

UTAH MEDICAL PRODUCTS INC
Form 10-K
March 12, 2014

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, 2013

Commission File Number: 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 S 300 W, Midvale Utah
(Address of principal executive offices)

84047
(Zip Code)

Registrant's telephone number, including area code: Telephone (801) 566-1200
Facsimile (801) 566-7305

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

Title of each class
Common Stock, \$.01 Par Value
Preferred Stock Purchase Rights

Name of each exchange on which registered
The NASDAQ Global Market

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the 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, 2013, the aggregate market value of the voting and nonvoting common equity held by nonaffiliates of the registrant was \$177,627,000.

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 11, 2014, common shares outstanding were 3,753,000.

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

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PART I

ITEM 1 – BUSINESS

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

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

- a) UTMD's own direct channels into markets where the Company enjoys an established reputation and has a critical mass of sales and support resources, or
- b) relationships with other medical companies that have the resources to effectively distribute and support the Company's products.

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

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

UTMD's products are sold directly to end users in the U.S. domestic market by the Company's own direct sales representatives and independent manufacturers' representatives. In addition, some of UTMD's products are sold through specialty distributors, national hospital distribution companies and other medical device manufacturers. Internationally, products are sold directly to end users in the UK and Australia, and through other medical device companies and through independent medical products distributors in many other countries. UTMD has representation in all major developed countries as well as many underdeveloped countries through several hundred distributors, 142 of which purchased at least five thousand dollars in UTMD medical devices during 2013.

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 \$112,680 in the form of share repurchases, and an additional \$34,459 in the form of 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 international customers. In 1997, UTMD purchased Columbia Medical, Inc. (CMI), a Redmond, Oregon 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. Femcare is best known for its leading global gyn brand, the Filshie Clip System, a female surgical contraception device (tubal ligation). The addition of Femcare provides product and distribution channel

diversification and expansion. Sales of the products, or derivatives of the products, from the four acquisitions noted above, comprised 63% of UTMD's consolidated 2013 sales.

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 Stuart Court, Spursholt Place, Salisbury Road, Romsey, Hampshire SO51 6DJ, UK. The UK phone number is 44 (179) 452-5100. Australia operations are located at Unit 12, 5 Gladstone Road, Castle Hill, NSW 2154, Australia. The Australia phone number is 612 9869 7544.

PRODUCTS

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

Labor and Delivery/ Obstetrics:

Fetal Monitoring Accessories.

The majority of births are considered "higher risk" due to lack of prenatal care, or use of anesthesia, among other factors. In many of these births, labor may become complicated and does not progress normally. The obstetrician or perinatologist must assess progression of labor to be able to intervene with drug therapy, infuse a solution to augment amniotic fluid, or ultimately if necessary, perform an operative procedure, and then be prepared for complications immediately following childbirth.

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

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

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

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

UTMD markets tocodynamometer belts, disposable electrodes, catheters and accessories as outlined above, but does not currently market electronic monitors, the capital equipment that process the electrical signals. In addition to products currently offered, UTMD intends to continue to investigate and introduce tools that enhance fetal monitoring techniques.

Vacuum-Assisted Delivery Systems (VAD).

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

knowledgeable physicians with a trial vaginal operative delivery prior to a more invasive C-section intervention. Although there are risks associated with vaginal operative deliveries which may currently represent 3-5% 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 estimates that the VAD operative approach is used for about 3-5% of all U.S. births, with forceps as the alternative. UTMD's patented bell-shaped soft silicone TENDER TOUCH® cups enjoy a low reported complication rate compared to other vacuum cup designs, as evidenced by the FDA Medical Device Reporting System (MAUDE) which lists serious injuries reported by hospitals using specific brand names of products.

Other Obstetrical Tools.

AROM-COT™ is a finger cover with a patented prong design to rupture maternal membranes with less patient pain and anxiety. MUC-X is an aspiration device used immediately after birth to clear neonatal respiratory passages and reduce exposure to potential infections. CORDGUARD® is a product which unifies the multiple steps of clamping the neonate's cord close to the umbilicus, severing the cord without splattering blood, drawing a clean cord blood sample, and assisting in the removal of the placenta. CORDGUARD's sharpless, closed system reduces the risk of exposure to potentially infected blood, and consequently reduces the high cost of exposure treatment under OSHA and CDC guidelines. In addition, CORDGUARD facilitates obtaining neonatal blood that is otherwise hard to obtain safely and cleanly. BT-Cath® is a uterine balloon tamponade catheter for controlling severe postpartum hemorrhage. Its benefits include the ease of rapid deployment and ability to monitor further bleeding after the tamponade has been placed. Abcorp toco belts and straps for fetal monitoring by an external tocodynamometer are provided in latex-free form in several configurations.

