

UTAH MEDICAL PRODUCTS INC  
Form 10-K  
March 10, 2016

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-K  
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2015  
Commission File Number: 001-12575  
UTAH MEDICAL PRODUCTS, INC.

(Exact name of registrant as specified in its charter)

Utah 87-0342734  
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

7043 S 300 W, Midvale Utah 84047  
(Address of principal executive offices) (Zip Code)

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

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

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

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

(Title of Class)

None

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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, 2015, the aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was \$199,695,980.

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 9, 2016, common shares outstanding were 3,753,400.

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 differentiated devices represent significant incremental improvements in patient safety, clinical outcomes and/or total cost over preexisting clinical tools. UTMD's experience is that, in the case of labor saving devices, the improvement in cost effectiveness of clinical procedures also leads to an improvement in overall healthcare including lower risk of complications. UTMD markets a broad range of medical devices used in critical care areas, especially the neonatal intensive care unit (NICU), the labor and delivery (L&D) department and the women's health center in hospitals, as well as products sold to outpatient clinics and physician's offices.

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

Domestically, UTMD's medical devices are sold directly to clinical end user facilities by the Company's own direct sales representatives and independent manufacturers' representatives. In addition, some of UTMD's devices 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, Ireland and Australia, and through other medical device companies and through independent medical products distributors in many other countries. UTMD has representation globally in all major developed countries as well as many underdeveloped countries through several hundred distributors, 132 of which purchased at least five thousand dollars in UTMD medical devices during 2015.

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 \$114,418 in the form of share repurchases, and an additional \$42,764 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 international customers. In 1997, UTMD purchased Columbia Medical, Inc. (CMI), a company specializing in silicone injection molding, assembly and marketing vacuum-assisted obstetrical delivery systems. In 1998, UTMD acquired the neonatal product line of Gesco International, a subsidiary of Bard Access Systems and C.R. Bard, Inc. In 2004, UTMD acquired Abcorp, Inc., its supplier of fetal monitoring belts. In 2011, UTMD purchased all of the common shares of Femcare Holdings Ltd (Femcare) of the United Kingdom, and its subsidiaries. The addition of Femcare provided product and distribution channel diversification and expansion. Sales of the products, or derivatives of the products, from the four acquisitions noted above, comprised 63% of UTMD's consolidated 2015

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 9045 4110.

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## PRODUCTS

More complete descriptions including part numbers and pictures of UTMD's devices can be conveniently obtained at [www.utahmed.com](http://www.utahmed.com) and [www.femcare-nikomed.co.uk](http://www.femcare-nikomed.co.uk).

### Labor and Delivery/ Obstetrics:

#### Fetal Monitoring Accessories.

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

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

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

Introduced in 1987, INTRAN was the first disposable intrauterine pressure catheter that placed the pressure transducer at the pressure source within the uterine cavity. This design eliminated the complicated setup of fluid filled systems and provided more accurate pressure waveforms. INTRAN I was discontinued in 1995 in favor of the more widely preferred INTRAN PLUS, 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, catheters and accessories as outlined above, but does not currently market electronic monitors, the capital equipment that processes 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 reusable hand-held vacuum pumps which UTMD believes are the safest products available for use in vacuum-assisted operative deliveries. UTMD's soft silicone cup is a bell-shaped cup design that should be preferred for fetal well-being in low or outlet fetal stations with occiput anterior presentations, which represent more than 90% of the cases where VAD is indicated. Operative vaginal deliveries using forceps or vacuum-assisted delivery systems provide knowledgeable

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

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Other Labor & Delivery Tools.

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

Neonatal Intensive Care:

DISPOSA-HOOD™

The DISPOSA-HOOD is an infant respiratory hood that is used in the NICU to administer oxygen to neonates and flush CO<sub>2</sub> (carbon dioxide) while maintaining a neutral thermal environment (NTE) critical to proper physiologic responses. The DISPOSA-HOOD, placed over the infant's head, incorporates a round diffusor connection specifically designed to disperse the incoming gases along the inner surfaces of the hood, rather than allowing them to blow directly on the infant's head. The design allows more precise FIO<sub>2</sub> (fractional inspired oxygen) control, minimizes convective heat loss from the head, provides optimum flows for elimination of CO<sub>2</sub> by ventilation and allows for humidification. DISPOSA-HOOD, in contrast to an incubator, allows for excellent access to and visualization of the underdeveloped infant. Because it is a disposable product, it also prevents potential cross contamination that might occur with an incubator. Less invasive than nasal cannulae, Disposa-Hood avoids potential damage to fragile premature neonatal nasal/ orotracheal tissues, as well as facial tissues as cannulae are often secured with tape. A nasal cannula by itself cannot provide a NTE.

DELTRAN® PLUS

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

GESCO®

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

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



line, Gesco pioneered the use of soft, biocompatible silicone catheters, helping to reduce the number of insertions required as well as other complications associated with invasive applications. UTMD has expanded the UVC product line to include catheters made from a proprietary thermosensitive polyurethane (Tecoflex®) that offers many of the flexibility and biocompatibility advantages of silicone after insertion, with the greater rigidity of polyurethane preferred by many clinicians for ease of 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.

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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. In October 2007, UTMD added dispensing syringes with interlocking connectors to its NUTRI-CATH/NUTRI-LOK family of enteral feeding devices. In 2008, UTMD expanded the NUTRI-LOK system with specialty extension sets for GI tubes and for continuous connection to a fluid pump. In 2009, UTMD added a Kangaroo bag for larger feeds along with other NUTRI-LOK accessories. In 2011, UTMD added variations in adapters and extension sets used with NUTRI-CATH. Recognizing the important need to prevent misadministration of enteral feeding or medication by the wrong route, the FDA in February 2015 released its final guidance, "Safety Considerations to Mitigate the Risks of Misconnections with Small Bore Connectors Intended for Enteral Applications." The guidance includes compliance with ISO 80369-3 standard connectors. This new standard was released to create a universal connection that is not compatible with a luer connection or any other type of small bore medical connector. In 2016, UTMD will introduce a completely revamped enteral feeding family of devices to incorporate ENFit™ ISO 80369-3 compliant connectors. These purple connectors will replace the current Nutri-Lok connectors on catheters and extension sets. UTMD will also distribute ENFit oral syringes.

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

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

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

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

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

Gynecology /Urology /Electrosurgery:

LETZ® System

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

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

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

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

UTMD has FDA clearance to market its electrosurgical system and tools for use in general surgery applications, including dermatology, plastic surgery and otolaryngology. In 2002, UTMD introduced a product line of ultra-fine tipped microdissection needles, called OptiMicro™ Needles. These electrosurgical needles are particularly useful in small-scale plastic and reconstructive surgery applications. In 2009, UTMD added extended length OptiMicro needle versions useful in certain head and neck procedures. FILTRESSE is a stand-alone surgical smoke filtration system that combines high filtration efficiency, low cost and convenient use in a surgical office setting. Other electrosurgery tools and accessories include disposable electrosurgical pens, dispersive pads, footswitches, filter packs, speculums, retractors, forceps, tenacula and hooks. UTMD acquired the distribution rights to a unique reusable four-way

expander system which facilitates access to, and visualization of, the cervix, eliminating the need for less effective specula and lateral retractors. In 2007, UTMD developed OptiSpec®, a patented ultra-bright light for cervical visualization without physician distraction during exams, pap smears and other vaginal procedures requiring direct cervical visualization without the use of a colposcope. In 2011, UTMD acquired Femcare's single patient use trocars and cannulae available in shielded, bladeless, optical bladeless, blunt and thoracic designs. In addition, UTMD acquired Femcare's laparoscopic instrument range and accessories which includes instruments suitable for all routine laparoscopic procedures requiring dissection, cutting, grasping and coagulation, e.g., monopolar scissors, various grasping forceps, dissecting forceps, L and J hooks, spatulae, Veress needles, suction and irrigation tubing, insufflation tubing and connectors, pressure infusor bags and control valves.

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### EPITOME®

EPITOME is a patented electrosurgical scalpel which delivers precise performance in surgical incision and excision with hemostasis while minimizing thermal side effects. Where rapid yet precise dissection of dense tissue is necessary, such as in 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 other devices in wound healing. EPITOME allows a rapid incision without countertraction, yielding limited morbidity, less post-surgical pain and cosmetically superior results. EPITOME is useful where minimization of thermal tissue injury is important but control of bleeding needed. A bendable version of EPITOME with a smaller active electrode was introduced in 1998. Designed to significantly reduce the chance of tissue burns due to inadvertent electrode contact and where a smaller, bent scalpel tip is needed, the bendable EPITOME is of particular value, e.g., to thoracic surgeons in harvesting the internal mammary artery during coronary artery bypass surgery, as well as to otolaryngologists for tonsillectomies or uvulopalatoplasties.

### FILSHIE CLIP System

UTMD acquired the Filshie Clip System as part of its acquisition of Femcare in March 2011. In 2015, sales of Filshie Clips, applicators and accessories represented 35% of UTMD's total U.S. Dollar denominated sales. The Filshie Clip is a female surgical contraception device used for tubal ligation, i.e., placed on the fallopian tubes, generally laparoscopically but also post partum during a C-Section procedure. The Filshie Clip, in use for over 30 years, is at least 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 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. 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 competing device is the ESSURE by Conceptus, Inc. (acquired by Bayer AG in 2013). The device, considered a permanent implant, is inserted transvaginally. Bayer reports that Essure is similar to the Filshie Clip in its sterilization effectiveness as measured after successful application, but Essure's "typical" effectiveness including reported misapplication rate has been documented to be substantially lower. Filshie Clips are immediately effective upon application and do not require follow-up physician visits. Essure takes some time after placement to become effective, requiring interim alternative contraception and an additional subsequent procedure to confirm that the tubes are blocked. Essure is not reversible (allowing later pregnancy) without significant surgical intervention and post-operative patient pain is reportedly significantly greater, than using Filshie Clips.

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 CooperSurgical Inc. (CSI). In 2015, sales to CSI for distribution in the U.S. were up 12% compared to 2014, representing 30% of total Filshie Clip System sales. Outside the U.S., Femcare has obtained numerous regulatory approvals for the Filshie Clip System, which is being sold directly by UTMD to clinicians in Ireland, the U.K. and Australia and through specialty distributors in many other countries.

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### PATHFINDER PLUS™

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

### SUPRAPUBIC CATHETERIZATION

The Add-a-Cath introducer is a Femcare device designed for easy 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".

### 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 tip of the EndoCurette was specially 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 may utilize transvaginal ultrasound imaging of the uterus. UTMD's TVUS/HSG-Cath was designed and released for marketing in 2007 to provide effective cervical occlusion that allows distention of the uterus to differentiate anterior and posterior endometrium, among other irregularities, together with minimal visual obstruction of the uterus near the internal os. In addition, the TVUS/HSG-Cath may be used in hysterosalpingography radiographic procedures to assess the patency of fallopian tubes. A related device acquired in 2011 is Femcare's Spackman Style uterine cannula designed for the manipulation of the uterus and injection of fluid to test the patency of the fallopian tubes.

### LUMIN®



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

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Blood Pressure Monitoring:

DELTRAN® Disposable Pressure Transducer (DPT)

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

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

Pressure Monitoring Accessories, Components and Other Molded Parts.

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

1) Domestic sales.

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

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

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

In 2015, UTMD sold components and finished devices to 162 other companies in the U.S. (OEM sales). For over 37 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.

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

2) International sales.

After the years 2011-2014 in which international sales represented a majority of consolidated total USD sales, international sales slipped to 49% in 2015 due to the strength of the USD. The changes in foreign currency exchange (FX) rates in 2015 reduced UTMD's foreign currency sales by \$1,635 (12%). Prior to 2011, with only a few exceptions, UTMD's international 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 selling direct to end user facilities in the UK, Australia and Ireland, which has had a positive impact on revenues as well as gross profit margins. UTMD's website provides information that frequently results in unsolicited contacts from foreign entities. The Company has hundreds 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, it is UTMD's belief that U.S. hospitals are not currently saving costs under 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. 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 (excluding Filshie Clip sales to CSI).

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

Additionally, UTMD sells component parts as well as finished devices to other companies for use with their product lines. This OEM distribution channel effort 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.

Internationally, the Company distributes directly to end user facilities in the UK, Ireland and Australia, and sells to over 300 regional distributors and OEMs (other medical device manufacturers and/or distributors) in over a hundred countries. Ten percent of UTMD's independent international distributors represented 81% of UTMD's indirect international sales in the years of 2013 - 2015.

