin per US GAAP, which includes the IIA amortization expense of the 2011 acquisition, was negative in both 2021 and 2020 compared to 27.8% in 2019. Femcare Australia's 2021 Operating Income margin was 45.9% compared to 41.7% in 2020 and 38.6% in 2019. Femcare Canada's 2021 Operating Income margin was 34.5% compared to 40.7% in 2020 and 41.9% in 2019. UTMD's 2021 Operating Income margin in the U.S. was 33.2% compared to 28.5% in 2020 and 33.7% in 2019. 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 \$12,037 (24.5% of sales) in 2021, \$11,840 (28.1% of sales) in 2020 and \$11,834 (25.2% of sales) in 2019. The following table provides a comparison of operating expense categories, as well as further segmentation of G&A expenses, for the last three years.

	<u>2021</u>	<u>2020</u>	<u>2019</u>
S&M expenses	\$ 1,414	\$ 1,554	\$ 1,738
R&D expenses	526	486	483
G&A expenses:			
a) litigation expense provision	22	-	16
b) corporate legal	1	14	32
c) outside directors fees	125	116	118
d) stock option compensation	166	160	113
e) profit-sharing bonus accrual	448	587	653
f) outside accounting audit/tax	179	223	216
g) Femcare IIA amortization	2,189	2,049	2,037
h) CSI IIA amortization	4,421	4,421	4,053
i) property & liability insurance premiums	99	95	91
j) all other G&A expenses	<u>2,447</u>	<u>2,135</u>	<u>2,284</u>
G&A expenses – total	<u>10,097</u>	<u>9,800</u>	<u>9,613</u>
Total Consolidated Operating Expense:	\$ 12,037	\$ 11,840	\$ 11,834
Percent of sales:	24.5%	28.1%	25.2%

Description of Operating Expense Categories:

i) S&M expenses:

S&M expenses in 2021 were \$1,414 (2.9% of sales) compared to \$1,554 (3.7% of sales) in 2020 and \$1,738 (3.7% of sales) in 2019. UK sales salaries were \$130 lower in 2021 than in 2020 due to a reduction in the UK sales force.

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 2019-2021 included the U.S., Ireland, UK, Australia, France and Canada plus New Zealand in 2021, the largest components of S&M expenses were the cost of customer service required to timely process orders and the distribution costs associated with shipping products.

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 in 2021 were \$526 (1.1% of sales) compared to \$486 (1.2% of sales) in 2020 and \$483 (1.0% of sales) in 2019. 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 2021, UTMD continued to customize configurations of its existing devices based on specific clinical requests and R&D played a significant 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 2021 were \$10,096 (20.6% of sales) compared to \$9,800 (23.2% of sales) in 2020 and \$9,613 (20.5% of sales) in 2019. 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.

As indicated in the table above, amortization of the Femcare IIA acquired in 2011 is part of G&A expenses. The IIA GBP amortization expense in 2021 was £1,590 compared to £1,595 in 2020, practically the same. However, because of a stronger GBP for the year as a whole, the USD 2021 IIA amortization expense was \$140 higher than in 2020. But 16.3% higher consolidated sales allowed better absorption of the resulting 6.8% higher USD Femcare IIA expense, i.e. Femcare IIA amortization expense was 4.5% of sales in 2021 compared to 4.9% of 2020 sales. The G&A noncash amortization expense of Femcare IIA was 4.3% of 2019 total consolidated 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 2022 may be \$25 lower due to an average stronger USD in 2022 compared to 2021.

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 will be through 3Q 2023 (unless it becomes impaired before that, which is unlikely). This CSI IIA amortization expense is included in U.S. G&A expenses. In 2021 and 2020, the CSI IIA amortization expense was the same at \$4,421. But again, due to the 16.3% higher consolidated sales, the CSI IIA amortization expense represented only 9.0% of sales compared to 10.5% of sales in 2020. The CSI IIA amortization expense in 2019, which was a partial year due to the timing of the acquisition, was \$4,053 (8.6% of 2019 annual sales). In 2022, the constant \$4,421 CSI IIA amortization expense will lower as a percentage of sales if further diluted by projected higher sales.

It seems worth noting that the combined Filshie Clip System and Femcare non-cash IIA amortization expenses represented more than half of all of UTMD's total consolidated operating expenses during the three years of 2019-2021; 54.9% in 2021, 54.6% in 2020 and 51.5% in 2019.

d) Non-operating income/Non-operating expense, and Income 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.