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 and provides optimum flows for elimination of CO₂ by ventilation.

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 cross-contamination. Less invasive and constraining than nasal cannulae, Disposa-Hood avoids potential damage to fragile premature neonatal nasal/orotracheal tissues and maintains 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. In 2013, UTMD continued its customization of Deltran kits for specific hospital applications.

GESCO®

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

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

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

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

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

In 2006, UTMD developed a unique enteral feeding-only extension set named NUTRI-LOK® that addresses important safety risks in the NICU – inadvertent connections with IV lines and inadvertent disconnections of components of the system spanning the dispensing container through the infusion catheter. NUTRI-LOK was launched to the market in January 2007. In October 2007, UTMD added dispensing syringes with interlocking connectors to its NUTRI-CATH/NUTRI-LOK family of enteral feeding devices. In 2008, UTMD expanded the NUTRI-LOK system with specialty extension sets for GI tubes and for continuous connection to a fluid pump. In 2009, UTMD added a Kangaroo bag for larger feeds along with other NUTRI-LOK accessories. In 2011, UTMD added variations in adapters and extension sets used with NUTRI-CATH.

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

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

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

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

In 2014, UTMD expects to continue to improve and expand its neonatal product line, seeking to reinforce a reputation as having the most developmentally-friendly NICU specialty products in the medical device industry.

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

After more than 20 years on the market, in 2012 UTMD completed a significant redesign, and achieved certification to the latest EN 60601 international safety standards, for a new FINESSE+ electrosurgical generator. The new 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 modern electronic components which reduces the number of required components and increases service life, and an easy change internal filter for integral smoke evacuation, a unique feature of Finesse. UTMD obtained FDA premarketing clearance for Finesse+ in January 2013.

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

UTMD has FDA clearance to market its electrosurgical system and tools for use in general surgery applications, including dermatology, plastic surgery and otolaryngology. In 2002, UTMD introduced a product line of ultra-fine tipped microdissection needles, called OptiMicro™ Needles. These electrosurgical needles are particularly useful in small-scale plastic and reconstructive surgery applications. In 2009, UTMD added extended length OptiMicro needle versions useful in certain head and neck procedures. FILTRESSE is a stand-alone surgical smoke filtration system that combines high filtration efficiency, low cost and convenient use in a surgical office setting. Other electrosurgery tools and accessories include disposable electrosurgical pens, dispersive pads, footswitches, filter packs, speculums, retractors, forceps, tenacula and hooks. UTMD acquired the distribution rights to a unique reusable four-way expander system which facilitates access to, and visualization of, the cervix, eliminating the need for less effective specula and lateral retractors. In 2007, UTMD developed OptiSpec®, a patented ultra-bright light for cervical visualization without physician distraction during exams, pap smears and other vaginal procedures requiring direct cervical visualization without the use of a colposcope. In 2009, UTMD entered into a distribution agreement for the CompuMed anesthesia injection system for providing computer-controlled, accurate, and pain-free injection of Lidocaine in LETZ procedures. In 2011, UTMD acquired Femcare's single patient use trochars and cannulae available in shielded, bladeless, optical bladeless, blunt and thoracic designs. In addition, UTMD acquired Femcare's laparoscopic instrument range and accessories which includes instruments suitable for all routine laparoscopic procedures requiring dissection, cutting, grasping and coagulation, e.g., monopolar scissors, various grasping forceps, dissecting forceps, L and J hooks, spatulae, Verres needles, suction and irrigation tubing, insufflation tubing and connectors, pressure infusor bags and control valves.

EPITOME®

EPITOME is a patented electrosurgical scalpel which delivers precise performance in incision and excision with hemostasis while minimizing thermal side effects. Where rapid yet precise dissection of dense tissue is necessary, such as in mammoplasty or abdominoplasty, UTMD believes that EPITOME has no close substitute. Furthermore, an independent study concludes that the EPITOME scalpel provides a significant improvement over older devices in wound healing and patient comfort. 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 patented bendable version of EPITOME with a smaller active electrode was introduced in 1998. Designed to significantly reduce the chance of tissue burns due to inadvertent electrode contact and where a smaller, bent scalpel tip is needed, the bendable EPITOME is of particular value, e.g., to thoracic surgeons in harvesting the internal mammary artery during coronary artery bypass surgery, as well as to otolaryngologists for tonsillectomies or uvulopalatalplasties.

