UTAH MEDICAL PRODUCTS INC

Form 10-Q August 08, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10 Q

Quarterly Report Under Section 13 or 15(d) of The Securities Exchange Act of 1934

For quarter ended: June 30, 2016 Commission File No. 001-12575

#### **UTAH MEDICAL PRODUCTS, INC.**

(Exact name of Registrant as specified in its charter)

<u>UTAH</u> 87 0342734

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

7043 South 300 West

<u>Midvale, Utah 84047</u>

Address of principal executive offices

Registrant's telephone number: (801) 566 1200

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and; (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant 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

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 the number of shares outstanding of each of the issuer's classes of common stock as of August 5, 2016: 3,761,000.

# <u>UTAH MEDICAL PRODUCTS, INC.</u> <u>INDEX TO FORM 10</u> Q

PART I	- FINANCIAL INFORMATION	PAGE
Item 1.	Financial Statements	
	Consolidated Condensed Balance Sheets as of June 30, 2016 and December 31, 2015	1
	Consolidated Condensed Statements of Income for the three and six months ended June 30, 2016 and June 30, 2015	2
	Consolidated Condensed Statements of Cash Flows for the six months ended June 30, 2016 and June 30, 2015	3
	Notes to Consolidated Condensed Financial Statements	4
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	6
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	15
Item 4.	Controls and Procedures	15
PART I	I - OTHER INFORMATION	
Item 1.	Legal Proceedings	16
Item 1A.	Risk Factors	16
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	17
Item 6.	Exhibits	18
SIGNAT	TURES	18

#### PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

#### <u>UTAH MEDICAL PRODUCTS, INC. AND SUBSIDIARIES</u> <u>CONSOLIDATED CONDENSED BALANCE SHEETS AS OF</u> <u>JUNE 30, 2016 AND DECEMBER 31, 2015</u>

(in thousands)

ASSETS	(unaudited) JUNE 30, 2016	(audited) DECEMBE 31, 2015	ER
Current assets:			
Cash	\$ 29,395	\$ 23,278	
Investments, available-for-sale	45	55	
Accounts & other receivables, net	4,976	4,563	
Inventories	4,103	4,196	
Other current assets	705	781	
Total current assets	39,224	32,873	
Property and equipment, net	7,191	7,369	
Goodwill	13,954	14,725	
Other intangible assets	34,147	37,772	
Other intangible assets - accumulated amortization	(13,473		)
Other intangible assets, net	20,674	24,208	
Total assets	\$ 81,043	\$ 79,175	
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities: Accounts payable Accrued expenses Total current liabilities Deferred tax liability - intangible assets Deferred income taxes Total liabilities	\$ 1,056 4,128 5,184 3,784 1,004 9,972	\$ 649 3,417 4,066 4,452 1,009 9,527	
Stockholders' equity:			
Preferred stock - \$.01 par value; authorized - 5,000 shares; no shares issued or			
outstanding	-	-	
Common stock - \$.01 par value; authorized - 50,000 shares; issued - June 30, 2016, 3,760			
shares and December 31, 2015, 3,751 shares	38	38	
Accumulated other comprehensive income (loss)	(9,393		)
Additional paid-in capital	3,044	2,710	
Retained earnings	77,382	72,861	
Total stockholders' equity	71,071	69,648	
Total liabilities and stockholders' equity	\$ 81,043	\$ 79,175	

### UTAH MEDICAL PRODUCTS, INC. AND SUBSIDIARIES CONSOLIDATED CONDENSED STATEMENTS OF INCOME FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2016 AND JUNE 30, 2015

(in thousands, except per share amounts - unaudited)