[Table of Contents](#)

Net non-operating income (combination of non-operating income and non-operating expense) was \$181 in 2021, \$132 in 2020 and \$252 in 2019. The higher non-operating income in 2021 compared to 2020 was due to \$142 higher rent income in Ireland from renting unneeded warehouse space. A description of components of UTMD's non-operating income or expense follows:

- 1) Interest Expense. There was no interest expense in 2019-2021. Absent an acquisition or large repurchase of shares that requires new borrowing, UTMD does not expect any interest expense in 2022.
- 2) Investment of excess cash. Consolidated investment income (including gains and losses on sales of investments) was \$46 in 2021, \$64 in 2020 and \$255 in 2019. Interest rates in 2021 remained practically zero, and UTMD had to pay negative interest on EUR bank balances in Ireland. UTMD is expecting interest rates to improve marginally in 2022.
- 3) Royalties. Royalties in 2021 were \$15 compared to \$20 in 2020, and \$5 in 2019. Presently, there is only one 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 a \$23 loss in 2021 compared to a \$45 gain in 2020 and a \$76 loss in 2019 from gains or losses on remeasured foreign currency bank balances. EUR 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 net non-operating income of \$124 in 2021 compared to a net non-operating expense of \$10 in 2020 and \$85 in 2019.

EBT results from adding net non-operating income or subtracting net non-operating expense from Operating Income. Consolidated EBT was \$19,061 (38.9% of sales) in 2021 compared to \$13,840 (32.8% of sales) in 2020 and \$17,884 (38.1% of sales) in 2019. The 2021 EBT of UTMD Ltd. (Ireland) was €6,277 (56.6% of sales) compared to €3,728 (48.3% of sales) in 2020 and €2,577 (38.2% of sales) in 2019. Femcare Ltd's (UK) 2021 EBT was (£1,003) compared to (£593) in 2020 and £1,566 (28.3% of sales) in 2019. Femcare Ltd, as the legal manufacturer of the Filshie Clip System, supports worldwide regulatory requirements in addition to absorbing the IIA amortization expense of the 2011 Femcare Group acquisition. Femcare AUS's 2021 EBT was AUD 1,042 (45.9% of sales) compared to AUD 857 (41.8% of sales) in 2020 and AUD 952 (38.8% of sales) in 2019. Femcare Canada's 2021 EBT was CAD 592 (34.2% of sales) compared to CAD 798 (40.5% of sales) in 2020 and CAD 1,280 (41.8% of sales) in 2019.

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 2019-2021 adjustments to income tax provisions as a result of income tax rate changes in the UK enacted in 2Q 2020 and 2Q 2021, which increased UTMD's long term deferred tax liability, and the 2019 corrected estimate of the repatriation tax and associated GILTI tax and FDII tax credit, all of which resulted from the U.S. TCJA enacted in December 2017.

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

	2021	2020	2019
EBT	\$19,061	\$13,840	\$17,884
Depreciation Expense	636	655	700
Femcare IIA Amortization Expense	2,189	2,049	2,037
CSI IIA Amortization Expense	4,421	4,421	4,053
Other Non-Cash Amortization Expense	34	45	54
Stock Option Compensation Expense	166	160	113
Remeasured Foreign Currency Balances	23	(45)	76
UTMD non-US GAAP EBITDA:	\$26,530	\$21,125	\$24,917

In summary, UTMD's 2021 non-US GAAP EBITDA increased 25.6% compared to 2020 and 6.5% compared to 2019, when 2021 sales were 16.3% higher than in 2020 and 4.6% higher than in 2019. This metric is expected to also grow faster than the projected increase in sales in 2022.

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 2021 was \$14,788 (30.1% of sales) compared to \$10,798 (25.6% of sales) in 2020 and \$14,727 (31.4% of sales) in 2019. Because of changes in UTMD's repatriation tax estimate in the year 2019 due to the TCJA enacted in December 2017, as well as UK income tax changes enacted in 2020 and 2021, management does not believe either that the tax provision adjustments have a direct relationship to sales in the same periods, or that the year-to-year changes in US GAAP Net Income is an accurate measure of UTMD's bottom-line financial performance in the applicable time periods. Ignoring the income tax adjustments, 2021 non-US GAAP Net Income was \$15,178 (30.9% of sales) compared to \$11,023 (26.1% of sales) in 2020 and \$14,145 (30.2% of sales) in 2019. 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.

[Table of Contents](#)

The US GAAP consolidated income tax provision rate for 2021 was 22.4% compared to 22.0% in 2020 and 17.7% of EBT in 2019. The estimated tax provision adjustments in 2019 reduced the 2019 average rate, whereas the adjustments in 2020 and 2021 increased the average rates. The non-US GAAP consolidated combined income tax provision rate for both 2021 and 2020 was 20.4% compared to 20.9% of EBT in 2019. For clarity, the UK income tax rate change in 2021 from 19% to 25% beginning in April 2023 added \$390 to UTMD's 2021 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. Similarly, 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 due to UTMD's initial estimates of taxes due under the TCJA being too high.

More normally and in general, year-to-year fluctuations in the combined average 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. UTMD expects, barring any new tax law changes which are currently unknown, that its combined income tax rate for 2022 will be within the (non-GAAP) 20.4%-20.9% range of the three years of 2019-2021.

The UK had an income tax rate of 19% for all three years 2019-2021. 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 Utah 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.

Earnings Per Share (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 2021 per US GAAP were \$4.041 (\$4.147 prior to the UK deferred tax liability adjustment) compared to \$2.941 (\$3.002 prior to the UK deferred tax liability adjustment) in 2020 and \$3.939 (\$3.784 prior to the Utah state TCJA tax correction) in 2019. The 2021 non-US GAAP EPS result exceeded management's projection at the beginning of the year.