FILSHIE CLIP System

UTMD acquired the Filshie Clip System as part of its acquisition of Femcare in March 2011. In 2013, sales of Filshie Clips, applicators and accessories represented 35% of UTMD's total 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 post partum during a C-Section procedure. The Filshie Clip, in use for over 30 years, is as effective as the newest occlusive devices and much more effective than the more traditional tubal ligation sterilization approaches, is as easy or easier to place as any of the traditional techniques and much easier than the newer hysteroscopic devices, is safer than electrocautery and the newer hysteroscopic devices when placed by less than well-trained and skilled clinicians, and has a substantially higher probability of reversibility when compared to all of the other approaches for women who later decide they may like to get pregnant.

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 at post-partum, 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. Although these common methods are relatively easy to perform, the "failure rate" of these methods, defined as the percentage of patients having undergone the procedure who subsequently get pregnant, has been reported to be about 3%. The Filshie Clip, which can be used at either interval or post-partum, is at least as easy to use and has a failure rate an order of magnitude less than Bipolar Cautery and the Pomeroy technique.

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

In more recent years, hysteroscopic sterilization has been introduced as an alternative to laparoscopic tubal ligation. The device is the ESSURE by Conceptus, Inc. After a patent dispute with Conceptus, Hologic, Inc. terminated sales of its hysteroscopic sterilization ADIANA device in 2012. Both these devices are/were inserted transvaginally, and are considered to be permanent implants. Although similar to the Filshie Clip in their effectiveness as measured after successful application, they take some time after placement to become effective, require an additional later procedure to confirm the tubes are blocked, are not reversible allowing later pregnancy and require more clinical skill to apply correctly. Thus greater physician training and skill is required to successfully complete the procedure. These devices may also preclude a patient from receiving later electrosurgical procedures, for example ablation to address abnormal uterine bleeding, unless they are first surgically removed.

The U.S. FDA released the Filshie Clip for marketing in 1996 after a Femcare PMA submission. Now the Filshie Clip is effectively marketed in the U.S. through an exclusive distribution agreement with Cooper Surgical, Inc. In 2013, sales to Cooper Surgical for use in the U.S. were 23% of total Filshie Clip System sales. Outside the U.S., the Filshie Clip has numerous regulatory approvals and is now being sold directly by UTMD to clinicians in Ireland, the U.K. and Australia, and through specialty distributors in other countries.

PATHFINDER PLUS™

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

LAWRENCE ADD-A-CATH

The Lawrence Add-a-Cath introducer is a proprietary Femcare device designed for easy 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. Previous to UTMD's acquisition of Femcare, it was distributed in the U.S. through an OEM customer. In 2013, UTMD introduced suprapubic catheterization procedure kits featuring the Lawrence Supra-Foley introducer which it now distributes directly to end users in the U.S.

HOLMIUM LASER FIBRES

As part of its urology product line, Femcare distributes reusable and single patient use laser energy delivery devices which can dependably transmit both the Holmium and Nd:YAG wavelengths.

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 patented tip of the EndoCurette was designed to obtain a more thorough tissue specimen 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 are increasingly utilizing 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 patented 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, patented 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 internationally.

The Company believes that the DELTRAN DPT which it designed over twenty-five years ago (original patents have expired), and currently manufactures, remains the standard in terms of accuracy, reliability and ease of use. UTMD has an automated assembly line which allows the Company to effectively compete with larger suppliers on the basis of consistent quality and low manufacturing costs. Introduced in 1998, the DELTRAN PLUS provides a closed system for blood sampling, without the use of needles, reducing the risk of an unwanted infection for both the patient and the practitioner. In 2009, in conjunction with its other NICU devices, UTMD continued to configure neonatal Deltran custom kits which satisfy the special needs of conserving limited blood volume and protecting the neonate from infection.

Pressure Monitoring Accessories, Components and Other Molded Parts.