UTMD's Internet website [www.utahmed.com](http://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 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 and process development projects are in the following areas: 1) augmentation and internal manufacturing 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 2016.

## EMPLOYEES

At December 31, 2015, the Company had 169 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. Almost all of UTMD's internally-manufactured devices are made either in Utah or in Ireland. The average tenure with the Company of the 123 employees in the U.S. is fifteen years, and of the 29 employees in Ireland is twelve 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. 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 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 twelve unexpired U.S. patents, numerous associated patents in sovereignties outside the U.S. 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 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.

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

As a matter of policy, UTMD has acquired and will continue to acquire the use of technology from third parties that can be synergistically combined with UTMD proprietary product ideas. During 2015, royalties included in cost of goods sold were \$293. 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 2015 the Company received \$93 in royalty income, compared to \$99 in 2014 and \$90 in 2013.

#### GOVERNMENT REGULATION

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

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

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

Except for the Filshie Clip System, all of UTMD's present 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 July 2014, which did not result in the issuance of any FDA-483 observations.

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



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

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## 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 2015 trade revenues in US Dollar terms from customers outside the U.S. were \$19,793 (49% of total sales), compared to \$21,795 (53% of total sales) in 2014 and \$21,528 (53% of total sales) in 2013. U.S. international trade sales (Exports) from the U.S. to international customers were \$5,714 in 2015, \$5,632 in 2014 and \$5,203 in 2013. Exports represented 29%, 26% and 24% of total international trade sales in 2015, 2014 and 2013, respectively. U.S. Exports exclude Utah intercompany sales to foreign subsidiaries which distribute U.S.-made finished devices directly to end-users in the UK, Ireland and Australia.

For sales by international geographic area, please see notes 1 and 10 to the Consolidated Financial Statements.

## BACKLOG

"Backlog" is defined as orders received and accepted by UTMD which have not shipped yet. As a supplier of primarily disposable hospital products, the nature of UTMD's non-distributor or non-OEM business requires fast response to customer orders. Virtually all direct shipments to end user facilities are accomplished within a few days of acceptance of purchase orders. Consequently, UTMD's backlog at any point in time is comprised mainly of orders from OEM and independent international distributors, which purchase in larger quantities at less frequent intervals. Backlog shippable in less than 90 days was \$2,463 as of January 1, 2016, \$2,516 as of January 1, 2015 and \$2,002 as of January 1, 2014.

## 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 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 37-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 over the last twenty-three years was \$17 per year, well below the deductible level of product liability insurance policies. 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 £63 per year. The deductible level of the Femcare policy is \$150 per claim for the U.S. and Canada, and £50 elsewhere in the world. Since acquiring Femcare in 2011, UTMD has had to (successfully) defend one claim at a total cost of £7.

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-three years, UTMD has been named as a defendant in a total of seven lawsuits. Four lawsuits involved a patient injury related to operative vaginal deliveries where a UTMD VAD birthing cup or hand pump was used. The VADS devices in all four cases did conform to specifications. UTMD was ultimately dismissed as a defendant in all four VADS lawsuits, and legal costs were not material to performance. In the first of the other two lawsuits involving non-Femcare devices, regarding the use of EndoCurette, there was no evidence of patient injury. The lawsuit was settled in 2010 for an immaterial amount to avoid the diversion of management time and substantial costs of litigation, even though UTMD was confident that the case was without merit. In the second, UTMD was brought into a lawsuit by a defendant physician, speculating a design deficiency in a Finesse electrosurgical generator (ESU) which had been in use for eighteen years before the injury event, and used successfully by the same physician in multiple procedures after the event. The injured patient did not allege any fault by UTMD. The case was settled in 2012 without any UTMD involvement or liability. Since acquiring Femcare five years ago, the Company has experienced one lawsuit regarding Femcare's devices. In 2014, a patient claimed damages for becoming pregnant eight years after the placement of Filshie Clips. Her medical record indicated that she chose to employ Filshie Clips after being advised by her physician that he believed there would be a 1% chance of pregnancy. The case was dismissed after the patient who was also a malpractice attorney declined to respond in discovery.

In summary, during the last twenty-three year period of time during which over forty million finished devices were distributed by UTMD, there have been no judgments resulting from a fault in UTMD's devices. Presently, there are no product liability lawsuits, or threats of lawsuits, in which UTMD is a defendant. In the current tort system in the U.S., meritless product liability cases do get filed where aggressive attorneys calculate that a company will find it cheaper to settle for some nominal amount in lieu of 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") added a substantial excise tax (MDET) in 2013-2015 that increased administrative costs and has lead to decreased revenues in the U.S.:

The voluminous Acts, administrative rules to enforce the Acts and promised efforts to reform the Acts, make the U.S. medical device marketplace unpredictable, particularly for the thousands of small medical device manufacturers including UTMD that do not have the overhead structure that the larger medical device companies can afford.

Fortunately, the U.S. Congress has suspended the MDET for two years of 2016-2017. To the extent that the Acts will in the future continue to place additional burdens on small medical device companies in the form of the excise tax on medical device sales, additional oversight of marketing and sales activities and new reporting requirements, the result

is likely to continue to be negative for UTMD's ability to effectively compete and support continued investments in new product development and marketing of specialty devices in the U.S.

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

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

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

New premarketing submission administrative burdens and substantial increases in "user fees" increase product development costs and result in delays to revenues from new or improved devices.

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

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

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

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

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

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

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

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

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

UTMD's distributors have varying expertise in marketing and selling specialty medical devices. They also sell other devices that may result in less focus on the Company's products. In some countries, notably China, Pakistan and India not subject to similarly rigorous standards, by copying, 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. 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.

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Fluctuations in foreign currencies relative to the U.S. Dollar (USD) can result in significant differences in period to period financial results:

Since a significant portion of UTMD's sales are outside the U.S. and consolidated financial results are reported in USD terms, a stronger USD can have negative effects. 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 and profits are reduced, but also gross profits and operating profits in foreign currency terms are reduced because finished distributed products and/or U.S. made raw materials and components are likely being purchased in fixed USD.

ITEM 1B – UNRESOLVED STAFF COMMENTS

None

ITEM 2 PROPERTIES

Office and Manufacturing Facilities.

At the beginning of 2016, 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 3,200 square foot facility in Castle Hill NSW, Australia. In 2011, UTMD assumed the lease for its Romsey facilities which house Femcare in the UK. In the U.S., Ireland and Australia, UTMD owns its property and facilities with the exception of a long term lease with 15 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 or threatened litigation for which the Company believes the outcome may be material to its financial results.

ITEM 4 RESERVED

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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:

	2015		2014	
	High	Low	High	Low
1st Quarter	\$63.98	\$54.15	\$59.42	\$48.72
2nd Quarter	61.19	51.69	58.87	44.52
3rd Quarter	61.48	50.00	53.79	47.50
4th Quarter	61.20	52.42	61.00	47.33

## Stockholders.

The approximate number of beneficial stockholders of UTMD's common stock as of March 4, 2016 was 2,400.

## Dividends.

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

<u>Record Date</u>	<u>Payable Date</u>	<u>Per Share Amount</u>
March 18, 2014	April 2, 2014	0.25
June 18, 2014	July 3, 2014	0.25
September 18, 2014	October 2, 2014	0.25
December 16, 2014	December 30, 2014	0.255
March 18, 2015	April 2, 2015	0.255
June 19, 2015	July 2, 2015	0.255
September 18, 2015	October 2, 2015	0.255
December 16, 2015	December 30, 2015	0.26

2014 total cash dividends paid per share \$ 1.005

2015 total cash dividends paid per share \$ 1.025

## Issuer Purchases of Equity Securities.

The Company did not purchase any of its own securities during 4Q 2015.

UTMD purchased a total of 13,000 of its own shares during 2015 for \$683 including commissions and fees, pursuant to a continued open market repurchase program instituted in August 1992. During 2014, UTMD purchased 22,207 of its shares for \$1,055 including commissions and fees. UTMD did not purchase any of its own shares during 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, 2015, 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				
	2015	2014	2013	2012	2011
Net Sales	\$40,157	\$41,278	\$40,493	\$41,552	\$37,860
Net Income	11,843	11,378	11,406	10,169	7,414
Earnings Per Common Share (Diluted)	3.14	3.02	3.02	2.74	2.03
Total Assets	79,175	81,076	80,711	76,935	76,389
Working Capital	28,807	20,704	16,675	10,712	7,385
Long-term Debt	0	973	5,065	9,003	16,242
Cash Dividends Per Common Share	1.025	1.005	0.985	0.965	0.945

	Quarterly Data for 2015			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net Sales	\$10,233	\$10,397	\$9,945	\$9,582
Gross Profit	6,112	6,099	6,079	5,894
Net Income	2,667	2,918	3,047	3,211
Earnings Per Common Share (Diluted)	.71	.77	.81	.85

	Quarterly Data for 2014			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net Sales	\$9,827	\$10,491	\$10,717	\$10,243
Gross Profit	6,050	6,349	6,196	6,388
Net Income	2,722	2,834	2,822	3,000
Earnings Per Common Share (Diluted)	.72	.75	.75	.80

## 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), the Great Britain Pound (GBP), the Euro (EUR) and Australian Dollar (AUD).

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

### Overview

As an international company, UTMD's financial results in 2015 were dominated by changes in foreign currency exchange (FX) rates. Income statement results in 2015 compared to 2014 were as follows:

	2015	2014	change
Net Sales	\$40,157	\$41,278	-2.7%
Gross Profit	24,185	24,983	-3.2%
Operating Income	15,651	16,202	-3.4%
Income Before Tax	15,545	15,812	-1.7%
Net Income	11,843	11,378	+4.1%
Earnings per Share	3.140	3.015	+4.1%

A comparison of profit margins in 2015 to 2014 follows:

	2015	2014
Gross Profit Margin	60.2%	60.5%
Operating Income Margin	39.0%	39.3%
Net Income Margin	29.5%	27.6%

Net Income (NI) and earnings per share (EPS) in 2015 benefited from a \$351 reduction in the 2015 income tax provision (increasing NI \$351 and EPS \$.093) due to the United Kingdom (UK) enacting lower corporate income tax rates beginning in 2017 over the remaining ten year amortization life of Femcare Identifiable Intangible Assets (IIA).

As stockholders likely remember, in March 2011 UTMD acquired 100% of the stock of Femcare Holdings Limited in the UK, and its subsidiaries (Femcare). Included in the purchase price were IIA of \$38.8 million, almost all of which are being amortized over a fifteen-year useful life, with the amortization expense included in (G&A) operating expenses. This approximately \$2.6 million per year amortization expense reduces the income statement tax provision, but is not deductible on the tax return. As a consequence, on the acquisition date in 2011, UTMD created a deferred tax liability (DTL) on its balance sheet, using UK tax rates then in effect, which represented the future tax impact of the amortization of IIA over the fifteen year life.

According to U.S. GAAP, the total effect of tax rate changes on deferred tax balances is recorded as a component of the income tax provision related to continuing operations in the period in which the law is enacted. In other words, the total reduction in the DTL in 2015 that resulted from lower future tax rates over the remaining almost 10 years of Femcare IIA amortization, which amounted to \$351, reduced UTMD's reported 2015 tax provision and increased reported NI by the same amount per U.S. GAAP. The adjustment only affected UTMD's income tax provision, NI and EPS, not Revenues (Sales), Gross Profit (GP), Operating Income (OI) or Earnings Before Taxes (EBT).

Without including the effect of the UK tax law change on the DTL and the income tax provision, UTMD's 2015 NI and EPS compared to 2014 on a non-GAAP basis were as follows:

	2015	2014	Change
Net Income	\$11,493	\$11,378	+1.0%
Earnings per Share	3.047	3.015	+1.0%

Similarly, UTMD's NI Margin (NIM) in 2015 compared to 2014 on a non-GAAP basis (before the DTL adjustment) was as follows:

	2015	2014
Net Income Margin	28.6%	27.6%

The Company believes that the presentation of results excluding the adjustments in DTL and 2015 tax provision provides meaningful supplemental information to both management and investors that is indicative of UTMD's core operating results in 2015 compared to 2014.

The Company's continued excellent positive cash flow in 2015 allowed it to eliminate the remaining balances on bank loans that it incurred to help finance the purchase of Femcare in March 2011, while increasing cash dividends paid to shareholders and continuing its program to repurchase shares in the open market. Less than four years after acquiring Femcare for \$41 million without diluting stockholders, the Company became debt free again.

