

UTAH MEDICAL PRODUCTS INC  
Form 10-K  
March 07, 2008

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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, 2007

Commission File Number: 000-11178

UTAH MEDICAL PRODUCTS, INC.  
(Exact name of registrant as specified in its charter)

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

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) 566-2062

Securities registered pursuant to Section 12(b) of the Act:  
Title of each class Name of each exchange on which registered  
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 o No x

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

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 x No o

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

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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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input type="checkbox"/>

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, 2007, the aggregate market value of the voting and nonvoting common equity held by nonaffiliates of the registrant was \$112,144,000.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. As of March 5, 2008, common shares outstanding were 3,884,000.

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

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PART I

ITEM 1 – BUSINESS

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) establishing relationships with other medical companies that have the resources to effectively introduce and support the Company's products.

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

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

UTMD's products are sold directly to end users in the U.S. domestic market by the Company's own direct sales representatives and independent manufacturers' representatives. In addition, some of UTMD's products are sold through specialty distributors, national hospital distribution companies and other medical device manufacturers. Internationally, products are sold through other medical device companies and through independent medical products distributors. UTMD has representation in all major developed countries through 136 international distributors, each of which purchased at least five thousand dollars in UTMD products during 2007.

UTMD was formed as a Utah corporation in 1978. UTMD publicly raised equity capital one time in 1982. In 1994, UTMD acquired all of the tangible and intangible assets of OB Tech, Inc, a Huntington Beach, CA company, the original owner of the Cordguard® concept. In 1995, Utah Medical Products Ltd., a wholly-owned subsidiary located in Ireland, was formed to establish an international manufacturing capability. In 1997, UTMD purchased Columbia Medical, Inc. (CMI), a Redmond, Oregon company specializing in silicone injection molding, assembly and marketing vacuum-assisted obstetrical delivery systems. In 1998, UTMD acquired the neonatal product line of Gesco International, a subsidiary of Bard Access Systems and C.R. Bard, Inc. On March 8, 2000, UTMD returned to the Nasdaq Stock Market after trading on the New York Stock Exchange for about 3 years. The Company was previously listed on Nasdaq for 14 years. In 2004, UTMD acquired Abcorp, Inc., its supplier of fetal monitoring belts. The Company's corporate offices are located at 7043 South 300 West, Midvale, Utah 84047 USA. The corporate telephone number is (801) 566-1200. Ireland operations are located at Athlone Business and Technology Park, Athlone, County Westmeath, Ireland. The telephone number in Ireland is 353 (90) 647-3932. CMI's mailing address is 1830 S.E. 1st, Redmond, Oregon 97756. The phone number in Oregon is (541) 548-7738.



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

## PRODUCTS

### Labor and Delivery/ Obstetrics:

#### Fetal Monitoring Accessories.

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

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

- IUP-075 and UTMD's other custom fluid-filled clear catheter kits utilize a saline-filled catheter that is placed within the uterine cavity, connected to a separate external reusable or disposable transducer. This product package, utilizing double lumen catheters, was the traditional mode of intrauterine monitoring prior to the introduction of INTRAN. An intrauterine pressure change is transmitted through the fluid column to the external pressure transducer.
- Introduced in 1987, INTRAN was the first disposable intrauterine pressure catheter that placed the pressure transducer at the pressure source within the uterine cavity. This design eliminated the complicated setup of fluid-filled systems and provided more accurate pressure waveforms. INTRAN I was discontinued in 1995 in favor of the more widely preferred INTRAN PLUS, also covered by UTMD's original INTRAN patent.
- INTRAN PLUS was introduced in 1991. The INTRAN PLUS catheter combines the transducer tip concept of INTRAN I with a refined tip design, a zeroing switch that allows the clinician to reset the reference of the monitor, and a dedicated amnio lumen which provides access to the amniotic fluid environment which may be helpful in the diagnosis and intervention of certain fetal conditions. In 1996, a viewport enhancement which allows physicians to observe amniotic fluid in a closed system was added to INTRAN PLUS. In 1997, UTMD introduced several variations to allow user preferences in tip size, zero switch location and amniotic fluid visualization.