The 2021-ending weighted average number of diluted common shares (the number used to calculate diluted EPS) was 3,660 (in thousands) compared to 3,672 in 2020 and 3,739 in 2019. Dilution for "in the money" unexercised options for the year 2021 was 13 (in thousands) shares compared to 14 shares in 2020 and 18 shares in 2019. Actual outstanding common shares as of December 31, 2021 were 3,655.

[Table of Contents](#)

UTMD management believes the presentation of Net Income and EPS results excluding the tax liability estimate adjustments in 2021, 2020 and 2019 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:

	<u>2021</u>	<u>2020</u>	<u>2019</u>
Net Income	\$14,788	\$10,798	\$14,727
Net Income Margin	30.1%	25.6%	31.4%
EPS	\$ 4.041	\$ 2.941	\$ 3.939

Non-US GAAP (excluding 2020 and 2021 UK DTL changes and TCJA tax adjustments in 2019):

	<u>2021</u>	<u>2020</u>	<u>2019</u>
Net Income	\$15,178	\$11,023	\$14,145
Net Income Margin	30.9%	26.1%	30.2%
EPS	\$ 4.147	\$ 3.002	\$ 3.784

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.

In short, UTMD realized a substantial recovery in 2021 revenues from 2020, and profitability returned to pre-pandemic levels.

Looking forward to 2022, there remains a significant lack of predictability of demand for UTMD's medical devices due to governments' now entrenched desire to control people's health care as a result of the pandemic. Nevertheless, management believes that 2022 sales are likely to be higher than in 2021 due to UTMD having to raise prices of its devices, offset by a slower recovery OUS combined with a stronger USD reducing foreign currency sales. Because the high rate of inflation in costs and the difficulty in hiring people which resulted from uncontrolled government spending continues to grow at a rate that is likely to exceed the rate of growth in sales, the Company also expects that the rate of growth in Gross Profit in 2021 will be lower than the growth in sales. A lower GPM will be partially offset by better absorption of UTMD's high fixed IIA amortization expenses. For the sake of specificity and as an example, UTMD estimates that a 5% increase in sales in 2022 will yield a 1% increase in EBT compared to 2021 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 2021 ROE before stockholder dividends (with US GAAP Net Income) was 14.1%. In comparison, 2020 ROE was 10.6% and 2019 ROE was 15.5%.

Before dividends, UTMD's 2021 ROE (using non-US GAAP Net Income) was 14.5% compared to 10.8% in 2020 and 14.9% in 2019, excluding the effect of the tax adjustments on Net Income. The higher 2021 ROE compared to 2020 was the result of 37.7% higher non-US GAAP Net Income with 3.0% higher average Stockholders' Equity. Average Stockholders' Equity was \$104,980 in 2021 compared to \$101,957 in 2020 and \$95,042 in 2019. UTMD's Stockholders' Equity has more than doubled over the last ten years despite being reduced by \$46 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 29 years was 25%.

Liquidity and Capital Resources

Cash Flows.

Net cash provided by operating activities totaled \$21,203 compared to \$20,137 in 2020 and \$17,056 in 2019. Net Profit at \$3,990 higher in 2021 compared to 2020 allowed 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, to be \$1,066 higher than in 2020. Total cash provided by operating activities was not in the magnitude of increased Net Profit as a result of changes in 2021 cash required for operating activities compared to 2020 changes (second order derivative), which were a function of the higher 2021 business activity related to recovering from restrictions on nonessential medical procedures during the pandemic, i.e. 1) a \$1,705 higher use of cash as a result of increasing trade accounts receivable (A/R) \$1,088 instead of the \$617 decrease in 2020, and 2) a \$1,408 higher use of cash as a result of increasing inventories \$485 instead of the \$923 decrease in 2020. Additional changes that consumed more cash in 2021 than in 2020 included a \$66 greater reduction in deferred income taxes, a \$42 reduction in interest and other receivables instead of a \$45 increase in 2020 and an \$81 reduction in prepaid expenses and other current assets instead of a \$108 increase in 2020. In addition to higher Net Profit, greater cash was provided in 2021 compared to 2020 from \$129 higher non-cash amortization expense, a \$32 higher tax benefit attributable to exercise of employee stock options and a \$106 higher increase in accrued expenses.

In investing activities, during 2021 UTMD used \$552 in capital expenditures to purchase new molds and manufacturing equipment for new capabilities as well as to maintain, improve or expand existing operating capabilities, compared to investing \$860 in 2020.

In 2021 UTMD received \$560 and issued 11,702 shares of stock upon the exercise of employee stock options. Employees exercised a total of 13,711 option shares in 2021, with 2,009 shares immediately being retired as a result of optionees trading the shares in payment of the exercise price of the options. Option exercises in 2021 were at an average price of \$57.40 per share. The Company received a \$39 tax benefit from option exercises in 2021. UTMD did not repurchase shares of its stock in the open market during 2021.