As a result of the weaker FX rates on UTMD's foreign currency sales, Consolidated Net Sales were 2.7% lower in 2015 compared to 2014. Foreign currency sales were reduced by \$1,635 (12.0%) compared to sales using the same FX rates of 2014 ("constant currency sales"). On a transaction weighted-average basis, the change in FX rates reduced GBP sales 7.5%, EUR sales 15.9% and AUD sales 17.0%. On a constant currency basis, 2015 total Consolidated Sales were 1.2% higher.

Except for Sales, UTMD met or exceeded all of its financial performance objectives for 2015 which were disclosed in the 2014 SEC Form 10-K despite the fact that the actual FX impact on Sales was substantially more negative than anticipated.

In 2015 compared to 2014, domestic sales were 5% higher and international sales were 9% lower. On a constant currency basis, international sales were less than 2% lower.

Better absorption of fixed manufacturing overheads in Utah and Ireland due to higher production activity, in-house assembly and packaging of Filshie Sterishot kits instead of using an external vendor, lower transportation costs and lower employee health plan expenses in the U.S. compared to the prior year combined to almost offset the negative FX impact of USD cost of materials for Ireland, the UK and Australia. On the other hand, consolidated operating expenses were \$247 lower in 2015 than in 2014 due to the favorable effect of FX rates on reducing the USD equivalent of subsidiary expenses in foreign currencies. As a result, UTMD was able to manage total operating expenses at the same ratio of sales (21.3%) in both 2015 and 2014 despite lower USD Sales in 2015. Non-operating expenses were \$284 lower in 2015 compared to the prior year, primarily due to \$224 lower interest expense. Without the benefit of the DTL adjustment and consequent reduction in income tax provision, UTMD improved its NIM by a full percentage point in 2015. This was accomplished as a result of a shift in EBT mix to Ireland, the sovereignty with the lowest income tax rate, and a lower UK income tax rate compared to the prior year. With the DTL adjustment, UTMD increased its U.S. GAAP 2015 EPS 4% to \$3.140 from \$3.015 in 2014.

EPS in 2015 benefited slightly from open market purchases of 13,000 UTMD shares and a lower dilution impact from employee stock options by 7,500 shares.

The Company believes that investors benefit from referring to the 2015 non-GAAP financial measures in assessing UTMD's performance. The non-GAAP financial measures also facilitate management's internal comparisons for purposes of planning future performance. The non-GAAP financial measures disclosed by UTMD should not be considered a substitute for or superior to financial measures calculated in accordance with GAAP, and the financial results calculated in accordance with GAAP and reconciliations to those financial statements should be carefully evaluated.

Measures of the Company's liquidity and overall financial condition improved in 2015 as UTMD reduced total liabilities 42% and increased current assets 11%. The total debt ratio (total liabilities to total assets) declined to 12% at the end of 2015 from 20% at the end of 2014. The current ratio (current assets to current liabilities) increased to 8.1 from 3.3 at the end of 2014. Cash generation remained strong, allowing a 2% increase in cash dividends to shareholders while paying off total bank loan principal balances of \$4.9 million and making open market share repurchases of \$0.7 million. Stockholders' Equity increased to \$69.6 million from \$64.6 million despite combined

dividends and share repurchases of \$4.5 million, which reduce Stockholders' Equity. The return on average Stockholders' Equity (ROE) prior to the payment of dividends was 17% in 2015 compared to 18% ROE in 2014 due to a 7% increase in average Stockholders' Equity in 2015.

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### Productivity of Assets and Working Capital Assets. Assets.

Year-end 2015 total consolidated assets were \$79,175 comprised of \$32,873 in current assets, \$7,369 in consolidated net property, plant and equipment (PP&E) and \$38,933 in net intangible assets. This compares to \$81,076 total assets at the end of 2014 comprised of \$29,675 in current assets, \$8,236 in consolidated net PP&E and \$43,165 in net intangible assets. Total asset turns (total consolidated sales divided by average total assets for the year) in 2015 were 50%, compared to 51% in 2014.

Current assets increased \$3,198 due to a \$4,001 increase in cash and investments, a \$141 decrease in accounts and other receivables and a \$676 decrease in year-end inventories. Year-end 2015 and 2014 cash and investment balances were \$23,333 and \$19,332, representing 29% and 24% of total assets, respectively. Net (after allowance for doubtful accounts) year-end trade accounts receivable (A/R) balances decreased \$231 due to lower 4Q 2015 sales and to 0.5% of A/R over 90 days from date of invoice at the end of 2015 compared to 1.9% at the end of 2014. The Company believes any older A/R will be collected or are within its reserve balances for uncollectible amounts. Average days in A/R from date of invoice on December 31, 2015 were 34 days based on 4Q 2015 shipments, slightly better than at the end of 2014. This performance remains well within management's trade A/R objective. Average 2015 inventory turns improved to 3.5 compared to 3.4 in 2014. The higher turns were back within management guidelines after dipping below in 2014, when UTMD substantially increased its inventory of Filshie Sterishot disposable applicator components as a hedge against an interruption of supply during the early stages of conversion to manufacturing in-house.

Current liabilities were \$4,906 (55%) lower at the end of 2015 compared to the end of 2014 primarily because of paying off the bank loans. Working capital (current assets minus current liabilities) at year-end 2015 was \$28,807 compared to \$20,704 at year-end 2014. The end of 2015 working capital exceeds UTMD's needs for normal operations and funding organic growth.

PP&E includes Utah, Ireland, England and Australia manufacturing molds, production tooling and equipment, test equipment, product development laboratory equipment, computers and software, warehouse equipment, furniture and fixtures, buildings and real estate. UTMD owns its facilities in Utah, Ireland and Australia, the fungible market value of which increases UTMD's enterprise value relative to most of its industry peers. Almost all of UTMD's devices are manufactured either in its Utah or Ireland facilities. The Australia facility is a distribution operation. The Femcare UK subsidiary facility is leased. Ending 2015 net consolidated PP&E (depreciated book value of all fixed assets) decreased \$867 as a result of \$619 in depreciation, capital expenditures of \$176 and the lower year-end USD value of PP&E in Ireland, England and Australia from changes in FX rates. The net book value of U.S. PP&E at the end of 2015 compared to the end of 2014 declined \$234. In USD terms, PP&E in Ireland declined \$460, in England declined \$84 and in Australia declined \$89, according to the following end-of-year FX rates which applied to all assets and liabilities of each applicable foreign subsidiary:

	12-31-15	12-31-14
EUR	1.0866	1.2110
GBP	1.4763	1.5586
AUD	0.7294	0.8181

The year-end 2015 net book value (after accumulated depreciation) of consolidated PP&E was 27% of purchase cost. End-of-year PP&E turns (Sales divided by Net PP&E) improved to 5.4 in 2015 compared to 5.0 in 2014. Since UTMD's PP&E is in good working order and capable of supporting increased sales activity, the continued productivity of fixed assets will remain a source of future profitability. In 2016, PP&E purchases to support ongoing operations are not likely to exceed depreciation of fixed assets.

Net intangible assets (after accumulated amortization) are comprised of the capitalized costs of obtaining patents and other intellectual property, as well as identifiable intangible assets (IIA) and goodwill resulting from acquisitions. Net intangible assets were \$38,933 (49% of total assets) at the end of 2015 compared to \$43,165 (53% of total assets) at

the end of 2014. Per U.S. GAAP, intangible assets are categorized as either 1) IIA, which are amortized over the estimated useful life of the assets, or 2) goodwill, which is not amortized or expensed until the associated economic value of the acquired asset becomes impaired. The two categories of Femcare intangibles at year-end 2015 were net IIA of \$24,102 and goodwill of \$7,533. The accumulated amortization of Femcare IIA as of December 31, 2015 since the March 18, 2011 acquisition was \$11,416. UTMD's goodwill balance was \$14,725 at the end of 2015, 38% of total net intangibles. Because the products associated with UTMD's acquisitions of Columbia Medical in 1997, Gesco in 1998 and Abcorp in 2004 continue to be viable parts of UTMD's overall business, UTMD does not expect the current goodwill value associated with the four acquisitions (including Femcare) to become impaired in 2016. Additions to intangibles in 2015 were \$70, while there was \$2,528 in amortization expense. The 2015 non-cash amortization expense of Femcare IIA was \$2,467 compared to \$2,660 in 2014. The difference was due to the change in USD/GBP FX rate. The 2016 non-cash amortization expense of Femcare IIA will be GBP 1,599, or \$2,431 if the average USD/GBP FX rate is 1.52.



#### Liabilities.

As noted above, UTMD's current liabilities declined 55% (\$4,906) and total liabilities declined 42% (\$6,992), at the end of 2015 from the end of 2014. The resulting 2015 year-end total debt ratio was 12%, compared to 20% at the end of 2014. Total liabilities declined because of \$4,867 repayment of bank loans and a \$1,128 reduction in the DTL. The DTL, which was created as a result of the fifteen year deferred tax consequence of the amortization of Femcare's IIA, had a 2015 year-end balance of \$4,452, down from \$5,581 at the end of 2014. The large decline in the DTL was the result of a combination of the 2015 amortization of IIA, the 4Q 2015 adjustment to the DTL due to the enactment of lower future UK income tax rates, and the change in the USD/GBP year-end FX rates. In addition to liabilities stated on the balance sheet, UTMD has operating lease and purchase obligations described in Note 7 to the financial statements.

#### Results of Operations.

a) Revenues. Global Consolidated Sales in 2015 were \$40,157 compared to \$41,278 in 2014 and 40,493 in 2013.

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

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

Terms of sale are established in advance of UTMD's acceptance of customer orders. In the U.S., Ireland, UK and Australia, UTMD generally accepts orders directly from and ships directly to end user clinical facilities, as well as third party medical/surgical distributors, under UTMD's Standard Terms and Conditions (T&C) of Sale. About 14% of UTMD's domestic end user sales go 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 are substantially the same in the U.S., Ireland, UK and Australia.

UTMD may have separate discounted pricing agreements with a 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 determine the fixed price by part number for the next agreement period of one or two years. For new customers, the customer's best estimate of volume is accepted by UTMD for determining the ensuing fixed prices for the agreement period. New customers typically have no longer than one-year agreements. 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 international sales. Domestic sales include 1) direct domestic sales, sales of finished devices to end-user facilities and med/surg distributors in the U.S.; 2) domestic OEM sales, sales of components or finished products, which may not be medical devices, to other companies for inclusion in their products; and 3) sales of the Filshie Clip System by Femcare UK to its U.S. distributor, CooperSurgical Inc. (CSI). International sales are sales from UTMD in the U.S. to customers outside the U.S. and all sales from UTMD subsidiaries in Ireland, Australia and the UK other than Femcare UK sales to CSI. The term

"trade" means sales to customers which are not part of UTMD. Each UTMD entity except Femcare Australia also has intercompany sales of components and/or finished devices to other UTMD entities.

U.S. domestic sales in 2015 were \$20,364 (51% of total sales) compared to \$19,483 (47% of total sales) in 2014 and \$18,965 (47% of total sales) in 2013. The contributors to the \$881 (+5%) higher domestic sales were \$458 (+12%) higher Filshie Clip System sales to CSI, \$261 (+11%) higher sales of components and devices to OEM customers and \$162 (+1%) higher sales to direct users.

By product category, domestic direct sales of neonatal products were \$4,363 (about the same), labor & delivery (L&D) products \$3,916 (3% lower), BPM products \$782 (1% lower) and gynecology/urology products excluding the Filshie Clip System \$4,521 (3% higher). The lower L&D sales were due to further tightening of compliance under GPO contracts by U.S. hospitals and lower intrauterine pressure monitoring utilization rates by existing customers.

International sales in 2015 were \$19,793 compared to \$21,795 in 2014 and \$21,528 in 2013. International sales in 2015 were overall \$2,002 (9%) lower than in 2014, but \$1,635 (82%) of the decline was due to the change in FX rates. As a result, international sales slipped to 49% of global consolidated sales in 2015 from 53% in both 2014 and 2013. Sixty percent of international sales, or 30% of total sales, were invoiced in foreign currencies. A 12% combined negative FX rate impact on 30% of total sales created a 3.6% decline in total consolidated sales. GBP, EUR and AUD currency sales represented 15%, 8% and 6% of total 2015 USD-converted sales, respectively. UTMD's FX rates for income statement purposes are transaction-weighted averages. The average FX rates from the applicable foreign currency to USD during 2015 compared to 2014 FX rates were:

	2015	2014	Change
GBP	1.528	1.650	( 7.4% )
EUR	1.105	1.314	(16.5%)
AUD	0.750	0.904	(17.0%)
Sales Weighted Average			(12.0%)

Despite a 16.5% weaker EUR, USD denominated trade (excludes intercompany) sales of devices to international customers by UTMD's Ireland facility (UTMD Ltd) were up \$2,194 (62%) for 2015 compared to 2014, 1) because BPM kit sales to UTMD's China distributor, which were suspended for nine months in 2014, resumed for the full year of 2015, and 2) because Filshie Sterishot II kits manufactured in Ireland were shipped directly to international distributors for the full year rather than a partial year in 2014 after UTMD Ltd. began manufacturing them. In EUR terms, UTMD Ltd 2015 sales including intercompany shipments were up 82% for the year.