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

MARKETING and COMPETITION

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

In the past, UTMD has divided domestic U.S. sales into "direct sales" and "OEM sales." Included in direct sales have been sales of finished devices through hospital distributors. OEM sales are theoretically to other medical device (or non-medical device) companies where UTMD products are components of their finished product offerings. The distinction starts to blur when distributors purchase components or finished devices that they relabel or market as part of a kit, or other medical device companies purchase finished devices that they sell as a distributor. A significant recent example is the Filshie Clip System sold to Cooper Surgical by Femcare-Nikomed Ltd, a subsidiary of UTMD, under a distribution agreement for the U.S. Because Cooper Surgical is another medical device company, UTMD has included these sales in its Domestic OEM Sales category since the 2011 acquisition of Femcare. However, Cooper is really a distributor of Femcare's finished devices. The regulatory responsibility is Femcare's with respect to product safety and effectiveness. However, from a marketing perspective, labels include both the Femcare and the Cooper Surgical names. UTMD could classify the sales as domestic direct because Cooper Surgical is a distributor of UTMD's subsidiary finished devices, or as domestic OEM because Cooper Surgical is another medical device company which has its name on the label. As sales of components to non-medical device entities are immaterial, UTMD will no longer try to make the distinction between domestic direct sales and domestic OEM sales. As an observation, UTMD stopped trying to make the distinction for its international sales over a decade ago, because a greater portion of its international sales were to foreign "distributors" which are difficult to classify as either direct or OEM.

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 and trade shows. However, in competitive bidding processes, UTMD works primarily with administrators who are responsible for hospital purchasing decisions.

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

As a general rule, because of UTMD's differences in design and manufacturing reliability, competitors' devices represent substitutes rather than equivalent devices. The Company's primary marketing challenge is to keep its customers focused on those differences and their important clinical benefits. In recent years, UTMD's access to 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 hospitals become less focused on patient safety and clinical outcomes and more on out-of-pocket unit price, UTMD's competitive position weakens.

In 2013, UTMD sold components and finished devices to 153 other companies in the U.S. For over 30 years, the Company has utilized its manufacturing capabilities and engineering know-how to produce high quality components for other companies. Because it is well-known in that regard, UTMD does not actively market its OEM business. UTMD's website, which lists its capabilities, is often the basis for contacts for new OEM work.

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

2) International sales.

In 2011-2013, international sales represented a majority of consolidated total sales. Prior to 2011, with only a few exceptions, UTMD's international sales were to other medical device companies and distributors, not to clinical users. After the acquisition of Femcare, UTMD began the transition to selling direct to end user facilities in the UK, Australia and Ireland, which has a positive impact on revenues as well as gross margins. UTMD expects that international sales will continue to grow more rapidly than its domestic sales, as the standard of living in emerging countries continues to improve. UTMD's website provides information that frequently results in unsolicited contacts from foreign entities. The Company has thousands of competitors worldwide.

DISTRIBUTION

An important success factor in the current U.S. healthcare industry is access to customers. Although the U.S. hospital supplier environment has been consolidating as a result of group purchasing organizations (GPOs), or their equivalents, the financial relationships and true benefits for hospitals has come under scrutiny, both by hospitals' managements themselves and by the government. As a potential positive factor to UTMD's future performance, the increased scrutiny may lead to an understanding consistent with UTMD's belief that U.S. hospitals are not currently saving money under the GPO contracts when it comes to specialty medical devices that can reduce complications and unwanted side effects.

In addition, 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, as well as the medical device excise tax levied under the 2010 Patient Protection and Affordable Care Act. The length of time and number of administrative steps required in evaluating new products for use in hospitals has grown substantially in recent years. 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 products through national distribution companies, also known as Med/Surg distributors. Sales to Med/Surg distributors currently comprise about 14% of total domestic direct sales.

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

In addition to traditional sales approaches, UTMD encourages customers to take advantage of fast and easy online ordering at <https://storefront.utahmed.com>. UTMD introduced this advanced portal website in 2006. It provides a

convenient and secure method for placing orders, allows the customer to easily monitor the status of orders and shipments, simplifies the reordering process and gives quick access to account information.

Additionally, UTMD sells component parts to other companies for use with their product lines. This OEM distribution channel effort is simply maximizing utilization of manufacturing capabilities that are otherwise needed for UTMD's primary business, and, except in the case of distribution of the Filshie Clip System in the U.S. by Cooper Surgical, Inc., does not compete with or dilute UTMD's direct distribution and marketing programs.