In comparison, 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 further 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.

UTMD did not borrow in any of the three years 2019-2021. Cash dividends paid to stockholders were \$11,465 in 2021 compared to \$4,116 in 2020 and \$4,096 in 2019.

Management believes that future income from operations and effective management of working capital will continue to 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 2022 capital expenditures for ongoing operations are expected to be about the same in magnitude as depreciation of PP&E, although additional capital expenditure opportunities are being considered.

[Table of Contents](#)

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 and reliable manufacturer 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 2022, UTMD again plans to

- 1) leverage distribution and manufacturing synergies by further integrating capabilities and resources in its multinational operations;
- 2) expand manufacturing capacity at a time when resources are particularly scarce;
- 3) focus on effectively differentiating the benefits of the Filshie Clip System in the U.S.;
- 4) introduce additional products helpful to clinicians through internal product development;
- 5) continue to achieve excellent overall financial operating performance;
- 6) 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
- 7) remain vigilant for affordable 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 the combined form of cash dividends and share repurchases, UTMD "returned" \$11,465 (78% of Net Income) to stockholders in 2021 compared to \$11,092 (103% of Net Income) in 2020 and \$4,494 (31% of Net Income) in 2019).

In 2021, the value of UTMD's stock improved 19%, ending the year at \$100.00/ share, while \$3.14 in cash dividends/ share were paid. The DJIA, S&P 500 and NASDAQ (where UTMD is traded) indices were up 19%, 27% and 27% respectively in 2021.

In comparison, 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. The DJIA, S&P 500 and NASDAQ (where UTMD is traded) indices were up 7%, 16% and 44% respectively in 2020.

In further 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 average compounded appreciation in UTMD stock value for the last 23 years was 12.6% per year, substantially outpacing all of the major indices. Adding dividends, UTMD stockholder value increased at an annually compounded rate of 13.4% over the last 23 years since 1998.

Combining share price appreciation as a result of a long term 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

[Table of Contents](#)

Contractual Obligations

The following is a summary of UTMD's significant contractual obligations and commitments as of December 31, 2021:

<u>Contractual Obligations and Commitments</u>	<u>Total</u>	<u>2022</u>	<u>2023- 2024</u>	<u>2025-2026</u>	<u>2027 and thereafter</u>
Long-term debt obligations	\$ -	\$ -	\$ -	\$ -	\$ -
Operating lease obligations	523	66	123	98	236
Purchase obligations	4,368	4,353	15	-	-
Total	<u>\$ 4,891</u>	<u>\$ 4,419</u>	<u>\$ 138</u>	<u>\$ 98</u>	<u>\$ 236</u>

Critical Accounting Policies and Estimates

The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as well as the reported amounts of revenues and expenses during the reporting period.

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

- Allowance for doubtful accounts: The majority of the Company's receivables are with healthcare facilities and medical device distributors. Although the Company has historically not had significant write-offs of bad debt, the possibility exists, particularly with foreign distributors where collection efforts can be difficult or in the event of widespread hospital bankruptcies.
- Inventory valuation reserves: The Company strives to maintain inventory to 1) meet its customers' needs and 2) optimize manufacturing lot sizes while 3) not tying-up an unnecessary amount of the Company's capital increasing the possibility of, among other things, obsolescence. The Company believes its method of reviewing actual and projected demand for its existing inventory allows it to arrive at a fair inventory valuation reserve. While the Company has historically not had significant inventory write-offs, the possibility exists that one or more of its products may become unexpectedly obsolete for which a reserve has not previously been created. The Company's historical write-offs have not been materially different from its estimates.

Accounting Policy Changes

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

ITEM 7A - QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company had manufacturing operations, including related assets, in the U.S. denominated in the U.S. Dollar (USD), in Ireland denominated in the Euro (EUR), and in England denominated in the British Pound (GBP). UTMD also has trading activities in the U.S. and in subsidiaries in other countries denominated in the USD, EUR, GBP, the Australian Dollar (AUD) and the Canadian Dollar (CAD). The currencies are subject to exchange rate fluctuations that are beyond the control of UTMD. The exchange rates were .8790, .8178 and .8907 EUR per USD as of December 31, 2021, 2020 and 2019, respectively. Exchange rates were .7388, .7319 and .7537 GBP per USD as of December 31, 2021, 2020 and 2019, respectively. Exchange rates were 1.3759, 1.2974 and 1.4226 AUD per USD on December 31, 2021, 2020 and 2019, respectively. Exchange rates were 1.2656, 1.2754 and 1.2962 CAD per USD on December 31, 2021, 2020, and 2019, 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.

TABLE OF CONTENTS

Management’s Report on Internal Control Over Financial Reporting	36
Report of Independent Registered Public Accounting Firm (Haynie) on Financial Statements and the Company’s Internal Control Over Financial Reporting	37
Report of Independent Registered Public Accounting Firm (Nortons) on Financial Statements and the Company’s Internal Control Over Financial Reporting	38
Consolidated Balance Sheets	39
Consolidated Statements of Income and Comprehensive Income	40
Consolidated Statements of Cash Flow	41
Consolidated Statements of Stockholders’ Equity	42
Notes to Consolidated Financial Statements	43

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, 2021. 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, 2021.