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

### Vacuum-Assisted Delivery Systems (VAD).

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

VAD is indicated. Operative vaginal deliveries using forceps or vacuum-assisted delivery systems provide knowledgeable physicians with a trial vaginal operative delivery prior to a more invasive C-section intervention. Although there are risks associated with vaginal operative deliveries which may currently represent 6-10% of all U.S. hospital births, the procedures are generally regarded as safer for the mother, and at least as safe for the fetus, as abdominal (Cesarean) delivery in comparable clinical situations. UTMD estimates that the VAD operative approach is used for about 4-8% of all U.S. births, with forceps continuing to lose ground as the alternative. UTMD's patented bell-shaped soft silicone TENDER TOUCH® cups enjoy a low reported complication rate compared to other vacuum cup designs, as evidenced by the FDA Medical Device Reporting System which reports specific names of products used in hospitals.

#### Other Obstetrical Tools.

AROM-COT™ is a finger cover with a patented prong design to rupture maternal membranes with less patient pain and anxiety. MUC-X is an aspiration device used immediately after birth to clear neonatal respiratory passages and reduce exposure to potential infections. CORDGUARD® is a patented 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. Abcorp toco belts and straps for fetal monitoring by an external tocodynamometer are provided in latex-free form in several configurations.

#### Neonatal Intensive Care:

##### DISPOSA-HOOD™

The DISPOSA-HOOD is an infant respiratory hood that is used in the NICU to administer oxygen to neonates and flush CO<sub>2</sub> (carbon dioxide) while maintaining a neutral thermal environment 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 and provides optimum flows for elimination of CO<sub>2</sub> by ventilation. DISPOSA-HOOD, in contrast to an incubator, allows for excellent access to and visualization of the underdeveloped infant. Because it is a disposable product, it also prevents cross-contamination.

##### 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.

##### GESCO®

In the third quarter of 1998, UTMD acquired the neonatal product line of Gesco International. GESCO, best known for innovative 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 patented thermosensitive polyurethane (Tecoflex®) that offers many of the flexibility and biocompatibility advantages of silicone after insertion, with the greater rigidity of polyurethane preferred by many clinicians for insertion. In addition, GESCO provides a convenient catheterization procedure tray of implements and supplies necessary to place UVC catheters, as well as perform other similar procedures.

The primary distinction of GESCO products is that they were developed with the special needs of the neonate in mind, not just cut-down or smaller versions of adult devices. For example, in the case of invasive catheters, the introducer, the soft rounded distal tip, mode of securing to the patient after insertion to avoid migration, luer-locking hub with



minimal dead space, number of lumens, catheter radiopaque striping for visualization, variations in catheter lengths and diameters and special packaging are all features specially designed for neonates. UTMD continues to modify product features to incorporate current neonatal nurse practitioner preferences.

The soft, biocompatible silicone catheter concept had important advantages in other applications including peripherally inserted central venous catheters (PICC lines), enteral feeding tubes, urinary drainage catheters, and chest drainage tubes. GESCO developed and marketed initial versions of all of these neonatal products. In order to keep pace with the trend of caring for smaller babies, UTMD has added smaller diameter versions of its URI-CATH® and NUTRI-CATH® products. In 2000, UTMD gained FDA premarketing clearance of a new 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 that addresses an important safety risk in the NICU – inadvertent delivery of enteral feeding intravenously. Named Nutri-Lok, the adapter ensures a secure connection to the enteral feeding catheter (Nutri-Cath) and will not mate with an IV line connector. Nutri-Lok was launched to the market in January 2007. In October 2007, UTMD added dispensing syringes with interlocking connectors to its Nutri-Cath/Lok family of devices. UTMD has applied for a patent on its Nutri-Lok design. Also in 2006, UTMD completed the replacement of all DEHP plasticizer PVC materials in its Gesco product line that may come in contact with neonatal patients, addressing another evolving safety concern related specifically to the possible maldevelopment of male neonates.

Other GESCO specialty products include a disposable peritoneal dialysis set that is a pre-assembled, sterile, closed system, called DIALY-NATE®; a patented silicone oral protection device used to prevent palatal soft tissue injury by orotracheal tubes, called PALA-NATE®; and a lumbar sampling kit with a tiny, specially-beveled needle for obtaining cerebral spinal fluid samples, called MYELO-NATE®. In 2006, UTMD introduced a second configuration of Dially-Nate with uncoiled tubing to facilitate clinician use of a fluid/blood warmer.