	Three Months Ended Six Month June 30, June 30,		hs Ended	
Sales, net	2016 \$10,490	2015 \$10,397	2016 \$20,791	2015 \$20,630
Sules, net	Ψ10,170	Ψ10,557	Ψ20,771	Ψ20,030
Cost of goods sold	4,238	4,298	8,316	8,419
Gross profit	6,252	6,099	12,475	12,211
Operating expense				
Selling, general and administrative	1,818	1,992	3,619	4,071
Research & development	119	140	229	296
Total operating expenses	1,937	2,132	3,848	4,367
Operating income	4,315	3,967	8,627	7,844
Other income (expense)	64	(43)	165	(252)
Income before provision for income taxes	4,379	3,924	8,792	7,592
Provision for income taxes	1,120	1,006	2,316	2,006
Net income	\$3,259	\$2,918	\$6,476	\$5,586
Earnings per common share (basic)	\$0.87	\$0.78	\$1.72	\$1.49
Earnings per common share (diluted)	\$0.86	\$0.77	\$1.72	\$1.48
Shares outstanding - basic	3,758	3,755	3,756	3,753
Shares outstanding - diluted	3,776	3,773	3,773	3,775
Other comprehensive income (loss):				
Foreign currency translation net of taxes of \$0 in all periods	\$(3,016)	\$2,360	\$(3,426)	\$(175)
Unrealized gain (loss) on investments net of taxes of \$0, \$2, (\$4) and \$0	0	2	(6)	
Total comprehensive income	\$243	\$5,280	\$3,044	\$5,412
see notes to consolidated condensed financial statements				

# <u>UTAH MEDICAL PRODUCTS, INC. AND SUBSIDIARIES</u> <u>CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS</u> FOR THE SIX MONTHS ENDED JUNE 30, 2016 AND JUNE 30, 2015

(in thousands - unaudited)

	June 30,	hs Ended
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$6,476	\$5,586
Adjustments to reconcile net income to net cash provided by operating activities	• • • •	201
Depreciation	298	301
Amortization	1,179	
Provision for (recovery of) losses on accounts receivable	(7)	
(Gain) loss on disposal of assets	-	1
Deferred income taxes	(237)	
Stock-based compensation expense	42	44
Changes in operating assets and liabilities:		
Accounts receivable	(450)	
Accrued interest and other receivables	(34)	` /
Inventories	196	218
Prepaid expenses and other current assets	61	104
Accounts payable	427	5
Accrued expenses	(222)	(654)
Total adjustments	1,253	147
Net cash provided by operating activities	7,729	5,733
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital expenditures for:		
Property and equipment	(90)	(109)
Intangible assets	(9)	(7)
Net cash provided by (used in) investing activities	(99)	(116)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock - options	257	245
Common stock purchased and retired	-	(215)
Payment of taxes for exchange of stock options	-	(42)
Tax benefit attributable to exercise of stock options	35	107
Repayment of notes payable	-	(4,778)
Payment of dividends	(976)	(957)
Net cash provided by (used in) financing activities	(684)	(5,640)
Effect of exchange rate changes on cash	(829)	(82)
Net increase (decrease) in cash and cash equivalents	6,117	(105)
Cash at beginning of period	23,278	19,274
Cash at end of period	\$29,395	\$19,169
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION: Cash paid during the period for income taxes	\$2,422	\$2,781

Cash paid during the period for interest

0 65

see notes to consolidated condensed financial statements 3

# UTAH MEDICAL PRODUCTS, INC. NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS (unaudited)

(1) The unaudited financial statements have been prepared in accordance with the instructions to Form 10-Q and do not include all of the information and note disclosures required by accounting principles generally accepted in the United States. These statements should be read in conjunction with the financial statements and notes included in the Utah Medical Products, Inc. ("UTMD" or "the Company") annual report on Form 10 K for the year ended December 31, 2015. In the opinion of management, the accompanying financial statements include all adjustments (consisting only of normal recurring adjustments) necessary to summarize fairly the Company's financial position and results of operations. Currency amounts are in thousands except per-share amounts and where noted.

#### (2) Recent Accounting Standards.

In March 2016, new accounting guidance was issued to simplify several aspects of accounting for employee share-based payment (including stock option) transactions, including the accounting for income taxes, forfeitures and statutory tax withholding requirements, as well as classification in the statement of cash flows. Under the guidance, entities recognize all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement. This guidance becomes effective for fiscal years and interim periods beginning after December 15, 2016 and early adoption is permitted. UTMD believes that the 2017 adoption of this standard will have an insignificant impact on its consolidated financial statements.

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 UTMD is currently assessing the impact that this standard will have on its consolidated financial statements and expects to adopt it in 2018.