Internationally, the Company sells its products through over 350 regional distributors and OEMs (other medical device manufacturers and/or distributors) in addition to its own direct representatives in the UK and Ireland. Although sales by Femcare Australia are direct to end users, UTMD does not currently employ direct sales representatives there. The international business activity outside the UK and Ireland is driven by UTMD's brand awareness by clinicians and the initiative and resourcefulness of independent distributors. Ten percent of these distributors represented over 80% of UTMD's indirect international sales in both 2013 and 2012.

UTMD's Internet website www.utahmed.com is a frequent conduit for international customer inquiries.

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 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 new 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. Approximately ten projects on the average, depending on the level of resources required, are underway at UTMD at any given time. More than 50% of assigned projects do not 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 development projects are in the following areas: 1) augmentation of Femcare devices acquired in 2011, 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 be in the range of 1-2% of sales in 2014.

EMPLOYEES

At December 31, 2013, the Company had 177 employees, and an additional eleven subcontract employees in Utah. The subcontract employees represent UTMD's desire to provide handicapped persons additional work opportunities, hired through the Utah state-supported Work Activity Center. The average tenure of UTMD employees in the U.S. is over fourteen years and in Ireland is over eleven years, which conveys an important benefit due to the level of training required to produce consistently high quality medical devices. The Company's continued success will depend to a large extent upon its ability to retain skilled and experienced employees. No assurances can be given that the Company will be able to retain or attract such employees in the future, although management is committed to providing an attractive environment in which reliable, creative and high achieving people wish to work.

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

PATENTS, TRADEMARKS AND TECHNOLOGY LICENSES

The Company owns or exclusively licenses twenty unexpired patents, 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 forty 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, 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 incremental clinical utility, which may be dominated by a number of other factors including relative cost, ease of use, ease of training/adoption, perceived clinical value of different design features, risk of use in applicable procedures, the reliability of achieving a desired outcome in the hands of different users and market access to potential users. In cases where competitors introduce products that may infringe on UTMD's technology or trademarks, the Company has an obligation to its stockholders to defend its intangible property to the extent that it can afford to do so, and that it is material to the Company's success. The Company must also defend itself when competitors allege that UTMD may be infringing their technology.

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 2013, ongoing royalties included in cost of goods sold were \$282. Other royalties have been previously paid as a lump sum, or were incorporated into the price of acquisitions or into the cost of purchased components which practice certain patents of third parties. Also as a matter of policy, UTMD licenses its proprietary technology to others in circumstances where licensing does not directly compete with UTMD's own marketing initiatives. UTMD's future financial performance may also depend on the marketing ability of other companies that license UTMD's technology. During 2013 the Company received \$90 in royalty income, compared to \$89 in 2012 and \$71 in 2011.

GOVERNMENT REGULATION

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

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

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

Except for the Filshie Clip System, all of UTMD's present products are unclassified, Class I or Class II devices. The Filshie Clip System is a Class III device which has more stringent regulatory controls. The Company is in compliance with all applicable U.S. regulatory standards including CFR Part 820, the FDA Quality System Regulation (QSR) effective in 1997, also known as cGMPs (current good manufacturing practices). The Company's most recent FDA inspection was in March 2010, which did not result in the issuance of any FDA-483 observations.

In 1994, UTMD received certification of its quality system under the ISO9001/EN46001 standards ("ISO" stands for "International Organization of Standardization") which it maintained until December 2003. In October 2003, UTMD's Utah facility was certified under the more stringent ISO13485 standard for medical devices. UTMD's Ireland facility was certified under the concomitant ISO13488 standard. In July 2006, both facility ISO certifications were upgraded to the even more stringent ISO13485:2003 standards, which continue to be maintained. UTMD's Femcare subsidiary is also certified under ISO13485:2003. UTMD remains on a continuous periodic audit schedule by its independent notified body in order to stay current with international regulatory standards, and retain its certifications. UTMD has

received CE Mark certifications (demonstrates proof of compliance with the European Community's ISO standards) for essentially all of its products. The U.S. FDA QSR was developed in harmony with the ISO standards.

SOURCES AND AVAILABILITY OF RAW MATERIALS

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

EXPORTS

UTMD regards the international marketplace as the most important element of its growth strategy. UTMD is keenly aware that not only are international 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 three international facilities; in Romsey, Hampshire, England; in Castle Hill, NSW, Australia and in Athlone, County Westmeath, Ireland. These facilities offer a number of advantages: 1) from a marketing point of view, better response to Europe, Middle East, 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 existing U.S. facilities.