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

In 2008, UTMD will continue to improve and expand its neonatal product line, seeking to reinforce a reputation as having the most developmentally-friendly NICU specialty products in the medical device industry. In addition to products already offered and being developed internally, UTMD will look to continue to expand sales through international distribution arrangements, and through selective complementary product acquisitions.

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.

In mid-2006, the FDA licensed the first vaccine for HPV, which has gained widespread media attention. Such an advance is welcome as an effective preventive measure for 70% of higher level CIN lesions which may progress into

cervical cancer. UTMD believes there will be a significant time lag, however, before the new vaccine affects the approximately 500,000 current annual CIN removal procedures based on several factors: the adoption rate of the vaccine, the evolution of the disease in patients already infected and the fact that a portion of CIN-types are unaffected by the vaccine. In early 2007, the American Society for Colposcopy and Cervical Pathology (ASCCP) published revised guidelines for the treatment of cervical intraepithelial neoplasia (CIN) which advised greater monitoring of lower grade lesions in lieu of surgical treatment, which includes LETZ.

UTMD's LETZ System includes patented disposable electrodes, the patented 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 patented Safe-T-Gauge® that can be positioned so the physician can accurately colposcopically monitor the amount of tissue being excised. UTMD continues to augment its specialty electrodes. For example, the Company introduced a patented conization electrode for deep endocervical disease called C-LETZ®, designed to limit the removal of healthy tissue margins that might compromise adequate cervical function. UTMD also will continue to provide adapters and other components which allow its market-leading specialty electrodes to be used with other manufacturers' electrosurgical generators. The FINESSE electrosurgical generator is the only generator on the market that contains an integral smoke evacuator, required to filter smoke and vapors that contain potentially hazardous particulate material produced during electrosurgery.

FINESSE® Generator; Specialty Loop, Ball, and Needle Electrodes; FILTRESSE® Evacuator; Other Specialty Electrodes; Other Supplies and Gynecologic Tools.

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. 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 and filed for a patent on its design for OptiSpec , an 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.

#### EPITOME®

EPITOME is a patented electrosurgical scalpel which delivers precise performance in incision and excision with hemostasis while minimizing thermal side effects. Where rapid yet precise dissection of dense tissue is necessary, such as in mammoplasty or abdominoplasty, UTMD believes that EPITOME has no close substitute. Furthermore, an independent study concludes that the EPITOME scalpel provides a significant improvement over older devices in wound healing and patient comfort. EPITOME allows a rapid incision without countertraction, yielding limited morbidity, less post-surgical pain and cosmetically superior results. EPITOME is useful where minimization of thermal tissue injury is important but control of bleeding needed. A patented bendable version of EPITOME with a smaller active electrode was introduced in 1998. Designed to significantly reduce the chance of tissue burns due to inadvertent electrode contact and where a smaller, bent scalpel tip is needed, the bendable EPITOME is of particular value, e.g., to thoracic surgeons in harvesting the internal mammary artery during coronary artery bypass surgery, as well as to otolaryngologists for tonsillectomies or uvulopalatalplasties.

#### 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.



#### 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.

#### 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 dilation of the cervix and without general anesthetic. The inherent weakness of this type of device, which is related to its small size, is that it may not remove enough tissue of the endometrium for an accurate histologic assessment, in contrast to a more invasive D&C hospital procedure. The patented tip of the EndoCurette was designed to obtain a more thorough tissue specimen without the need for dilation, and without an increase in patient discomfort.

#### TVUS/HSG-Cath

In order to further assess persistent abnormal or dysfunctional uterine bleeding and other suspected abnormalities of the uterus, or as a next step after endometrial tissue sampling with an EndoCurette, gynecologists are increasingly utilizing transvaginal ultrasound imaging of the uterus. UTMD's TVUS/HSG-Cath was designed 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 patent has been filed on the design of the TVUS/HSG-Cath, which was released for marketing in October 2007.