USD-denominated sales of devices to domestic and international customers by Femcare-Nikomed, Ltd (UK subsidiary), excluding intercompany sales, were down \$3,184 (24%) compared to 2014, partly due to the 7.4% weaker GBP but also due to the conversion of international Sterishot kit shipments to Ireland. In GBP terms, 2015 UK subsidiary trade sales were down 18% for the year.

USD-denominated sales of devices to end-users in Australia by Femcare's Australia distribution subsidiary (Femcare Australia) were down \$635 (20%) in 2015 compared to the previous year due primarily to the 17.0% weaker AUD relative to the USD. Although demand for UTMD devices remains stable in Australia, UTMD expects that in 2016, USD-converted AUD sales may again decline by 6-7% due to a continued weaker AUD FX rate, on the average, compared to 2015.

Like in 2015, fluctuations in FX rates relative to the USD can have a significant effect on consolidated sales reported in USD terms in any particular reporting period. Looking forward to 2016, UTMD expects that its foreign currency sales are likely to be negatively impacted by an additional 3-4% on the average when converting from EUR, GBP and AUD to USD, compared to a negative 12% impact in 2015. Assuming that foreign currency sales will remain about 30% of total consolidated sales, UTMD is planning for an FX rate impact in 2016 that will likely reduce total consolidated constant currency sales by about 1%.

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

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## Global revenues by product category:

	2015	%	2014	%	2013	%
Obstetrics	\$4,587	11	\$4,669	11	\$5,085	12
Gynecology/ Electrosurgery/ Urology	22,356	56	24,088	58	22,687	56
Neonatal	6,299	16	6,222	15	5,920	15
Blood Pressure Monitoring and Accessories*	6,915	17	6,299	15	6,801	17
Total:	\$40,157	100	\$41,278	100	\$40,493	100

## International revenues by product category:

	2015	%	2014	%	2013	%
Obstetrics	\$670	3	\$642	3	\$579	3
Gynecology/ Electrosurgery/ Urology	13,534	68	15,928	73	15,037	70
Neonatal	1,936	10	1,844	8	1,550	7
Blood Pressure Monitoring and Accessories*	3,653	19	3,381	16	4,362	20
Total:	\$19,793	100	\$21,795	100	\$21,528	100

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

As a summary description of revenues in the above tables:

1. Obstetrics. Lower domestic obstetrics (L&D) device sales in 2015 were the result of lower utilization of specialty devices in U.S. hospitals together with restrictive U.S. GPO administrative agreements.
2. The gynecology/ electrosurgery/ urology (ES/Gyn) product category, which includes all of Femcare's products, were 7% lower in 2015 compared to 2014. The decrease was predominantly driven by the decline in foreign currency sales in USD terms due to changes in FX rates. Thirty percent of global Filshie Clip System sales were to CSI in the U.S. in fixed USD currency.
3. Neonatal intensive care unit (NICU) device sales were up 1% overall. A 5% increase in international sales of neonatal devices was due to continued growth by independent distributors.
4. Global blood pressure monitoring and accessories (BPM) sales were 10% higher in 2015 compared to 2014, helped by \$1.2 million higher sales to UTMD's China distributor. U.S. domestic BPM sales in 2015 increased 12% as a result of \$261 higher sales to OEM customers.

For calendar year 2016, UTMD expects to achieve slightly higher consolidated sales by offsetting continued FX headwinds on 30% of its sales made in foreign currencies with continued domestic growth, particularly in OEM sales, plus another year of good growth in sales of BPM and neonatal devices to international distributors.

b) Gross Profit (GP). UTMD's 2015 consolidated GP, the surplus after subtracting costs of manufacturing (CGS), including purchasing raw materials, forming components, assembling, inspecting, testing, packaging, sterilizing and shipping products, from net revenues, was \$24,185 compared to \$24,983 in 2014 and \$24,273 in 2013. UTMD's average gross profit margin (GPM), consolidated gross profits expressed as a percentage of consolidated net sales, was 60.2% in 2015 compared to 60.5% in 2014 and 59.9% in 2013. UTMD was able to exceed its projected 2015 GPM despite lower sales as a result of better utilization of fixed manufacturing overhead costs in both Ireland and the U.S., 13% lower health plan expense for U.S. employees, and substantially lower transportation costs for goods shipped intercompany. With few exceptions, device unit prices to customers remained the same as in the prior year. Because UTMD's medical devices are differentiated and not subject to GPO agreements in the U.S., the Company was able to avoid price reduction pressures recently publicly disclosed by other medical device suppliers.

Ireland subsidiary GP was EUR 3,312 in 2015 compared to EUR 1,293 in 2014 and EUR 1,189 in 2013. The associated GPMs were 48.5% in 2015, 34.5% in 2014 and 35.3% in 2013. The higher gross profits were due to 1)

UTMD Ltd in Ireland directly selling devices to Ireland domestic clinical users instead of selling through distributors, 2) UTMD Ltd in Ireland directly selling devices that it manufactures to international customers previously sold by Femcare UK, and 3) increased intercompany sales (which absorb fixed overhead costs) from manufacturing products previously purchased from outside vendors by Femcare UK.

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Femcare UK GP was GBP 4,607 in 2015 compared to GBP 5,895 in 2014 and GBP 5,851 in 2013. UK GP was lower due to 1) transfer of sales to UTMD Ireland for Femcare devices now manufactured in Ireland, 2) 10% lower domestic UK sales, and 3) although weaker than the USD, the GBP was substantially stronger than the EUR so that UK sales in EUR currency to European distributors were reduced 9% when converted to GBP. Partially offsetting these negative factors, Filshie Clip System sales to CSI in the U.S. were 12% higher in 2015. Despite lower sales and GP, Femcare UK GPM improved to 68.8% in 2015 compared to 67.6% in 2014 and 67.1% in 2013.

Femcare AUS GP was AUD 1,971 in 2015 compared to AUD 2,001 in 2014 and AUD 2,006 in 2013. Femcare AUS GPMs were 58.4% in 2015, 57.1% in 2014 and 62.1% in 2013. The GPM was higher despite 4% lower AUD sales because of reduced transportation costs. Femcare AUS purchases all of its finished devices for distribution in Australia from other UTMD subsidiaries.

In the U.S., GP was \$12,222 in 2015 compared to \$11,802 in 2014 and \$11,683 in 2013. GPMs were 54.2% in 2015, 53.7% in 2014 and 53.4% in 2013. The GPM was higher because total trade and intercompany sales from Utah were 2.5% higher in 2015 compared to 2014, while CGS was only 1.2% higher. This was evidence that UTMD's fixed overhead costs and excess capacity provide leverage in profitability when sales increase.

In 2015, UTMD achieved a GPM more than one full percentage point higher than it projected at the beginning of the year, despite a negative FX rate impact resulting in much lower USD sales than projected. This was achieved because of greater productivity of fixed overhead resources, absorption of the supplier margin for more products manufactured in-house, lower health plan costs for U.S. employees and lower shipping costs. With UTMD's current mix of direct sales, sales through distributors and OEM sales, a GPM at 60% allows management to achieve its profit objectives. Similar to a year ago, because UTMD's costs are disproportionately incurred in USD terms, management expects a lower GPM in 2016, in the range of 59%-59.5% due to an expected continued negative FX rate impact on its foreign currency sales. The 2016 management target is to achieve the same consolidated GP as in 2015 on slightly higher sales.

c) Operating Income (OI). OI is the surplus after operating expenses (Op Ex) are subtracted from GP. Consolidated OI in 2015 was \$15,651 compared to \$16,202 in 2014 and \$14,828 in 2013. UTMD's consolidated OI margin (OIM), consolidated OI divided by total sales, was 39.0% in 2015, compared to 39.3% in 2014 and 36.6% in 2013. The UTMD Ltd (Ireland subsidiary) OIM in 2015 was 44.5% compared to 27.3% in 2014 and 25.7% in 2013. Femcare UK's 2015 OIM was 32.5% compared to 39.7% in 2014 and 37.7% in 2013. Femcare AUS's 2015 OIM was 46.5% compared to 42.4% in 2014 and 27.5% in 2013. UTMD U.S. OIM in 2015 was 35.4% compared to 35.6% in 2014 and 35.4% in 2013.

Op Ex includes sales and marketing (S&M) expenses, product development (R&D) expenses and general and administrative (G&A) expenses. Consolidated Op Ex was \$8,534 in 2015, compared to \$8,781 in 2014 and \$9,445 in 2013. When it comes to expenses incurred in foreign currencies, a stronger USD has a positive FX rate impact, not negative. Constant currency (using same FX rates as in 2014) Op Ex in 2015 were \$415 higher than reported. The largest single positive impact was in IIA amortization expense, which is part of G&A expenses. Femcare IIA amortization expense was GBP 1,615 in both 2015 and 2014, but as a result of the lower FX rate for GBP conversion to USD, it was \$193 lower in 2015. Constant currency S&M expenses were \$64 higher than reported. Constant currency G&A expenses (excluding the IIA expense) were \$148 higher than reported. Constant currency R&D expenses were \$4 higher than reported. Because of the better than projected GPM and more favorable FX rate impact on Op Ex than expected, OI was down only 3% in 2015, much better than the negative 5-8% that management projected in the 2014 SEC Form 10-K. The following table provides a comparison of operating expense categories for the last three years.

	2015	2014	2013
S&M expenses excluding the MDET	\$1,881	\$1,930	\$2,500
S&M expense – U.S. MDET	283	281	290
R&D expenses	522	460	491
G&A expenses:			
a) litigation expense provision	40	80	80
b) corporate legal	70	34	27
c) stock option compensation	87	74	28
d) management bonus accrual	465	645	467
e) outside accounting audit/tax	191	227	211
f) intangible asset amortization	2,528	2,719	2,584
g) property & liability insurance premiums	231	290	270
h) all other G&A expenses	2,236	2,041	2,497
G&A expenses – total	5,848	6,110	6,164
Total operating expenses	\$8,534	\$8,781	9,445
Operating expenses % of sales:	21.3%	21.3%	21.3%

#### Description of Operating Expenses (Op Ex)

i) S&M expenses: S&M expenses are the costs of communicating UTMD's differences and product advantages, providing training and other customer service in support of the use of UTMD's solutions, attending clinical meetings and medical trade shows, administering customer agreements, advertising, processing orders, shipping, paying commissions to outside representatives, funding GPO fees and paying the MDET in the U.S. In markets where UTMD sells directly to end-users, which in 2015 was the U.S., Ireland, UK and Australia, the largest component of S&M expenses is the cost of employing direct sales representatives, including associated costs of travel, subsistence and communications. The trade-off between higher gross profit margins for selling directly at end-user prices is higher S&M expenses as a percent of sales.

S&M expenses 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 agree to provide hospital members in-service and clinical training as required and reasonably requested.

UTMD promises prospective customers that it will provide, at no charge in reasonable quantities, copies of videotapes and other instruction materials developed for the use of its products. UTMD provides customer support from offices in the U.S., 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, all of these services are allocated from fixed S&M overhead costs included in Operating Expenses. Historically, marginal consulting costs have been immaterial to financial results, which is also UTMD's expectation for the future.

The Medical Device Excise Tax (MDET), a component of the Patient Protection and Affordable Care Act, (known commonly as Obamacare) was effective between 2013 and 2015. In December 2015, U.S. legislators suspended the MDET for 2016 and 2017. The excise tax was 2.3% of domestic sales of medical devices listed with the FDA. Medical devices designed for human use are taxed, whether or not they are sold for human use, e.g. veterinarian uses or laboratory use are also taxed. The impact of the tax was felt beyond 2.3%, as costs associated with administering, tracking, collecting and paying the tax were significant. Direct MDET S&M expenses in 2015 were \$283 compared to \$281 in 2014, and \$290 in 2013.