Total revenues from customers outside the U.S. in 2013 were \$21,528 (53% of total sales), compared to \$21,591 (52% of total sales) in 2012 and \$19,007 (50% of total sales) in 2011. Exports from the U.S. to international customers were \$5,203 in 2013, \$5,295 in 2012 and \$5,387 in 2011. Exports represented 24%, 25% and 28% of total UTMD international trade sales in 2013, 2012 and 2011, respectively. U.S. international trade sales (exports) exclude intercompany sales to UTMD subsidiaries which distribute U.S.-made finished devices directly to end-users in Ireland, the U.K. and Australia.

For sales by international geographic area, please see notes 1 and 11 to the Consolidated Financial Statements.

BACKLOG

“Backlog” is defined as orders received and accepted by UTMD which have not shipped yet. As a supplier of primarily disposable hospital products, the nature of UTMD’s business requires fast response to customer orders. Virtually all direct shipments to end users are accomplished within a few days of receipt of customer purchase orders. Consequently, UTMD’s backlog at any point in time is comprised mainly of orders from OEM and international customers, which purchase in larger quantities at less frequent intervals. Backlog shippable in less than 90 days was \$2,002 as of January 1, 2014, \$2,316 as of January 1, 2013 and \$1,293 as of January 1, 2012.

SEASONAL ASPECTS

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

PRODUCT LIABILITY RISK MANAGEMENT

The risk of product liability lawsuits is a negative factor in the medical device business 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 35 year history.

UTMD in the U.S. and Ireland is self-insured for product liability risk, and reserves funds against its current performance on an ongoing basis to provide for its defense should any lawsuits be filed. The Company's average cost of defense (excluding Femcare) over the last twenty-one years was \$21 per year. Because the Filshie Clip is a Class III device, Femcare insures its product liability risk through a third-party insurance company at a cost of about £90 per year.

The best defense the Company believes that it has is the consistent conformance to specifications of its proven safe and effective products. Over the time span of the last twenty-one years, UTMD has been named as a defendant in a total of six lawsuits. Four lawsuits involved a patient injury related to operative vaginal deliveries where a UTMD VAD birthing cup or hand pump was used. The VADS devices in all four cases did conform to specifications. UTMD was ultimately dismissed as a defendant in all four of the lawsuits, and legal costs were not material to performance. During the last twenty-one year period of time during which over twenty-seven million finished devices (excluding Femcare) were used, there were only two other lawsuits involving UTMD devices. In the first, regarding the use of EndoCurette, there was no evidence of patient injury. The lawsuit was settled in 2010 for an immaterial amount to avoid the diversion of management time and substantial costs of litigation, even though UTMD was confident that the case was without merit. In the second, UTMD was brought into a lawsuit by a defendant physician, speculating a design deficiency in a Finesse electrosurgical generator (ESU) which had been in use for eighteen years before the injury event, and used successfully by the same physician 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. UTMD is seeking reimbursement of its legal costs. Presently, there are no product liability lawsuits in which UTMD is a defendant.

In the current tort system in the U.S., frivolous product liability cases do get filed where aggressive attorneys calculate that a company will find it cheaper to settle for some nominal amount in lieu of substantial defense costs of going to court.

FORWARD LOOKING INFORMATION

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

ITEM 1A – RISK FACTORS

Legislative healthcare reform in the United States, as embodied in The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (the “Acts”) adds a substantial excise tax that began in 2013, increases administrative costs and may lead to decreased revenues:

The voluminous Acts, administrative rules to enforce the Acts and promised efforts to reform the Acts, make the U.S. medical device marketplace unpredictable, particularly for the thousands of small medical device manufacturers including UTMD that do not have the overhead structure that the large companies can afford. To the extent that the Acts place additional burdens on small medical device companies in the form of an excise tax on medical device sales, additional oversight of marketing and sales activities and new reporting requirements, the result is likely to be negative for UTMD’s ability to effectively compete and support continued investments in new product development and marketing of specialty devices.

Increasing regulatory burdens including premarketing approval delays may result in significant loss of revenue, unpredictable costs and loss of management focus on helping the Company thrive:

The Company's experience in 2001-2005, when the FDA sought to shut it down highlights the ongoing risk of being subject to a regulatory environment which can be arbitrary and capricious. The risks associated with such a circumstance relate not only to the substantial costs of litigation in millions of dollars, but also loss of business, the diversion of attention of key employees for an extended period of time, from new product development and routine quality control management activities, and a tremendous psychological and emotional toll on employees.