#### LUMIN®

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

#### Blood Pressure Monitoring:

##### DELTRAN® Disposable Pressure Transducer (DPT)

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

The Company believes that the DELTRAN DPT which it designed nearly twenty years ago, and currently manufactures, remains the standard in terms of accuracy, reliability and ease of use. UTMD has an automated assembly line which allows the Company to effectively compete with larger suppliers on the basis of consistent quality and low manufacturing costs. Introduced in 1998, the DELTRAN PLUS provides a closed system for blood sampling, without the use of needles, reducing the risk of an unwanted infection for both the patient and the practitioner.

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. 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

UTMD competes on the basis of its value-added technologies and cost effective clinical solutions. UTMD believes that a number of its products are strong brands because they are recognized as clinically different, and consistently reliable in achieving their intended results. The Company's primary marketing challenge is to keep its customers focused on those differences and their important clinical benefits. Access to the clinical decision-makers, together with the active involvement of clinicians in medical device purchasing decisions, is critical to the Company's success.

UTMD's specialty focus, innovation and extensive experience in its specialties are important marketing attributes which help ensure its ability to successfully compete and survive in a consolidating marketplace where competitors try to degrade UTMD's product differences.

For U.S. hospitals, which now represent about 56% of UTMD's device sales, marketing efforts are complicated and fragmented. Although UTMD's focus is with clinicians who take responsibility for obtaining optimal patient care outcomes, other people who are primarily administrative are often responsible for hospital purchasing decisions.

## DISTRIBUTION

An important success factor in the current 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 equivalent, establishing long term contracts with large medical device suppliers with diverse product lines in recent years, the financial relationships and true benefits for hospitals has come under increased scrutiny, both by hospitals' managements themselves and by the government. As a potential positive factor to UTMD's future performance, the increased scrutiny may lead to an understanding consistent with UTMD's belief that hospitals are not currently saving money under the GPO contracts. In addition, the longer term overall cost of care will be substantially higher, with quality of care lower, as innovative suppliers are excluded from participating in the marketplace.

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.

In the United States, UTMD sells its products through its own directly employed sales force and through selective independent manufacturer representatives. The direct representatives concentrate on applications for UTMD products where customer training and support are important. As of February 2008, the direct sales force is comprised both of "outside" representatives operating remotely in specific geographic areas, and "inside" representatives who operate 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 solutions to clinical problems. In addition to its direct representatives, UTMD utilizes third party consulting clinical specialists to augment its customer training programs.

When 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 less than 8% of total domestic sales. In contrast, eleven years ago, national distributors and independent stocking distributors in the U.S. represented more than 65% of UTMD's direct domestic Ob/Gyn and Neonatal products business.



In addition to the above traditional sales approaches, UTMD encourages customers to take advantage of fast and easy online ordering at <https://storefront.utahmed.com>. UTMD introduced this advanced “portal” website in 2006. It provides a convenient and secure method for placing orders, allows the customer to easily monitor the status of orders and shipments, and gives quick access to account information.

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Additionally, UTMD sells component parts to other companies for use with their product lines. This OEM distribution channel effort is simply maximizing utilization of manufacturing capabilities that are otherwise needed for UTMD's primary business, and does not compete with or dilute UTMD's direct distribution and marketing programs.

Internationally, the Company sells its products through over 300 regional distributors and OEMs (other medical device manufacturers). The international business is driven by the initiative and resourcefulness of those independent distributors. 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 three interrelated forms: 1) improvements, enhancements and extensions of current product lines in response to clinical needs or clinician requests, 2) introduction of new or augmented devices that represent a significant improvement in safety, effectiveness and/or cost of care, and 3) acquisitions of products or technology from others. Manufacturing process development is an equally important aspect that cannot be separated from the successful design and development of new products.

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 FDA 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 FDA, there remains a reasonable probability it cannot be successfully marketed for any number of reasons, not the least of which is being beaten to the market by a competitor with a better solution, or not having access to users because of limitations in marketing and distribution resources or exclusionary contracts of GPOs.