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, 2021 and 2020, 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, 2021 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021 in conformity with accounting principles generally accepted in the United States of America.

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 \$26,752,000 and \$28,666,000 as of December 31, 2021 and 2020, respectively and total revenues of \$4,419,000 and \$4,871,000 for the years ended December 31, 2021 and 2020, 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.

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.

Evaluation of income taxes

Description of the Matter:

As discussed in Note 1 to the consolidated financial statements, the Company operates in many parts in the world through its' subsidiaries. The Company or one of its' subsidiaries will file a tax return in the U.S. federal jurisdiction, in the United Kingdom, in Australia, in Ireland, and in Canada. Due to the complexity with dealing in multiple currencies/countries, along with the various tax laws and significant management judgment, we believe the account to be a critical audit matter.

How We Addressed the Matter in Our Audit:

We evaluated the appropriateness and consistency of management's methods and assumptions used in the identification, recognition, measurement, and disclosures of its' taxes. We read and evaluated management's documentation, including relevant accounting policies and information obtained by management from the outside tax specialists engaged to assist with their taxes.

/s/ Haynie & Company

Haynie & Company
Salt Lake City, Utah
March 25, 2022
Firm ID: 457

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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, 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 2021.

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 2021.

NORTONS ASSURANCE LIMITED

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

Reading, United Kingdom
March 25, 2022

UTAH MEDICAL PRODUCTS, INC.
CONSOLIDATED BALANCE SHEETS AS OF
DECEMBER 31, 2021 AND 2020
(In thousands)

	2021	2020
ASSETS		
Current assets:		
Cash	\$ 60,974	\$ 51,590
Accounts & other receivables, net (note 2)	5,132	4,104
Inventories (note 2)	6,596	6,222
Prepaid expenses and other current assets	456	346
Total current assets	73,158	62,262
Property and equipment, net (notes 4 and 10)	11,067	11,326
Goodwill	14,098	14,164
Other intangible assets (note 2)	55,865	56,159
Other intangible assets - accumulated amortization	(38,552)	(32,166)
Other intangible assets, net (note 2)	17,313	23,993
Total assets	\$ 115,636	\$ 111,745
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 761	\$ 788
Accrued expenses (note 2)	2,984	3,003
Total current liabilities	3,745	3,791
Long term lease liability	396	335
Long term income tax payable (REPAT tax) (note 7)	1,675	1,995
Deferred tax liability - intangible assets	2,105	2,151
Deferred income taxes (note 7)	577	651
Total liabilities	8,498	8,923
Commitments and contingencies (notes 6 and 12)	0	0
Stockholders' equity:		
Common stock, \$0.01 par value; 50,000 shares authorized, 3,655 shares issued and outstanding in 2021 and 3,643 shares in 2020	37	36
Accumulated other comprehensive loss	(9,054)	(8,281)
Additional paid-in capital	841	115
Retained earnings	115,314	110,952
Total stockholders' equity	107,138	102,822
Total liabilities and stockholders' equity	\$ 115,636	\$ 111,745

See accompanying notes to financial statements.

UTAH MEDICAL PRODUCTS, INC.
CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME FOR THE
YEARS ENDED DECEMBER 31, 2021, 2020 AND 2019

(In thousands, except per share amounts)

	2021	2020	2019
Sales, net (notes 1, 3, 9 and 11)	\$ 49,054	\$ 42,178	\$ 46,904
Cost of goods sold	18,137	16,630	17,438
Gross profit	30,917	25,548	29,466
Operating expense:			
Sales and marketing	1,414	1,554	1,738
Research and development	526	486	483
General and administrative	10,097	9,800	9,613
Operating income	18,880	13,708	17,632
Other income (expense):			
Dividend and interest income	166	112	254
Royalty income (note 12)	15	20	6
Other, net	-	-	(8)
Income before provision for income taxes	19,061	13,840	17,884
Provision for income taxes (note 7)	4,273	3,042	3,157
Net income	\$ 14,788	\$ 10,798	\$ 14,727
Earnings per common share (basic) (note 1)	\$ 4.05	\$ 2.95	\$ 3.96
Earnings per common share (diluted) (note 1)	\$ 4.04	\$ 2.94	\$ 3.94
Other comprehensive income (loss):			
Foreign currency translation net of taxes of \$0 in all periods	\$ (773)	\$ 1,502	\$ 1,507
Total comprehensive income	\$ 14,015	\$ 12,300	\$ 16,234

See accompanying notes to financial statements.