Since the FDA reserves to itself the interpretation of which vague industry standards comprise law at any point in time, it is impossible for any medical device manufacturer to ever be confident that it is operating within the Agency's version of the law. The result is that companies, including UTMD, are considered guilty prior to proving their innocence. New premarketing submission rules and substantial increases in "user fees" increase development costs and result in delays to revenues from new or improved products.

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

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

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

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

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

An aging population and an extended economic recession are 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 customers because of the existence of long term supply agreements for preexisting products, particularly from competitors which offer hospitals a broader range of products. Restrictions used by hospital administrators to limit clinician involvement in device purchasing decisions makes communicating UTMD's clinical advantages much more difficult.

A product liability lawsuit could result in significant legal expenses and a large award against the Company:

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

The Company's reliance on third party distributors in some markets may result in less predictable revenues:

UTMD's distributors have varying expertise in marketing and selling specialty medical devices. They also sell other devices that may result in less focus on the Company's products.

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. The rapid 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.

ITEM 1B – UNRESOLVED STAFF COMMENTS

None

ITEM 2 - PROPERTIES

Office and Manufacturing Facilities.

At the beginning of 2014, the Company's operations were located in 110,000 square feet of facilities near Salt Lake City, Utah, a 77,000 square foot facility in Athlone, County Westmeath, Ireland, a 12,000 square foot facility near Romsey, Hampshire, England, and a 1,000 square foot temporary facility in Baulkham Hills, NSW, Australia. In 2011, UTMD assumed the lease for its Romsey facilities which house Femcare in the UK. The Company has recently purchased a 3,200 square foot facility in Castle Hill NSW, Australia. Pending the completion of its new Australia facility, the Company is leasing nearby space on a short term basis. In the U.S. and Ireland, UTMD owns all of its property and facilities with the exception of a long-term lease with 18 years remaining on one section of its Midvale parking lot.

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 internationally, and administrative offices.

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 for which the Company believes the outcome may be material to its financial results.

ITEM 4 - RESERVED

PART II

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

Market Information.

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

	2013 High	Low	2012 High	Low
1st Quarter	\$ 49.85	\$ 36.18	\$ 31.90	\$ 26.61
2nd Quarter	54.59	40.84	36.00	27.97
3rd Quarter	64.84	48.30	34.74	33.30
4th Quarter	60.89	48.46	36.32	32.99

Stockholders.

The approximate number of beneficial stockholders of UTMD's common stock as of March 4, 2014 was 2,500.

Dividends.

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

Record Date	Payable Date	Per Share Amount
March 19, 2012	April 4, 2012	\$0.24
June 15, 2012	July 5, 2012	0.24
September 14, 2012	October 5, 2012	0.24
December 13, 2012	December 28, 2012	0.245
March 19, 2013	April 4, 2013	0.245
June 14, 2013	July 3, 2013	0.245
September 16, 2013	October 4, 2013	0.245
December 16, 2013	December 30, 2013	0.25
2012 total cash dividends paid per share		\$ 0.965
2013 total cash dividends paid per share		\$ 0.985

Issuer Purchases of Equity Securities.

UTMD did not purchase any of its own securities during fourth quarter 2013.

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, 2013, are derived from the audited financial statements and notes of UTMD and its subsidiaries, certain of which are included in this report. The selected consolidated financial data should be read in conjunction with UTMD's Consolidated Financial Statements and the notes included elsewhere in this report.

	Year Ended December 31				
	2013	2012	2011	2010	2009
Net Sales	\$ 40,493	\$ 41,552	\$ 37,860	\$ 25,121	\$ 25,916
Net Income	11,406	10,169	7,414	6,014	6,258
Earnings Per Common Share (Diluted)	3.02	2.74	2.03	1.65	1.72
Total Assets	80,711	76,935	76,389	41,238	41,754
Working Capital	16,675	10,712	7,385	23,239	24,472
Long-term Debt	5,065	9,003	16,242	909	1,403
Cash Dividends Per Common Share	0.985	0.965	0.945	1.665	0.925

	Quarterly Data for 2013			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net Sales	\$ 10,374	\$ 10,002	\$ 10,032	\$ 10,085
Gross Profit	6,281	6,048	5,949	5,994
Net Income	2,735	2,632	2,571	3,468
Earnings Per Common Share (Diluted)	.73	.70	.68	.92

	Quarterly Data for 2012			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net Sales				