UTMD's current product development projects are in three areas of focus: 1) labor & delivery, 2) neonatal intensive care, and 3) specialized procedures for the assessment and treatment of cervical/uterine disease. Internal product development expenses are expected to be in the range of 1-2% of sales in 2008. In 2007, UTMD spent \$382 on internal product development activities, or 1.3% of sales. In 2006 and 2005, internal new product development expenses were \$316 (1.1% of sales) and \$320 (1.2% of sales), respectively.

## EMPLOYEES

At December 31, 2007, the Company had 193 employees, and an additional six contract employees. The contract employees represent UTMD's desire to provide handicapped persons additional work opportunities, hired through the Utah state-supported Work Activity Center. The average tenure of UTMD's employees is about ten years, which conveys an important benefit due to the level of training required to produce consistently high quality medical devices. The Company's continued success will depend to a large extent upon its ability to retain skilled employees. No assurances can be given that the Company will be able to retain or attract such employees in the future, although management is committed to providing an attractive environment in which reliable, creative and high achieving people wish to work.

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

## PATENTS, TRADEMARKS AND TECHNOLOGY LICENSES

The Company owns or exclusively licenses twenty-eight unexpired patents, and is the licensee of certain other technology. There can be no assurance, however, that patents will be issued with respect to any pending applications, that marketable products will result from the patents or that issued patents can be successfully defended in a patent infringement situation. The Company also owns a number of trademarks which have achieved brand recognition.

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

As a matter of policy, UTMD has acquired and will continue to acquire the use of technology from third parties that can be synergistically combined with UTMD proprietary product ideas. During 2007, ongoing royalties included in cost of goods sold were \$3. Other royalties have been previously paid as a lump sum, or are incorporated into the price of acquisitions, or into the cost of purchased components which practice certain patents of third parties. Also as a matter of policy, UTMD licenses its proprietary technology to others in circumstances where licensing does not directly compete with UTMD's own marketing initiatives. During 2007, the Company received \$450 in royalty income, the same as in 2006 and 2005. Based on the expiration dates of the patents for which the current royalty income is being received and the \$450 annual maximum, UTMD expects royalties of at least \$450, \$450 and \$310 in 2008, 2009 and 2010, respectively. UTMD's future financial performance also depends on the marketing ability of other companies that license UTMD's technology.

## GOVERNMENT REGULATION

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

All manufacturers of medical devices must register with the FDA and list all medical devices produced by them. The listing must be updated annually. 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.

All of UTMD's present products are unclassified, Class I or Class II devices. 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).



In 1994, UTMD received certification of its quality system under the ISO 9001/EN 46001 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 ISO 13485 standard for medical devices. UTMD’s Ireland facility was certified under the concomitant ISO 13488 standard. In July 2006, both facility ISO certifications were upgraded to the even more stringent ISO 13485:2003 standards, which continue to be maintained. 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 certification. The most recent audit was conducted in February 2007. UTMD has received formal product certifications allowing the use of the CE Mark (demonstrates proof of compliance with the European Community’s ISO standards) for essentially all of its products. The U.S. FDA QSR was developed in harmony with the ISO standards.

#### SOURCES AND AVAILABILITY OF RAW MATERIALS

Most of the components which the Company purchases from various vendors are readily available from a number of sources. Alternative sourcing of various components is continually underway. Vendors are qualified by Corporate Quality Assurance. The Company has a vendor quality monitoring program that includes routinely checking incoming material for conformance to specifications, as required per written procedures.

#### EXPORTS

Revenues from customers outside the U.S. in 2007 were \$8,576 (30% of total sales), compared to \$7,390 (26% of total sales) in 2006 and \$6,392 (23% of total sales) in 2005. Blood pressure monitoring products represented 58% of international sales in 2007, compared to 58% in 2006 and 66% in 2005. International Ob/Gyn and neonatal product sales were \$3,586 in 2007, compared to \$3,109 in 2006 and \$2,191 in 2005. For financial information by geographical area, please see notes 1, 4 and 10 to the Consolidated Financial Statements.

UTMD continues to regard the international marketplace as an 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. In 1996 UTMD completed construction of a manufacturing facility in Athlone, County Westmeath, Ireland. The facility offers a number of advantages: 1) from a marketing point of view, better response to European Union customers, including a better understanding of customized needs, less costly distribution and duty-free access to over 350 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.