As a percent of total sales, S&M operating expenses (excluding the MDET) were 4.7% in both 2015 and 2014, and 6.2% in 2013. S&M expenses including the MDET were 5.4% of sales in both 2015 and 2014, compared to 6.9% of sales in 2013. The lower S&M expenses starting in 2014 resulted from UTMD converting from a third party S&M service provider in AUS as of December 2013 to UTMD's own employees. In 2016, UTMD plans to add direct salespeople. However the reduction in foreign subsidiary S&M expense in USD terms from a continued decline in FX rates is expected to help offset the increased cost of additional direct reps. As a result of the suspension of the MDET, the projected net change in S&M expense in 2016 should be approximately \$200, resulting in contribution to UTMD's OIM of about 0.5 percentage points.

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ii) R&D expenses: 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. As a percent of sales, R&D expenses were 1.3% in 2015 compared to 1.1% in 2014 and 1.2% in 2013. The 2015 increase resulted from the addition of a product development engineer. R&D expenses as a percentage of sales in 2016 are expected to remain about 1.3%.

iii) G&A expenses: G&A expenses include the "front office" functional costs of executive management, finance and accounting, corporate information systems, human resources, shareholder relations, corporate risk management, corporate governance, protection of intellectual property, amortization of identifiable intangibles and legal costs.

As a percent of total sales, G&A expenses were 14.6% in 2015 compared to 14.8% in 2014 and 15.2% in 2013. The lower G&A percent of sales in 2015 was due primarily to FX rates, as expenses in the UK, Ireland and Australia were converted into fewer USD. Please see the table above for a stratification of G&A expenses. UTMD expects consolidated USD G&A expenses in 2016 about \$100 lower than in 2015. As a result, if sales remain about the same as in 2015, UTMD projects G&A expenses in the range of 14.4%, not including unforeseen litigation expenses or possible acquisition costs.

In summary, in 2016, UTMD expects Op Ex to be about \$300 lower than in 2015. If sales increase slightly and GP remains the same as in 2015, UTMD expects its consolidated OI will be about 2% higher than in 2015. If successful in achieving its projection, UTMD's 2016 OIM would improve to about 39.4%.

d) Non-operating Income, Non-operating Expense and EBT. Non-operating income (NOI) includes royalties from licensing UTMD's technology, rent from leasing underutilized property to others, income earned from investing the Company's excess cash and gains or losses from the sale of assets, offset by non-operating expenses (NOE) which include interest on bank loans, bank service fees and excise taxes.

Net NOE (combination of NOE and NOI) was \$105 in 2015 compared to \$390 in 2014 and \$352 in 2013. Interest expense on bank loans was \$65 in 2015, \$224 lower than in 2014. UTMD paid off the loans in February 2015 and retained cash balances at the end of 2015 in excess of normal operating needs. Without new borrowing to help finance another acquisition or large repurchase of UTMD shares, there will be no interest expense in 2016. UTMD's 2015 NOE included \$141 from a loss on remeasured foreign currency value as a result of FX, primarily for EUR bank balances held in the UK, compared to a \$162 loss in 2014. The Company did not have an FX-related translation loss on bank account balances in 2013. A description of NOE and NOI components follows:

1) Interest Expense. In 2015, UTMD paid \$65 in interest on the Femcare loans, compared to \$289 in 2014 and \$438 in 2013. The interest resulted from borrowing £8,000 (\$12,934) in the UK and another \$14,000 in the U.S. in March 2011 for the purchase of Femcare. Absent an acquisition or large repurchase of shares that requires new borrowing, UTMD does not expect any interest expense in 2016.

2) Investment of excess cash. Investment income (including gains and losses on sales) was \$5 in 2015, compared to \$7 in both 2014 and 2013. Cash is generally currently held in non-interest bearing bank accounts because avoiding the bank operating fees which would result from lower balances more than offsets the interest that can be earned at current interest rates. UTMD estimates investment income will again be nominal in 2016.

3) Royalties. Femcare receives a royalty from licensing the use of the Filshie Clip System intangibles to CSI as part of its U.S. exclusive distribution agreement. Royalties in 2015 were \$93 compared to \$99 in 2014 and \$90 in 2013. UTMD expects to receive about \$90 in CSI royalties in 2016. Presently, there are no arrangements under which UTMD is receiving royalties from other parties.

4) Gains/ losses from remeasured currency in bank accounts. As noted above, UTMD recognized non-operating expense from losses on remeasured foreign currency bank balances of \$141 in 2015 and \$162 in 2014. EUR and AUD currency cash balances in the UK, and GBP currency cash bank balances in Ireland, are subject to remeasured

currency translation gains/ losses as a result of period to period changes in FX rates. Because of UTMD's subsidiaries' profitability, the subsidiaries will continue to accumulate cash until investments that increase shareholder value are completed. The cash could be repatriated to the U.S. for investment in the U.S. or payment of dividends to shareholders or share repurchases, but doing so would trigger additional substantial U.S. income taxes. Year-end 2015 balances were valued at the following FX rates: 1.0866 USD/EUR; .7294 USD/AUD and 1.4763 USD/GBP. A remeasured currency loss of \$50 is included in UTMD's projections for 2016.

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5) Other NOI. 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 non-MDET excise taxes was \$3 in 2015, \$(45) in 2014 and \$(11) in 2013. UTMD estimates Other NOI will be nominal again in 2016.

In summary, with no interest and minimal remeasured currency FX translation loss in 2016, UTMD projects about \$35 net NOI, which is \$140 net lower NOE in 2016 compared to 2015.

Income before Taxes (EBT) result from subtracting net NOE from OI. Consolidated EBT was \$15,545 in 2015 compared to \$15,812 in 2014 and \$14,476 in 2013. UTMD had projected 2015 EBT in the range of \$14.9 to \$15.3 million in its 2014 SEC 10-K report. EBT margin (EBTM) is EBT divided by total sales. UTMD's excellent consolidated EBTM was 38.7% in 2015, 38.3% in 2014 and 35.7% in 2013. The EBT of UTMD Ltd. (Ireland) was €2,890 in 2015, €995 in 2014 and €854 in 2013. The respective EBTMs of UTMD Ltd. (Ireland) were 42.2% in 2015, 26.5% in 2014 and 25.4% in 2013. Femcare UK's 2015 EBT was £2,243 compared to £3,311 in 2014 and £3,175 in 2013; UK EBTMs were 33.5% in 2015, 38.0% in 2014 and 36.4% in 2013. Femcare AUS's 2015 EBT was AUD 1,580 compared to AUD 1,493 in 2014 and AUD 894 in 2013; AUS EBTMs were 46.8% in 2015, 42.6% in 2014 and 27.7% in 2013.

With GP consistent with the prior year, \$300 lower Op Ex and \$140 lower net Non-Op Ex, UTMD is targeting consolidated 2016 EBT in the range of \$15.9 to \$16.1 million, about 3% higher than 2015 EBT.

e) Net Income (NI), EPS and ROE. NI is EBT minus income taxes, often called the "bottom line". NI was \$11,843 in 2015, \$11,378 in 2014 and \$11,406 in 2013. The 2015 NI includes a \$351 reduction to the 2015 income tax provision as a result of a deferred tax liability (DTL) adjustment due to the enactment of lower future income tax rates in the UK beginning in April 2017. Likewise, the 2013 NI included a \$976 reduction to the 2013 income tax provision as a result of a DTL adjustment from a former lowering of future income tax rates in the UK. The DTL was adjusted in compliance with U.S. GAAP by the entire impact of lower future UK corporate tax rates over the remaining 10 years (in 2015) and 12 years (in 2013) of Femcare IIA amortization. The \$351 and \$976 reductions in income tax provision increased 2015 and 2013 NI, respectively, by those same amounts. Without the DTL adjustment, 2015 NI would have been \$11,493 and 2013 NI would have been \$10,430.

The effective 2015 consolidated corporate income tax provision rate was 23.8% (26.1% without the DTL adjustment), 28.0% in 2014, and 21.2% (28.0% without the DTL adjustment) in 2013. Excluding the lower income tax provision for the DTL adjustment, the 1.9 percentage point lower consolidated tax provision rate resulted from an approximate 1.2 percentage point lower UK income tax rate in 2015 compared to 2014, and the shift in UTMD profits to Ireland, the sovereignty with the lowest income tax rate. Year to year fluctuations in the tax rate will result from variation in EBT contribution from subsidiaries in jurisdictions with different corporate income tax rates. The UK had an income tax rate of 24% in 1Q 2013, a 23% rate from April 1 2013 to April 1, 2014, a 21% rate from April 1, 2014 to April 1, 2015, and a 20% rate for the last three quarters of 2015. The current UK income tax rate of 20% is scheduled to decline to 19% beginning April 1, 2017. The income tax rate for AUS has been and is planned to remain at 30%. Profits of the Ireland subsidiary are taxed at a 12.5% rate on exported manufactured products, and a 25% rate on rental and other types of income including income from sales of medical devices in Ireland domestically. EBT contribution of UTMD U.S. operations are currently taxed at a 39% combined Federal and State rate prior to special U.S. tax exclusions such as the manufacturing profit deduction, accelerated depreciation of certain assets and R&D tax credit. Higher marginal income tax rates would apply for EBT in the U.S. above \$10 million. The possibility of a lower corporate income tax rate in the U.S. is not anticipated in UTMD's projection for 2016. Management expects the 2016 consolidated average income tax provision rate to be a little higher than the 26.1% 2015 rate (excluding the DTL adjustment) due to its projected EBT mix in 2016.

UTMD's Net Income margin (NIM), NI expressed as a percentage of sales, was 29.5% in 2015 (28.6% prior to the DTL adjustment), 27.6% in 2014 and 28.2% (25.8% prior to the DTL adjustment) in 2013. In its 2014 SEC Form 10-K, UTMD projected 2015 NIM in the range of 26.2-26.4% (not anticipating any DTL adjustment), more than two

percentage points lower than what was actually achieved. With the assumptions above, due to higher projected EBT together with slightly higher consolidated income tax provision rate, UTMD projects its 2016 NIM should improve to approximately 29%. If UTMD's projections above are correct, NI will be 2-3% higher in 2016 compared to 2015.

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Earnings per share (EPS) is NI divided by the number of shares of stock outstanding (diluted to take into consideration stock option awards which are "in the money," i.e., have exercise prices below the applicable period's weighted average market value). Diluted EPS were \$3.140 in 2015 (\$3.047 prior to the DTL adjustment), \$3.015 in 2014 and \$3.022 (\$2.763 prior to the DTL adjustment) in 2013. If UTMD achieves the projections above, EPS in 2016 should be in the range of \$3.10 - \$3.14/ share.

In summary, management expects to continue its pattern of steadily improving NI and EPS in 2016 (excluding the DTL adjustments) while struggling to achieve top line growth with the expected headwinds of an even stronger USD. The calendar year 2016 operating plan, which for conservative reasons excludes share repurchases, acquisitions and potential growth from new products, is flat to slightly higher consolidated sales, the same GP, 2% higher OI and 2-3% higher NI and EPS.

The 2015-ending weighted average number of diluted common shares (the number used to calculate diluted EPS) was 3,772 (in thousands), compared to 3,774 shares in 2014 and 3,775 shares in 2013. Dilution for "in the money" unexercised options for the year 2015 was 20 shares, compared to 27 in 2014 and 47 in 2013. Actual outstanding common shares as of December 31, 2015 were 3,751.

Return on stockholders' equity (ROE) is the portion of NI retained by UTMD (after payment of dividends) to internally finance its growth, divided by the average accumulated stockholders' equity during the applicable time period. ROE includes balance sheet measures as well as income statement measures. ROE for 2015 was 12% (17% before payment of dividends); ROE for 2014 was 12% (18% before payment of dividends); and for 2013 was 14% (20% before payment of dividends). UTMD's ROE is primarily driven by its high NIM although share repurchases and dividends help by reducing stockholders' equity. UTMD's 2015 ROE was lower than in 2014 because of a 7% increase in average stockholders' equity with only a 4% increase in NI. UTMD's ROE (before dividends) has averaged 28% per year over the last 30 years. This ratio determines how fast the Company can afford to grow without diluting stockholder interest. For example, a 28% ROE will financially support 28% annual growth in revenues without having to issue more stock.

Looking forward, without share repurchases, management believes that 2016 ROE (before dividends) will again be about 17%, although slightly lower since average stockholders' equity is expected to grow faster (5-6%) than NI (2-3%). The UTMD year-end 2015 stockholders' equity was about \$70 million.