UTAH MEDICAL PRODUCTS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOW FOR THE
YEARS ENDED DECEMBER 31, 2021, 2020 AND 2019

(In thousands)

	2021	2020	2019
Cash flows from operating activities:			
Net income	\$ 14,788	\$ 10,798	\$ 14,727
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	636	655	700
Amortization	6,645	6,515	6,144
Provision for losses on accounts receivable	24	(5)	14
Amortization of operating lease assets	3	39	38
Loss/(Gain) on disposal of assets	-	1	16
Deferred income taxes	(92)	(26)	(396)
Stock-based compensation expense	166	160	113
Tax benefit attributable to exercise of stock options	39	7	23
(Increase) decrease in:			
Accounts receivable	(1,088)	617	(738)
Other receivables	(42)	45	(16)
Inventories	(485)	924	(1,686)
Prepaid expenses and other current assets	(81)	108	(16)
Increase (decrease) in:			
Accounts payable	(23)	(308)	114
Accrued expenses	713	607	(1,651)
Long-term repatriation tax payable	-	-	(330)
Net cash provided by operating activities	21,203	20,137	17,056
Cash flows from investing activities:			
Capital expenditures for:			
Property and equipment	(552)	(860)	(540)
Intangible assets	-	-	(21,000)
Net cash (used in) investing activities	(552)	(860)	(21,540)
Cash flows from financing activities:			
Proceeds from issuance of common stock - options	560	358	283
Common stock purchased and retired	-	(6,976)	(398)
Dividends paid	(11,465)	(4,116)	(4,112)
Net cash (used in) financing activities	(10,905)	(10,734)	(4,227)
Effect of exchange rate changes on cash	(362)	260	386
Net increase (decrease) in cash and cash equivalents	9,384	8,803	(8,325)
Cash at beginning of year	51,590	42,787	51,112
Cash at end of year	\$ 60,974	\$ 51,590	\$ 42,787
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the period for income taxes	\$ 4,617	\$ 3,186	\$ 5,304
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, 2021, 2020 AND 2019

(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
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
Shares issued upon exercise of employee stock options for cash	14	-	787	-	-	787
Shares received and retired upon exercise of stock options	(2)	-	(227)	-	-	(227)
Stock option compensation expense	-	-	166	-	-	166
Foreign currency translation adjustment	-	-	-	(773)	-	(773)
Common stock dividends	-	-	-	-	(10,425)	(10,425)
Net income	-	-	-	-	14,788	14,788
Balance at December 31, 2021	3,655	\$ 36	\$ 842	\$ (9,053)	\$ 115,314	\$ 107,138

See accompanying notes to financial statements.

Utah Medical Products, Inc.
Notes to Consolidated Financial Statements
Years Ended December 31, 2021, 2020 and 2019

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.

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, 2021 except under an extreme global financial crisis.

[Table of Contents](#)

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 collectability 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, 2021, using the 2021 year-end 1.3536 USD/GBP and 0.7268 USD/AUD currency exchange rates, is about \$6,542 in 2022, \$5,805 in 2023, \$2,121 in 2024, \$2,121 in 2025, and \$463 in 2026 (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 2022, and \$3,684 in 2023 (see note 15).

[Table of Contents](#)

Stock-Based Compensation

At December 31, 2021, 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 2021, the Company recognized \$166 in stock-based compensation cost compared to \$160 in 2020 and \$113 in 2019.

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 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 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 ASC 740, "Accounting for Income 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.

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 2019 or 2021. 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, 2021 and 2020 was \$96 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:

	2021	2020	2019
Weighted average number of shares outstanding – basic	3,647	3,658	3,721
Dilutive effect of stock options	13	14	18
Weighted average number of shares outstanding, assuming dilution	3,660	3,672	3,739

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 2021 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.

[Table of Contents](#)

Note 2 – Detail of Certain Balance Sheet Accounts

	December 31,	
	2021	2020
Accounts and other receivables:		
Accounts receivable	\$ 5,287	\$ 4,224
Accrued interest and other	39	14
Less allowance for doubtful accounts	(156)	(134)
Total accounts and other receivables	<u>\$ 5,170</u>	<u>\$ 4,104</u>
Inventories:		
Finished products	\$ 1,468	\$ 1,363
Work-in-process	1,398	1,375
Raw materials	3,730	3,484
Total inventories	<u>\$ 6,596</u>	<u>\$ 6,222</u>
Goodwill:		
Balance as of January 1	\$ 14,164	\$ 13,961
Effect of foreign exchange	(66)	203
Subtractions as a result of impairment	-	-
Total Goodwill as of December 31	<u>\$ 14,098</u>	<u>\$ 14,164</u>
Other identifiable intangible assets:		
Patents	\$ 2,212	\$ 2,201
Non-compete agreements	135	137
Trademarks & trade names	9,930	10,021
Customer relationships	9,678	9,769
Distribution agreements	21,000	21,000
Regulatory approvals & product certifications	12,910	13,031
Total Other Identifiable Intangible Assets	55,865	56,159
Accumulated amortization	(38,552)	(32,166)
Other Identifiable Intangible Assets, Net	<u>\$ 17,313</u>	<u>\$ 23,993</u>
Accrued expenses:		
Income taxes payable	\$ 36	\$ 3
Payroll and payroll taxes	1,225	946
Reserve for litigation costs	96	113
Other	1,627	1,941
Total accrued expenses	<u>\$ 2,984</u>	<u>\$ 3,003</u>