#### BACKLOG

As a supplier of primarily disposable hospital products, the nature of UTMD’s business necessitates being very responsive to customer orders and delivering products quickly. Virtually all direct shipments to end users are accomplished within one week of receipt of customer purchase order. Backlog shippable in less than 90 days was \$823 as of January 1, 2008, \$906 as of January 1, 2007 and \$910 as of January 1, 2006.

#### SEASONAL ASPECTS

The Company's business is generally not affected by seasonal factors.

#### PRODUCT LIABILITY RISK MANAGEMENT

The risk of product liability lawsuits is a negative factor in the medical device business because products are frequently used in inherently life threatening situations to help physicians achieve a more positive outcome than what might otherwise be the case. In any lawsuit against a company where an individual plaintiff suffers a 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 29 year history.

UTMD 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 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 fifteen years, UTMD has been named as a defendant, along with each attending physician and hospital, in four product liability lawsuits. All four were related to operative vaginal deliveries where a UTMD VAD birthing cup or hand pump was used by the surgeon. The VADS products in all four cases did conform to specifications. UTMD was ultimately dismissed as a defendant in the lawsuits, and legal costs were not material to performance. During the same fifteen year period of time, in which more than 18 million UTMD finished devices were used, no other UTMD product was the subject of a product liability lawsuit. There have been no product liability lawsuits during the last four years.

#### 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

General risk factors that may impact the Company’s revenues include: the market acceptance of competitive products; administrative practices of group purchasing organizations; obsolescence caused by new technologies; the possible introduction by competitors of new products that claim to have many of the advantages of UTMD’s products at lower prices; the timing and market acceptance of UTMD’s own new product introductions; UTMD’s ability to efficiently and responsively manufacture its products, including the possible effects of lack of performance of suppliers; opportunities in gaining access to important global distribution channels; budgetary constraints; the timing of regulatory approvals for newly developed products; regulatory intervention in current operations; and third party reimbursement of health care costs of patients.

Negative factors that may adversely impact future performance include managed care reforms or hospital group buying agreements that may limit physicians’ ability to choose certain products or procedures, new products introduced by other companies that displace UTMD’s products, new product regulatory approval delays, changes in the Company’s relationships with distribution partners, and loss of key personnel.

The length of time and number of administrative steps required in adopting 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 preexisting 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 present unreasonable burdens.

Risk factors, in addition to the risks outlined in the previous paragraphs and elsewhere in this report that may impact the Company's assets and liabilities, as well as cash flows, include: risks inherent to companies manufacturing products used in healthcare, including claims resulting from the improper use of devices and other product liability claims; defense of the Company's intellectual property and infringement claims of others; productive use of assets in generating revenues; management of working capital, including inventory levels required to meet delivery commitments at a minimum cost; and timely collection of accounts receivable.

Additional risk factors that may affect non-operating income include: the continuing viability of the Company's technology license agreements; actual cash and investment balances; asset dispositions; and acquisition activities that may or may not require external funding.

#### ITEM 1B – UNRESOLVED STAFF COMMENTS

None

#### ITEM 2 - PROPERTIES

Office and Manufacturing Facilities.

The Company's current operations are located in a 100,000 square foot facility in Midvale, Utah, a suburb of Salt Lake City, a 20,000 square foot facility in Redmond, Oregon, and a 77,000 square foot facility in Athlone, County Westmeath, Ireland. UTMD owns its property and facilities in Utah and Ireland, with the exception of a long-term lease on one section of its Midvale parking lot. The Oregon facility is leased.

UTMD is a vertically-integrated manufacturing company. Capabilities include silicone and plastics-forming operations including injection molding, insert and over-molding, thermoforming and extrusion; sensor production; manual and automated assembly of mechanical, electrical and electronic components; parts printing; various testing modalities; advanced packaging in clean room conditions; and a machine shop for mold-making and fabrication of assembly tools and fixtures. Capabilities also include an R&D laboratory for both electronic and chemical processes, software development resources, communications and computer systems networked real time internationally, and administrative offices.

#### ITEM 3 - LEGAL PROCEEDINGS

The Company may be a party from time to time in litigation incidental to its business. Presently, there is no litigation for which the Company believes the outcome may be material to its financial results.