## Liquidity and Capital Resources

### Cash Flows.

Net cash provided by operating activities, including adjustments for depreciation and other non-cash operating expenses, along with changes in working capital and the tax benefit attributable to exercise of employee incentive stock options, totaled \$13,801 in 2015, compared to \$15,387 in 2014 and \$12,309 in 2013. The largest changes in 2015 compared to 2014 were a decrease of \$2,106 in accrued expenses following an increase in the prior year, a decrease in inventories of \$563, and a benefit to cash of \$501 from decreasing accounts receivable compared to increasing the prior year. Other changes were generally consistent with effective working capital management and sales activity. The decrease in accrued expenses was primarily due to year-end 2014 being high because estimated income tax payments normally made before the end of the year were made in January 2015.

The Company's notes payable repayments of \$4,777 in 2015, \$4,035 in 2014 and \$3,908 in 2013 were the most significant uses of cash in each of those years. Loans of \$26,934 were obtained in 2011 to help finance the acquisition of Femcare. In investing activities, during 2015 UTMD used \$176 for capital expenditures and \$70 for intangible assets.

In 2015, UTMD received \$343 and issued 15,786 shares of stock upon the exercise of employee and director stock options. Employees and directors exercised a total of 21,800 option shares in 2015, with 6,014 shares immediately

being retired as a result of optionees trading the shares in payment of the exercise price of the options and related taxes. Option exercises in 2015 were at an average price of \$29.36 per share. The Company received a \$114 tax benefit from option exercises in 2015. UTMD repurchased 13,000 shares of stock in the open market at a cost of \$683 during 2015, an average cost of \$52.54 per share. In 2014, UTMD received \$491 and issued 27,523 shares of stock upon the exercise of employee and director stock options. Employees and directors exercised a total of 35,503 option shares in 2014, with 7,980 shares immediately being retired as a result of optionees trading the shares in payment of the exercise price of the options. Option exercises in 2014 were at an average price of \$26.08 per share. The Company received a \$103 tax benefit from option exercises in 2014. UTMD repurchased 22,207 shares of stock in the open market at a cost of \$1,055 during 2014, an average cost of \$47.49. By comparison, in 2013, UTMD received \$787 and issued 40,033 shares of stock upon the exercise of employee and director stock options. Employees and directors exercised a total of 55,287 option shares in 2013, with 15,254 shares immediately being retired as a result of optionees trading the shares in payment of the exercise price of the options and related taxes. Option exercises in 2013 were at an average price of \$25.37 per share. The Company received a \$281 tax benefit from option exercises in 2013. The Company did not repurchase any of its own shares in 2013.

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UTMD repaid \$4,777 on its notes payable during 2015, compared to \$4,035 during 2014 and \$3,908 in 2013. All of UTMD's loan principal balances were paid off in February 2015. UTMD did not borrow in any of the three years 2013-2015. Cash dividends paid were \$3,846 in 2015, compared to \$3,765 in 2014 and \$3,675 in 2013.

Management believes that future income from operations and effective management of working capital will provide the liquidity needed to finance internal growth plans. In an uncertain economic environment, UTMD's cash balances allow management to operate with the long-term best interest of stockholders in mind. Planned 2016 capital expenditures for ongoing operations are expected to be less than depreciation of current PP&E.

Management plans to utilize cash not needed to support normal operations in one or a combination of the following: 1) in general, to continue to invest at an opportune time in ways that will enhance future profitability, for example, to purchase a facility in the UK specific to UTMD's needs that will replace its leased facility; 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 shareholders in the form of dividends and share repurchases when the stock appears undervalued.

#### Management's Outlook.

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

The safety, reliability and performance of UTMD's medical devices are high and represent significant clinical benefits while providing minimum total cost of care. UTMD will continue to leverage its reputation as a device innovator which will responsively take on challenges to work with clinicians who use its specialty devices. In doing so, UTMD will continue to differentiate itself, especially from commodity-oriented competitors. In 2016, UTMD plans to

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

UTMD's balance sheet was strong enough in early 2011 to be able to finance a substantial acquisition which met UTMD's investment criteria without issuing stock. After five years of integration and consolidation, UTMD's balance sheet is once again strong enough to support a similar acquisition significantly accretive to financial performance and shareholder value.

The Company has a fundamental focus to do an excellent job in meeting clinicians' and patients' needs, while providing stockholders with excellent returns. In 2015, the value of UTMD's stock declined 3% while EPS increased 4%. This compares to an increase of 6% in the NASDAQ Composite Index, a decrease of 1% in the S&P 500 Index and a 2% decrease in the Dow Jones Industrial Average. Taking a longer term view, as of the end of 2015 from the end of 1998, the NASDAQ Composite Index was up 128%, the S&P 500 Index was up 66% and the DJIA was up 90%. In comparison, UTMD's share price increased 792% over that same seventeen year time span (14% annually compounded increase per year). If additional returns to stockholders from cash dividends are added, shareholder value increased 962% (15% per year). Combining share price appreciation as a result of a long term profitable financial performance and a capital allocation strategy that includes opportunistic share repurchases with steadily growing quarterly cash dividends paid to stockholders since 2004, longer term UTMD stockholders have experienced excellent



returns. Management is committed to continue that performance.

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## Off Balance Sheet Arrangements

None

## Contractual Obligations

The following is a summary of UTMD's significant contractual obligations and commitments as of December 31, 2015:

Contractual Obligations and Commitments	Total	2016	2017- 2018	2019 - 2020	2021 and thereafter
Long-term debt obligations	\$-	\$-	\$-	\$-	\$ -
Operating lease obligations	930	166	209	86	469
Purchase obligations	2,610	2,507	103	-	-
Total	\$3,540	\$2,673	\$312	\$86	\$ 469

## 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 customers where collection efforts can be difficult or in the event of widespread U.S. hospital bankruptcies.

**Inventory valuation reserves:** The Company strives to maintain a good balance of 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.

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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 and the Australian Dollar (AUD). The currencies are subject to exchange rate fluctuations that are beyond the control of UTMD. The exchange rates were .9203, .8258 and .7259 EUR per USD as of December 31, 2015, 2014 and 2013, respectively. Exchange rates were .6774, .6416 and .6034 GBP per USD as of December 31, 2015, 2014 and 2013, respectively. Exchange rates were 1.3710, 1.2223 and 1.1201 AUD per USD on December 31, 2015, 2014 and 2013, respectively. Please see note 1 in Item, 8, below under "Translation of Foreign Currencies" for more information. UTMD manages its foreign currency risk without separate hedging transactions by either invoicing customers in the local currency where costs of production were incurred, or by converting currencies as transactions occur.

ITEM 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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MANAGEMENT'S REPORT ON INTERNAL CONTROL  
OVER FINANCIAL REPORTING

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

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

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

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2015. 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 (1992). Based on its assessment and those criteria, management believes that the Company maintained effective internal control over financial reporting as of December 31, 2015.

The Company's independent registered public accounting firm, Jones Simkins LLC, has audited the Company's internal control over financial reporting as of December 31, 2015, and its report is shown on the next page.

The Norton Practice audited the internal control over financial reporting of Femcare Group Limited as of December 31, 2015, and its report follows the report of Jones Simkins LLC.

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

By: /s/ Paul O. Richins  
Paul O. Richins  
Principal Financial Officer

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Utah Medical Products, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of income and comprehensive income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2015. We also have audited Utah Medical Products, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Utah Medical Products, Inc.'s management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on these financial statements and an opinion on the company's internal control over financial reporting based on our audits. We did not audit portions of the financial statements and we did not examine the effectiveness of internal control over financial reporting for portions of Femcare Group Limited, a wholly owned subsidiary. The portions not audited by us include assets of \$16,133,000 and \$14,886,000 as of December 31, 2015 and 2014, respectively, and total revenues of \$12,548,000, \$16,367,000, and \$15,372,000, respectively for each of the years in the three-year period ended December 31, 2015. Those portions of the statements and the effectiveness of internal control over financial reporting were audited by other auditors whose reports have been furnished to us, and our opinions, insofar as they relate to the amounts included for Femcare Group Limited and the effectiveness of Femcare Group Limited's internal control over financial reporting, is based solely on the reports of the other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

In our opinion, based on our audits and the report of the other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Utah Medical Products, Inc. as of December

31, 2015 and 2014, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, based on our audit and the report of the other auditors, Utah Medical Products, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

/s/ Jones Simkins LLC

JONES SIMKINS LLC

Logan, Utah

March 3, 2016

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Report of Independent Registered Public Accounting Firm

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

We have audited the individual balance sheet of Femcare Group Limited, including its subsidiaries, as of December 31, 2015, 2014 and 2013, and the related statements of income, stockholders' equity, and cash flows for the years ended December 31, 2015, 2014 and 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Femcare Group Ltd, including all subsidiaries, as of December 31, 2015, 2014 and 2013, and the results of its operations and its cash flows for the years ending December 31, 2015, 2014 and 2013, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Femcare Group Limited's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control – Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated 3 March 2016 expressed an unqualified opinion.

/s/ The Norton Practice

The Norton Practice  
Reading, United Kingdom

3 March 2016

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Utah Medical Products, Inc.

We have audited Femcare Group Limited, including its subsidiaries, internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Femcare Group's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on Femcare Group's internal control over financial reporting based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

In our opinion, Femcare Group Limited maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheet and the related statements of income, comprehensive income, stockholders' equity, and cash flows of Femcare Group Ltd., and our report dated 3 March 2016, expressed an unqualified opinion.

/s/ The Norton Practice

The Norton Practice  
Reading, United Kingdom

3 March 2016





UTAH MEDICAL PRODUCTS, INC.  
 CONSOLIDATED BALANCE SHEET  
 December 31, 2015 and 2014  
 (In thousands)

<u>ASSETS</u>	2015	2014
Current assets:		
Cash	\$23,278	\$19,274
Investments, available-for-sale (notes 3 and 4)	55	58
Accounts and other receivables, net (note 2)	4,563	4,703
Inventories (note 2)	4,196	4,872
Prepaid expenses and other current assets	418	465
Deferred income taxes (note 8)	363	303
Total current assets	32,873	29,675
Property and equipment, net (notes 5 and 11)	7,369	8,236
Goodwill	14,725	15,145
Other intangible assets (note 2)	37,772	39,675
Other intangible assets - accumulated amortization	(13,564)	(11,655)
Other intangible assets - net (note 2)	24,208	28,020
Total assets	\$79,175	\$81,076
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current liabilities:		
Accounts payable	\$649	\$929
Accrued expenses (note 2)	3,417	4,148
Current portion of notes payable (note 6)	-	3,894
Total current liabilities	4,066	8,971
Notes payable (note 6)	-	973
Deferred tax liability - intangible assets	4,452	5,581
Deferred income taxes (note 8)	1,009	995
Total liabilities	9,527	16,520
Commitments and contingencies (notes 7 and 13)	-	-
Stockholders' equity:		
Preferred stock, \$.01 par value; 5,000 shares authorized, no shares issued and outstanding	-	-
Common stock, \$.01 par value; 50,000 shares authorized, issued 3,751 shares in 2015 and 3,748 shares in 2014	38	37
Accumulated other comprehensive income (loss)	(5,961 )	(3,234 )
Additional paid-in capital	2,710	2,890
Retained earnings	72,861	64,863
Total stockholders' equity	69,648	64,556
Total liabilities and stockholders' equity	\$79,175	\$81,076

See accompanying notes to financial statements.

UTAH MEDICAL PRODUCTS, INC.  
CONSOLIDATED STATEMENT OF INCOME  
AND COMPREHENSIVE INCOME  
Years ended December 31, 2015, 2014 and 2013  
(In thousands, except per share amounts)

	2015	2014	2013
Sales, net (notes 10, 12 and 13)	\$40,157	\$41,278	\$40,493
Cost of goods sold	15,972	16,295	16,220
Gross profit	24,185	24,983	24,273
Operating expense:			
Sales and marketing	2,164	2,211	2,790
Research and development	522	460	491
General and administrative	5,848	6,110	6,164
Operating income	15,651	16,202	14,828
Other income (expense):			
Dividend and interest income	5	7	7
Royalty income (note 13)	93	99	90
Interest expense	(65 )	(289 )	(438 )
Other, net	(139 )	(207 )	(11 )
Income before provision for income taxes	15,545	15,812	14,476
Provision for income taxes (note 8)	3,702	4,434	3,070
Net income	\$11,843	\$11,378	\$11,406
Earnings per common share (basic) (note 1):	\$3.16	\$3.04	\$3.06
Earnings per common share (diluted) (note 1):	\$3.14	\$3.02	\$3.02
Other comprehensive income:			
Foreign currency translation net of taxes of \$0 in all periods	\$(2,724 )	\$(3,252 )	\$859
Unrealized gain (loss) on investments net of taxes of \$(1), \$1 and \$6	(2 )	1	8
Total comprehensive income	\$9,117	\$8,127	\$12,273

See accompanying notes to financial statements.