Note 3 – Quarterly Results of Operations (Unaudited)

	Unaudited Quarterly Data for 2021			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net Sales	\$ 10,964	\$ 12,604	\$ 12,572	\$ 12,914
Gross Profit	6,947	7,785	8,073	8,112
Net Income	3,024	3,426	4,206	4,131
Earnings Per Common Share (Diluted)	<u>0.83</u>	<u>0.94</u>	<u>1.15</u>	<u>1.13</u>

	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)	<u>0.84</u>	<u>0.36</u>	<u>0.80</u>	<u>0.94</u>

	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)	<u>0.84</u>	<u>0.94</u>	<u>0.99</u>	<u>1.17</u>

Note 4 – Property and Equipment

Property and equipment consists of the following:

	December 31,	
	2021	2020
Land	\$ 1,690	\$ 1,725
Buildings and improvements	14,172	14,531
Furniture, equipment and tooling	16,660	16,750
Right-of-Use Asset	449	377
Construction-in-progress	898	527
Total	33,869	33,910
Accumulated depreciation	(22,802)	(22,584)
Property and equipment, net	\$ 11,067	\$ 11,326

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, 2021			
	U.S. & Canada	England & Australia	Ireland	Total
Land	\$ 621	\$ 678	\$ 391	\$ 1,690
Buildings and improvements	6,541	3,384	4,247	14,172
Furniture, equipment and tooling	14,608	752	1,300	16,660
Right-of-Use Asset	411	-	38	449
Construction-in-progress	412	2	484	898
Total	22,593	4,816	6,460	33,869
Accumulated depreciation	(18,168)	(1,164)	(3,470)	(22,802)
Property and equipment, net	\$ 4,425	\$ 3,652	\$ 2,990	\$ 11,067

	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

[Table of Contents](#)

Note 5 – Long-term Debt

None in 2020 and 2021.

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, 2021 or December 31, 2020.

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.

[Table of Contents](#)

Note 7 – Income Taxes

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

	December 31,		
	2021	2020	2019
Inventory write-downs and differences due to UNICAP	\$ 88	\$ 86	\$ 84
Allowance for doubtful accounts	31	32	33
Accrued liabilities and reserves	58	68	55
Depreciation and amortization	(2,925)	(3,034)	(2,933)
Deferred income taxes, net	<u>\$ (2,748)</u>	<u>\$ (2,848)</u>	<u>\$ (2,761)</u>

The components of income tax expense are as follows:

	Years ended December 31,		
	2021	2020	2019
Current	\$ 3,983	\$ 3,253	\$ 3,467
Deferred	290	(211)	(310)
Total	<u>\$ 4,273</u>	<u>\$ 3,042</u>	<u>\$ 3,157</u>

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

	Years ended December 31,		
	2021	2020	2019
Federal income tax expense at the statutory rate	\$ 2,520	\$ 1,915	\$ 2,512
State income taxes	448	369	(124)
Foreign income taxes (blended rate)	1,010	550	985
ETI, manufacturing deduction and tax credits	(6)	(7)	(9)
Deemed repatriation transition tax	-	263	(266)
US Taxes on foreign income	(99)	(35)	59
Change in Rate	391	-	-
Other	9	(13)	-
Total	<u>\$ 4,273</u>	<u>\$ 3,042</u>	<u>\$ 3,157</u>

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

	Years ended December 31,		
	2021	2020	2019
Domestic	\$ 12,004	\$ 9,031	\$ 11,549
Foreign	7,057	4,809	6,335
Total	<u>\$ 19,061</u>	<u>\$ 13,840</u>	<u>\$ 17,884</u>

[Table of Contents](#)

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 461 thousand shares of common stock, of which 52 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
2021			
Granted	-	\$	- - -
Expired or canceled	3		74.64 - 77.05
Exercised	14		26.52 - 77.05
Total outstanding at December 31	52		33.30 - 77.05
Total exercisable at December 31	34		33.30 - 77.05
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
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

For the years ended December 31, 2021, 2020 and 2019, the Company reduced current income taxes payable by \$39, \$7 and \$23, 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 2021, the Company recognized \$166 in equity compensation cost, compared to \$160 in 2020 and \$113 in 2019.

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,		
	2021	2020	2019
Expected dividend amount per quarter	\$ -	\$ 0.2943	\$ -
Expected stock price volatility	-	27.5%	-
Risk-free interest rate	-	0.56%	-
Expected life of options	-	5.3 years	-

The per share weighted average fair value of options granted during 2020 is \$16.17. No options were granted in 2021 or 2019.