In 3Q 2007, the patent infringement lawsuit filed by Clinical Innovations Associates (CIA) in 2005 was resolved in favor of UTMD, including repayment of UTMD's court costs. CIA did not appeal the U.S. District Court's summary judgment confirming UTMD's non-infringement.

#### ITEM 4 - SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to a vote of security holders through the solicitation of proxies or otherwise during the fourth quarter of the fiscal year covered by this report.



## 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:

	2007		2006	
	High	Low	High	Low
1st Quarter	\$ 34.88	\$ 31.24	\$ 33.50	\$ 28.33
2nd Quarter	34.59	29.30	32.10	29.50
3rd Quarter	32.84	29.50	33.10	28.25
4th Quarter	31.99	29.27	34.96	31.51

## Stockholders.

The approximate number of beneficial stockholders of UTMD's common stock as of March 5, 2008 was 2,700.

## Dividends.

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

Record Date	Payable Date	Per Share Amount
December 16, 2005	January 5, 2006	\$ 0.17
March 16, 2006	April 5, 2006	0.18
June 16, 2006	July 5, 2006	0.19
September 15, 2006	October 4, 2006	0.20
December 14, 2006	January 4, 2007	0.21
March 15, 2007	April 4, 2007	0.22
June 15, 2007	July 5, 2007	0.22
September 14, 2007	October 3, 2007	0.22
December 14, 2007	January 3, 2008	0.225
2006 total paid		\$ 0.74
2007 total paid		\$ 0.87

## Issuer Purchases of Equity Securities.

The following table details purchases by UTMD of its own securities during fourth quarter 2007.

Period	Total Number of	Average Price Paid	Total Number of	Maximum Number (or Approximate Dollar
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	Shares purchased (1)	per Share	Shares Purchased as Part of Publicly Announced Plans or Programs (1)	Value) of Shares that May Yet be Purchased Under the Plans or Programs (1)
10/01/07 – 10/31/07	-	\$ -	-	see (1) below
11/01/07 – 11/30/07	8,730	30.09	8,730	
12/01/07 – 12/31/07	6,405	29.75	6,405	
Total	15,135	\$ 29.95	15,135	

(1) In fourth quarter 2007 UTMD repurchased an aggregate of 15,135 shares of its common stock at an average cost of \$29.95 per share pursuant to a continued open market repurchase program instituted in August 1992. Since 1993 through 2007, the Company has repurchased 6,393,176 shares at an average cost of \$11.85 per share including broker commissions and fees in open market transactions. In addition, the Company conducted tender offer transactions in which it purchased an additional 2,775,742 shares at an average cost of \$9.76 per share including fees and administrative costs. In total, UTMD has repurchased over 9.1 million of its shares at an average price of \$11.85 per share since 1993. To complete the picture relating to current shares outstanding, since 1993 the Company's employees and directors have exercised and purchased 1.6 million option shares at an average price of \$8.96 per share. All options were awarded at the market value of the stock on the date of the award.

The frequency of UTMD's open market share repurchases depends on the availability of sellers and the price of the stock. The board of directors has not established an expiration date or a maximum dollar or share limit for UTMD's continuing long term program of open market share repurchases.

The purpose of UTMD's share repurchases is to maximize the value of the Company for its continuing shareholders, and maximize its return on shareholder equity by employing excess cash generated from effectively managing its business. UTMD does not intend to repurchase shares that would result in terminating its NASDAQ Global Market listing.

#### 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, 2007, 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				
	2007	2006	2005	2004	2003
Net Sales	\$ 28,502	\$ 28,753	\$ 27,692	\$ 26,485	\$ 27,137
Net Income	7,905	8,168	7,547	10,220	20,761
Earnings Per Common Share (Diluted)	1.98	2.02	1.80	2.19	4.25
Total Assets	45,986	44,187	41,262	41,262	49,694
Working Capital	26,767	25,030	22,230	20,194	21,405
Long-term Debt	3,689	4,383	4,883	-	-
Cash Dividends Per Common Share	0.87	0.74	0.61	0.30	None

	Quarterly Data for 2007			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net Sales	\$ 7,118	\$ 7,211	\$ 7,097	\$ 7,076
Gross Profit	3,937			