UTAH MEDICAL PRODUCTS, INC.  
CONSOLIDATED STATEMENT OF CASH FLOW  
Years Ended December 31, 2015, 2014 and 2013  
(In thousands)

	2015	2014	2013
Cash flows from operating activities:			
Net income	\$11,843	\$11,378	\$11,406
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	619	637	611
Amortization	2,528	2,719	2,584
Provision for (recovery of) losses on accounts receivable	(10 )	(27 )	10
Loss on disposal of assets	1	35	6
Deferred income taxes	(901 )	(500 )	(1,399 )
Stock-based compensation expense	87	74	28
(Increase) decrease in:			
Accounts receivable	137	(365 )	213
Accrued interest and other receivables	(91 )	(100 )	(241 )
Inventories	422	(141 )	(249 )
Prepaid expenses and other current assets	28	(19 )	6
Increase (decrease) in:			
Accounts payable	(265 )	188	(216 )
Accrued expenses	(597 )	1,508	(28 )
Deferred revenue	-	-	(83 )
Other liability	-	-	(340 )
Net cash provided by operating activities	13,801	15,387	12,308
Cash flows from investing activities:			
Capital expenditures for:			
Property and equipment	(176 )	(1,110 )	(339 )
Intangible assets	(70 )	(22 )	(5 )
Net cash provided by (used in) investing activities	(246 )	(1,132 )	(344 )
Cash flows from financing activities:			
Proceeds from issuance of common stock - options	343	491	787
Common stock purchased and retired	(683 )	(1,055 )	-
Payment of taxes for exchange of stock options	(42 )	-	(85 )
Tax benefit attributable to exercise of stock options	114	103	281
Repayments of notes payable	(4,777 )	(4,035 )	(3,908 )
Dividends paid	(3,846 )	(3,765 )	(3,675 )
Net cash provided by (used in) financing activities	(8,891 )	(8,261 )	(6,600 )
Effect of exchange rate changes on cash	(660 )	(1,115 )	160
Net increase in cash and cash equivalents	4,004	4,879	5,524
Cash at beginning of year	19,274	14,395	8,871
Cash at end of year	\$23,278	\$19,274	\$14,395

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:

Cash paid during the year for:

Income taxes	\$5,341	\$3,094	\$3,971
Interest	65	296	439

See accompanying notes to financial statements.

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UTAH MEDICAL PRODUCTS, INC.  
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY  
Years Ended December 31, 2015, 2014 and 2013  
(In thousands)

	Common Shares	Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Retained Earnings	Total Stockholders' Equity
Balance at December 31, 2012	3,703	\$ 37	\$ 2,268	\$ (851	) \$49,519	\$ 50,972
Shares issued upon exercise of employee stock options for cash	55	1	1,402	-	-	1,403
Shares received and retired upon exercise of stock options	(15 )	(0 )	(701 )	-	-	(701 )
Tax benefit attributable to appreciation of stock options	-	-	281	-	-	281
Stock option compensation expense	-	-	28	-	-	28
Common stock purchased and retired	-	-	-	-	-	-
Foreign currency translation adjustment	-	-	-	859	-	859
Unrealized holding gain (loss) from investments, available-for-sale, net of taxes	-	-	-	8	-	8
Common stock dividends	-	-	-	-	(3,675 )	(3,675 )
Net income	-	-	-	-	11,406	11,406
Balance at December 31, 2013	3,743	\$ 37	\$ 3,278	\$ 16	\$57,250	\$ 60,581
Shares issued upon exercise of employee stock options for cash	35	0	926	-	-	926
Shares received and retired upon exercise of stock options	(8 )	(0 )	(435 )	-	-	(435 )
Tax benefit attributable to appreciation of stock options	-	-	103	-	-	103
Stock option compensation expense	-	-	74	-	-	74
Common stock purchased and retired	(22 )	(0 )	(1,055 )	-	-	(1,055 )
Foreign currency translation adjustment	-	-	-	(3,252 )	-	(3,252 )
Unrealized holding gain (loss) from investments, available-for-sale, net of taxes	-	-	-	1	-	1
Common stock dividends	-	-	-	-	(3,765 )	(3,765 )
Net income	-	-	-	-	11,378	11,378
Balance at December 31, 2014	3,748	\$ 37	\$ 2,890	\$ (3,234	) \$64,863	\$ 64,556
Shares issued upon exercise of employee stock options for cash	22	0	640	-	-	640
Shares received and retired upon exercise of stock options	(6 )	(0 )	(338 )	-	-	(338 )
Tax benefit attributable to appreciation of stock options	-	-	114	-	-	114
Stock option compensation expense	-	-	87	-	-	87
Common stock purchased and retired	(13 )	(0 )	(683 )	-	-	(683 )
Foreign currency translation adjustment	-	-	-	(2,724 )	-	(2,724 )
Unrealized holding gain (loss) from investments, available-for-sale, net of taxes	-	-	-	(2 )	-	(2 )
Common stock dividends	-	-	-	-	(3,846 )	(3,846 )

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Net income	-	-	-	-	11,843	11,843
Balance at December 31, 2015	3,751	\$ 38	\$ 2,710	\$ (5,961	) \$72,861	\$ 69,648

See accompanying notes to financial statements.

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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 subsidiaries, Femcare Nikomed Ltd located in Romsey, Hampshire, England, Femcare Australia Pty Ltd located in Castle Hill, NSW, Australia 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 and Australia, and through third party distributors in other international markets. Domestically, UTMD has an exclusive distribution relationship with CooperSurgical, Inc. for the Filshie Clip System. UTMD also sells subcontract manufactured components and finished products to over 160 companies in the U.S. for their medical and non-medical products.

##### Use of Estimates in the Preparation of Financial Statements

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

##### Principles of Consolidation

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

##### Cash and Cash Equivalents

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

##### Investments

The Company classifies its investments as "available-for-sale." Securities classified as "available-for-sale" are carried in the financial statements at fair value. Realized gains and losses, determined using the specific identification method, are included in operations; unrealized holding gains and losses are reported as a separate component of accumulated other comprehensive income. Declines in fair value below cost that are other than temporary are included in operations. As of December 31, 2015 the Company retained a freely tradeable investment in Citigroup (C) (see note 3).

##### 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, 2015 except under an extreme global financial crisis.

The Company maintains its cash in bank deposit accounts in addition to Fidelity Investment 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.

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Note 1 – Summary of Significant Accounting Policies (continued)

Accounts Receivable

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

Inventories

Finished products, work-in-process, raw materials and supplies inventories are stated at the lower of cost (computed on a first-in, first-out method) or market (see note 2).

Property and Equipment

Property and equipment are stated at cost. Depreciation and amortization are computed using the straight-line and units-of-production methods 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, using a fair value measurement test, 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 expense on intangible assets currently held, using the 2015 year-end 1.4763 USD/GBP and .7294 USD/AUD currency exchange rates, is about \$2,517 in 2016, \$2,501 in 2017, \$2,500 in 2018, and \$2,498 in 2019 and 2020 (see note 2).

Revenue Recognition

The Company recognizes revenue at the time of shipment as title generally passes to the customer at the time of shipment. Revenue recognized by UTMD is based upon documented arrangements and fixed contracts in which the selling price is fixed prior to the Company's acceptance of an order. Revenue from product and service sales is generally recognized at the time the product is shipped or service completed and invoiced, and collectibility is reasonably assured. There are circumstances under which revenue may be recognized when product is not shipped, which meet the criteria of SAB 104: the Company provides engineering services, for example, design and production of manufacturing tooling that may be used in subsequent UTMD manufacturing of custom components for other companies. This revenue is recognized when UTMD's service has been completed according to a fixed contractual agreement. UTMD includes handling fees charged to customers in revenues.

Note 1 – Summary of Significant Accounting Policies (continued)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 or one of its subsidiaries files income tax returns in the U.S. federal jurisdiction, in Utah, in the United Kingdom, in Australia and in Ireland. UTMD is no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for years before 2012. In 2010, the Internal Revenue Service (IRS) examined the Company's federal income tax return for 2008 and did not propose any adjustments.

The Company recognizes interest accrued related to unrecognized tax benefits in interest expenses and any related penalties in income taxes. The Company did not recognize any tax-related interest expense or have any tax penalties in any of the three years 2013 through 2015.

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, 2015 and 2014 was \$122 and \$110, 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:

	2015	2014	2013
Weighted average number of shares outstanding – basic	3,752	3,747	3,728
Dilutive effect of stock options	20	27	47
Weighted average number of shares outstanding, assuming dilution	3,772	3,774	3,775

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 international sales, and at least 85% of domestic 2015 sales were to customers who are tax exempt or who are in jurisdictions where UTMD is not required to withhold sales tax.

Stock-Based Compensation

At December 31, 2015, the Company has stock-based employee compensation plans, which are described more fully in note 9. 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 2015, the Company recognized \$87 in compensation cost compared to \$74 in 2014 and \$28 in 2013.



Note 1 – Summary of Significant Accounting Policies (continued)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/ expense.

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

Note 2 – Detail of Certain Balance Sheet Accounts

	December 31,	
	2015	2014
Accounts and other receivables:		
Accounts receivable	\$3,750	\$3,993
Income tax receivable	901	787
Accrued interest and other	12	36
Less allowance for doubtful accounts	(100 )	(113 )
Total accounts and other receivables	\$4,563	\$4,703
Inventories:		
Finished products	\$1,715	\$1,847
Work-in-process	961	1,103
Raw materials	1,520	1,922
Total inventories	\$4,196	\$4,872
Other intangible assets:		
Patents	\$2,180	\$2,113
Non-compete agreements	147	156
Trademarks & trade names	10,808	11,396
Customer relationships	10,556	11,144
Regulatory approvals & product certifications	14,081	14,866
Total other intangible assets	37,772	39,675
Accumulated amortization	(13,564)	(11,655)
Other intangible assets, net	\$24,208	\$28,020
Accrued expenses:		
Income taxes payable	\$1,632	\$2,445
Payroll and payroll taxes	1,053	940
Reserve for litigation costs	122	110
Other	610	653
Total accrued expenses	\$3,417	\$4,148

Note 3 – Investments

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

	December 31, 2015 2014	
Investments, at cost	\$42	\$42
Equity securities:		
-Unrealized holding gains	13	16
-Unrealized holding (losses)	-	-
Investments, at fair value	\$55	\$58

During the three years 2013 through 2015, UTMD did not have any proceeds from sales of available-for-sale securities.

Note 4 – Fair Value Measurements and Financial Instruments

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

The Company uses the following valuation techniques to measure fair value for its assets and liabilities:

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

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

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

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

	Levels 2				Total	
	Level 1	& 3		Total		
	2015	2014	2015	2014	2015	2014
Equities	55	58	-	-	55	58
Total	\$55	\$58	-	-	\$55	\$58

None of the Company's financial instruments, which are current assets and liabilities that could be readily traded, are held for trading purposes. Detail on investments is provided in note 3 above. The Company estimates that the fair value of all financial instruments at December 31, 2015 does not differ materially from the aggregate carrying value of its financial instruments recorded in the accompanying consolidated balance sheet.

Note 5 – Property and Equipment

Property and equipment consists of the following:

	December 31,	
	2015	2014
Land	\$ 1,299	\$ 1,342
Buildings and improvements	10,184	10,657
Furniture, equipment and tooling	15,566	15,483
Construction-in-progress	31	131
Total	27,080	27,613
Accumulated depreciation	(19,711)	(19,377)
Property and equipment, net	\$7,369	\$8,236

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

	December 31, 2015				
	Utah	England	Australia	Ireland	Total
Land	\$926	\$ -	\$ -	\$373	\$1,299
Building and improvements	5,677	-	525	3,982	10,184
Furniture, equipment and tooling	14,010	565	39	952	15,566
Construction-in-progress	31	-	-	-	31
Total	20,644	565	564	5,307	27,080
Accumulated depreciation	(16,825)	(300 )	(41 )	(2,545)	(19,711)
Property and equipment, net	\$3,819	\$ 265	\$ 523	\$2,762	\$7,369

  

	December 31, 2014				
	Utah	England	Australia	Ireland	Total
Land	\$926	\$ -	\$ -	\$416	\$1,342
Building and improvements	5,635	-	585	4,437	10,657
Furniture, equipment and tooling	13,854	554	43	1,032	15,483
Construction-in-progress	120	7	-	4	131
Total	20,535	561	628	5,889	27,613
Accumulated depreciation	(16,482)	(212 )	(16 )	(2,667)	(19,377)
Property and equipment, net	\$4,053	\$ 349	\$ 612	\$3,222	\$8,236

Note 6 – Long-term Debt

In March 2011, the Company obtained a \$14,000 loan from JPMorgan Chase Bank, N.A. and a \$12,934 loan from JP Morgan Chase, London Branch to help finance UTMD's purchase of Femcare. The notes were fully paid off in February 2015.