[Table of Contents](#)

All UTMD options vest over a four-year service period. At December 31, 2021 there was \$286 total unrecognized compensation expense related to non-vested stock options under the plans. A \$172 portion of the cost is expected to be recognized over the next twelve months, and the remaining \$114 recognized over the next 2 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, 2021:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 33.30 - 58.50	15,024	3.44	\$ 52.37	15,024	\$ 52.37
74.64 - 77.05	36,834	7.74	76.12	19,263	75.82
<u>\$ 33.30 - 77.05</u>	<u>51,858</u>	<u>6.49</u>	<u>\$ 69.24</u>	<u>34,287</u>	<u>\$ 65.55</u>

	2021	2020	2019
Intrinsic Value of Stock Options Exercised	\$ 591	\$ 371	\$ 354
Intrinsic Value of Stock Options Outstanding	\$ 1,595	\$ 1,178	\$ 2,553

Note 9 – Geographic Information

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

	2021	2020	2019
United States	\$ 30,659	\$ 25,866	\$ 27,493
Europe	7,434	6,399	8,906
Other	10,961	9,913	10,505

Note 10 – Long-lived Assets by Geographic Area

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

	2021	2020	2019
United States	\$ 19,104	\$ 23,327	\$ 27,605
England	19,339	21,871	23,548
Ireland	2,990	3,173	2,639
Australia	392	440	423
Canada	653	672	686

[Table of Contents](#)

Note 11 – Revenues by Product Category and Geographic Region

Global revenues by product category:

	2021	2020	2019
Obstetrics	\$ 4,675	\$ 4,523	\$ 5,000
Gynecology/ Electrosurgery/ Urology	21,973	20,552	25,354
Neonatal	6,691	5,870	6,066
Blood Pressure Monitoring and Accessories	15,715	11,233	10,484
Total:	\$ 49,054	\$ 42,178	\$ 46,904

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

	2021	2020	2019
Obstetrics	\$ 735	\$ 846	\$ 947
Gynecology/ Electrosurgery/ Urology	11,053	9,934	13,731
Neonatal	1,347	1,490	1,412
Blood Pressure Monitoring and Accessories	5,260	4,042	3,321
Total:	\$ 18,395	\$ 16,312	\$ 19,411

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 2021, 2020 and 2019, UTMD received royalties of \$15, \$20 and \$6, respectively, for the use of intellectual property.

UTMD had \$4,891 in operating lease and purchase commitments as of December 31, 2021.

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 \$165, \$167 and \$171 for the years ended December 31, 2021, 2020 and 2019, respectively.

[Table of Contents](#)

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 10 years and on the automobile it is 30 months. There are no options to extend or terminate the leases. The parking lot lease contains a provision that requires an adjustment every five years to the lease payment based on the change in the Consumer Price Index. This adjustment occurred in 2021 requiring an increase of \$87 to the value of the right-of-use asset and lease liabilities. 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.

Operating lease costs for the years ended December 31, 2021, 2020, and 2019 were \$63, \$61, and \$60, respectively.

Supplemental balance sheet information related to operating leases was as follows (*in thousands*):

	As of December 31, 2021
Operating lease right-of-use assets	\$449
Operating lease liabilities – current (included in Accrued Expenses)	52
Operating lease liabilities – long term	396
Total operating lease liabilities	\$449
Maturities of operating lease liabilities at December 31, 2021 were as follows (<i>in thousands</i>):	As of December 31, 2021
2022	\$66
2023	66
2024	57
2025	49
2026	49
Thereafter	227
Total lease payments	\$514
Less: imputed interest	(65)
Total lease liabilities	\$449

The following table provides information on the lease terms and discount rates:

As of December 31, 2021

Weighted average remaining lease term (in years)	9.1 years
Weighted average discount rate	3.6%

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 2021.

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

	2021	2020	2019
Numerator <i>(in thousands)</i>			
Net income	14,788	10,798	14,727
Denominator			
Weighted average shares, basic	3,647	3,658	3,721
Dilutive effect of stock options	13	14	18
Diluted shares	3,660	3,672	3,739
Earnings per share, basic	4.05	2.95	3.96
Earnings per share, diluted	4.04	2.94	3.94

Note 17 – Recent Accounting Pronouncements

The Company has determined that other recently issued accounting standards will either have no material impact on its consolidated financial position, results of operations or cash flows, or will not apply to its operations.

Note 18 – Subsequent Events

The Company evaluated its December 31, 2021 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 2021, 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, 2021, 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, 2021. 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, 2021, 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 2022 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: 2021 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 2022 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 2022 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 2022 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 2022 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 2022 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.

<u>Exhibit #</u>	<u>Title of Document</u>	<u>Location</u>
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 (3)
10.2	Amendment, effective May 15, 1998, to Employment Agreement dated December 21, 1992 with Kevin L. Cornwell*	Incorporated by Reference (3)
10.3	Utah Medical Products, Inc., 2003 Employees' and Directors' Incentive Plan*	Incorporated by Reference (4)
10.4	Utah Medical Products, Inc., 2013 Employees' and Directors' Incentive Plan*	Incorporated by Reference (5)
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, 2021 and December 31, 2020	This filing
23.2	Consent of Nortons Assurance Limited, Femcare Group Limited's independent auditors for the years ended December 31, 2021 and December 31, 2020	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, 2021, 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.

ITEM 16 – FORM 10-K SUMMARY

None.

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 25th day of March 2022.

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 25th day of March 2022.

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