Note 7 – Commitments and ContingenciesOperating Leases

The Company has a lease agreement for land adjoining its Utah facility for a term of forty years commencing on September 1, 1991. On September 1, 2001 and subsequent to each fifth lease year, the basic rental was and will be adjusted for published changes in a price index. The Company currently leases its UK facility, and some automobiles for employees in England and Ireland. Rent expense charged to operations under these operating lease agreements was approximately \$184, \$225 and \$219 for the years ended December 31, 2015, 2014 and 2013, respectively.

Future minimum lease payments under its lease obligations as of December 31, 2015 were as follows:

<u>Years ending December 31:</u>	Amount
2016	\$ 166
2017	166
2018	43
2019	43
2020	43
Thereafter	469
Total future minimum lease payments	\$ 930

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

Except for its Femcare subsidiaries, 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. Femcare's product liability indemnity limit through an independent insurer is £5 million each claim and in the annual aggregate.

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, 2015 or December 31, 2014.

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. The Company applies its accounting policy to accrue legal costs that can be reasonably estimated.

Irish Development Agency

In order to satisfy requirements of the Irish Development Agency in assisting the start-up of its Ireland subsidiary, the Company agreed to invest certain amounts and maintain a certain capital structure in its Ireland subsidiary. The effect of these financial relationships and commitments are reflected in the consolidated financial statements and do not represent any significant credit risk that would affect future liquidity.

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Note 8 – Income Taxes

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

	December 31,		2014	
	2015	Long-term	Current	Long-term
Inventory write-downs and differences due to UNICAP	\$78	\$ -	\$78	\$ -
Allowance for doubtful accounts	26	-	26	-
Accrued liabilities and reserves	121	-	65	-
Other - foreign	30	(49 )	27	(64 )
Depreciation and amortization	-	(5,412 )	-	(6,511 )
Unrealized investment loss	108	-	107	-
Deferred income taxes, net	\$363	\$ (5,461 )	\$303	\$ (6,575 )

The components of income tax expense are as follows:

	Years ended December 31,		
	2015	2014	2013
Current	\$4,877	\$5,288	\$4,266
Deferred	(1,175 )	(854 )	(1,196 )
Total	\$3,702	\$4,434	\$3,070

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

	Years ended December 31,		
	2015	2014	2013
Federal income tax expense at the statutory rate	\$2,704	\$2,632	\$2,580
State income taxes	262	255	250
Foreign income taxes (blended rate)	990	1,770	542
ETI, manufacturing deduction and tax credits	(257 )	(244 )	(244 )
Other	3	21	(58 )
Total	\$3,702	\$4,434	\$3,070

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

	Years ended December 31,		
	2015	2014	2013
Domestic	\$7,973	\$7,717	\$7,587
Foreign	7,572	8,095	6,889
Total	\$15,545	\$15,812	\$14,476

Note 9 – 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 229 thousand shares of common stock, of which 62 thousand are outstanding as of December 31, 2015. 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:

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Note 9 – Options (continued)

	Shares (000's)	Price Range Per Share	
<u>2015</u>			
Granted	-	\$ -	\$-
Expired or canceled	7	26.58 -	49.18
Exercised	22	21.68 -	49.18
Total outstanding at December 31	62	24.00 -	50.72
Total exercisable at December 31	41	24.00 -	50.72
<u>2014</u>			
Granted	39	\$49.18 -	\$50.72
Expired or canceled	4	25.59 -	49.18
Exercised	35	18.00 -	33.30
Total outstanding at December 31	91	21.68 -	50.72
Total exercisable at December 31	48	21.68 -	33.30
<u>2013</u>			
Granted	-		
Expired or canceled	3	\$17.71 -	\$33.30
Exercised	55	17.71 -	33.30
Total outstanding at December 31	91	18.00 -	33.30
Total exercisable at December 31	77	18.00 -	33.30

For the years ended December 31, 2015, 2014 and 2013, the Company reduced current income taxes payable and increased additional paid-in capital by \$114, \$103 and \$281, 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 2015, the Company recognized \$87 in equity compensation cost, compared to \$74 in 2014 and \$28 in 2013.

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,		
	2015	2014	2013
Expected dividend amount per quarter	\$n/a	\$.2624	\$n/a
Expected stock price volatility		27.0%	
Risk-free interest rate		1.50%	
		4.7	
Expected life of options		years	

The per share weighted average fair value of options granted during 2014 is \$9.64. No options were granted in 2015 or 2013.

All UTMD options vest over a four-year service period. 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.

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Note 9 – Options (continued)

The following table summarizes information about stock options outstanding at December 31, 2015:

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number Outstanding	Weighted Average Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$24.00 - \$24.00	9,859	3.08	\$ 24.00	9,859	\$ 24.00	
26.52 - 33.30	20,337	4.06	29.30	19,219	29.11	
49.18 - 50.72	31,862	8.35	49.23	11,812	49.23	
\$24.00 - \$50.72	62,058	6.11	\$ 38.69	40,890	\$ 33.69	

Note 10 – Geographic Information

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

	2015	2014	2013
United States	\$20,364	\$19,483	\$18,965
Europe	7,720	8,939	9,077
Other	12,073	12,856	12,451

Note 11 – Long-lived Assets by Geographic Area

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

	2015	2014	2013
United States	\$11,097	\$11,349	\$11,355
England	31,901	36,199	41,216
Ireland	2,761	3,222	3,829
Australia	543	631	24

Note 12 – Revenues by Product Category

The Company had revenues in the following product categories:

<u>Product Category</u>	2015	2014	2013
Obstetrics	\$4,587	\$4,669	\$5,085
Gynecology/Electrosurgery/Urology	22,356	24,088	22,687
Neonatal	6,299	6,222	5,920
Blood Pressure Monitoring and Accessories	6,915	6,299	6,801

Note 13 - 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 2015, 2014 and 2013, UTMD received royalties of \$93, \$99 and \$90, respectively, for the use of intellectual property of Filshie Clip System as part of Femcare's exclusive U.S. distribution agreement with CooperSurgical Inc.

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Note 14 – Employee Benefit Plans

The Company sponsors a contributory 401(k) savings plan for U.S. employees, and contributory retirement plans for Ireland, UK and Australia employees. The Company's matching contribution is determined annually by the board of directors. Company contributions were approximately \$161, \$165 and \$138 for the years ended December 31, 2015, 2014 and 2013, respectively.

Note 15 – Recent Accounting Pronouncements

In May 2014, new accounting guidance was issued that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to fulfill a contract. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. This guidance becomes effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. UTMD is currently assessing the impact that this standard will have on its consolidated financial statements when it is adopted in 2017.

Note 16 – Subsequent Events

The Company evaluated its December 31, 2015 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 2015, 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, 2015, 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, 2015. Jones Simkins LLC, the independent registered public accounting firm of the Company, has audited the effectiveness of the Company's internal control over financial reporting. The Norton Practice, the independent registered public accounting firm of Femcare Group Limited (Femcare Group) has audited the effectiveness of Femcare Group's internal control over financial reporting. Management's report, and the reports of Jones Simkins LLC and The Norton Practice appear on pages 33 through 36 of this Form 10-K under the captions "Management's Report on Internal

Control Over Financial Reporting" and "Report of Independent Registered Public Accounting Firm" and are incorporated herein by reference.

Changes in Internal Control Over Financial Reporting.

There have been no changes in UTMD's internal control over financial reporting that materially affected, or were reasonably likely to materially affect, the Company's internal control over financial reporting during the fourth quarter of the fiscal year ended December 31, 2015, and there were no material weaknesses.

ITEM 9B – OTHER INFORMATION

None.

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PART III

ITEM 10 – DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information from the definitive proxy statement of the registrant for the 2016 annual meeting of shareholders 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: 2015 Director Compensation,"

is incorporated herein by reference.

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

ITEM 11 - EXECUTIVE COMPENSATION

The information from the definitive proxy statement of the registrant for the 2016 annual meeting of shareholders 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 2016 annual meeting of shareholders 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 2016 annual meeting of shareholders 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 2016 annual meeting of shareholders 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 2016 annual meeting of shareholders under the caption "PROPOSAL NO 2. RATIFICATION OF THE APPOINTMENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM: Fees billed by Jones Simkins LLC," "Audit Committee Policy and Approval," and "Auditor Independence" are incorporated herein by reference.

PART IV

## ITEM 15 – EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

1. Financial Statements.

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

2. Supplemental Schedule.

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

3. Exhibits.

Exhibit #	SEC Reference #	Title of Document	Location
1	3	Articles of Restatement of the Articles of Incorporation	Incorporated by Reference (1)
2	3	Articles of Correction to the Restated Articles of Incorporation	Incorporated by Reference (1)
3	3	Bylaws	Incorporated by Reference (2)
4	4	Rights Agreement dated as of July 30, 2004, between Utah Medical Products, Inc., and Registrar and Transfer Company	Incorporated by Reference (4)
5	4	Extension of Shareholder Rights Agreement	Incorporated by Reference (5)
6	4	Designation of Rights, Privileges, and Preferences of Series "A" Preferred Stock	Incorporated by Reference (3)
7	10	Employment Agreement dated December 21, 1992 with Kevin L. Cornwell*	Incorporated by Reference (6)
8	10	Amendment, effective May 15, 1998, to Employment Agreement dated December 21, 1992 with Kevin L. Cornwell*	Incorporated by Reference (6)
9	10	Utah Medical Products, Inc., 2003 Employees' and Directors' Incentive Plan*	Incorporated by Reference (7)
10	10	Utah Medical Products, Inc., 2013 Employees' and Directors' Incentive Plan*	Incorporated by Reference (8)
11	10	Summary of Officer and Director Compensation	This filing

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12	21	Subsidiaries of Utah Medical Products, Inc.	Incorporated by Reference (8)
13	23	Consent of Jones Simkins LLC, Company's independent auditors for the years ended December 31, 2015, December 31, 2014 and December 31, 2013	This filing
14	23	Consent of The Norton Practice, Femcare Group Limited's independent auditors for the years ended December 31, 2015, December 31, 2014 and December 31, 2013	This filing
15	31	Certification of CEO pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	This Filing

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Exhibit #	SEC Reference #	Title of Document	Location
16	31	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
17	32	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
18	32	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.ins		XBRL Instance Document	This Filing
101.xsd		XBRL Taxonomy Extension Schema Document	This Filing
101.cal		XBRL Taxonomy Extension Calculation Linkbase Document	This Filing
101.def		XBRL Taxonomy Extension Definition Linkbase Document	This Filing
101.tab		XBRL Taxonomy Extension Label Linkbase Document	This Filing
101.pre		XBRL Taxonomy Extension Presentation Linkbase Document	This Filing

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

(1) Incorporated by reference from the Company's annual report on form 10-K filed with the Commission for the year ended December 31, 2004.

(2) Incorporated by reference from the Company's report on form 8-K filed with the Commission on February 13, 2014.

(3) Incorporated by reference from the Company's registration statement on form S-8 filed with the Commission effective February 10, 1995.

(4) Incorporated by reference from the Company's report on form 8-K filed with the Commission on October 1, 2004.

(5) Incorporated by reference from the Company's report on form 8-K filed with the Commission on October 24, 2014.

(6) Incorporated by reference from the Company's annual report on form 10-K filed with the Commission for the year ended December 31, 2003.

(7) Incorporated by reference from the Company's annual report on form 10-K filed with the Commission for the year ended December 31, 2002.

(8) Incorporated by reference from the Company's annual report on form 10-K filed with the Commission for the year ended December 31, 2012.

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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 10th day of March, 2016.

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 10th day of March, 2016.

By: /s/ James H. Beeson

James H. Beeson

Director

By: /s/ Kevin L. Cornwell

Kevin L. Cornwell

Chief Executive Officer & 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

Principal Financial and Accounting Officer & Director