(3) Inventories at June 30, 2016 and December 31, 2015 consisted of the following:

June December 30, 31, 2016 2015

Finished goods \$1,245 \$ 1,715

Work in process1,006 961

Raw materials 1,852 1,520

Total \$4,103 \$ 4,196

(4) Stock-Based Compensation. At June 30, 2016, the Company has stock-based employee compensation plans which authorize the grant of stock options to eligible employees and directors. The Company accounts for stock compensation under FASB Accounting Standards Codification ("ASC") 718, Stock Compensation. This statement requires the Company to recognize compensation cost based on the grant date fair value of options granted to

employees and directors. In the quarters ended June 30, 2016 and 2015, the Company recognized \$21 and \$22, respectively, in stock based compensation cost. In the six months ended June 30, 2016 and 2015, the Company recognized \$42 and \$44, respectively, in stock based compensation cost.

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 were immaterial, no warranty reserve was made at December 31, 2015 or June 30, 2016.

(6) Fair Value Measurements. The Company follows ASC 820, Fair Value Measurement to determine fair value of its financial assets. The following table provides financial assets carried at fair value measured as of June 30, 2016:

Fair Value Measurements Using Quoted Prices in Active Markets for Significant Total Fair Identi@ther Significant AssetsObservable Unobservable Value (LevelInputs **Inputs** at (Level 3) <u>Description</u> 6/30/2016 1) (Level 2) Equities \$ 45 \$45 \$ 0 \$ 0

(7) Subsequent Events. UTMD has evaluated subsequent events through the date the financial statements were issued, and concluded there were no other events or transactions during this period that required recognition or disclosure in its financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

#### General

UTMD manufactures and markets a well-established range of specialty medical devices. The Company's Form 10-K Annual Report for the year ended December 31, 2015 provides a detailed description of products, technologies, markets, regulatory issues, business initiatives, resources and business risks, among other details, and should be read in conjunction with this report. Because of the relatively short span of time, results for any given three month period in comparison with a previous three month period may not be indicative of comparative results for the year as a whole. Currency amounts in the report are in thousands, except per-share amounts or where otherwise noted. Currencies in this report are denoted as \$ or USD = U.S. Dollars; AUD = Australia Dollars; £ or GBP = UK Pound Sterling; and EUR = Euros.

#### Analysis of Results of Operations

#### a) Overview

In the second calendar quarter (2Q) and first half (1H) of 2016, UTMD continued to achieve results which are on track to meet its previously announced goals for 2016.

Income statement results in 2Q and 1H 2016 compared to the same periods of 2015 follow:

	2Q	2Q			1H	
	2015	2015	change	1H 2016	2015	change
Net Sales	\$10,490	\$10,397	+0.9 %	\$20,791	\$20,630	+0.8 %
Gross Profit	6,252	6,099	+2.5 %	12,475	12,211	+2.2 %
Operating Income	4,315	3,967	+8.8 %	8,627	7,844	+10.0 %
Income Before Tax	4,379	3,924	+11.6 %	8,792	7,592	+15.8 %
Net Income	3,259	2,918	+11.7 %	6,476	5,586	+15.9 %
Earnings per Diluted Share	.863	.773	+11.6 %	1.716	1.480	+16.0 %

The change in value of the USD did not have as significant an impact on 2016 results as it did in 2015, although 2Q 2016 and 1H 2016 revenues would each have been about 1% higher using the same foreign currency exchange (FX) rates as in the prior year ("constant FX"). UTMD's FX rates for income statement purposes are transaction-weighted averages. The average rates from the applicable foreign currency to USD during 2Q and 1H 2016 compared to the same periods of 2015 follow:

	2Q	2Q				
	2016	2015	change	1H 2016	1H 2015	change
GBP	1.430	1.531	(6.6 %)	1.431	1.522	(6.0 %)
EUR	1.123	1.110	+1.1 %	1.115	1.114	-
AUD	0.746	0.778	(4.2 %)	0.736	0.781	(5.8 %)

UTMD's revenues invoiced in foreign currencies represented 29.7% of total consolidated USD sales in 2Q 2016 and 29.0% in 1H 2016.

UTMD's FX rates for balance sheet purposes are the applicable rates at the end of each reporting period. The FX rates from the applicable foreign currency to USD for assets and liabilities at the end of June 2016 and the end of December 2015 follow:

	2016	2015	
GBP	1.325	1.476	(10.2 %)
EUR	1.108	1.087	+1.9 %
AUD	0.744	0.729	+2.1 %

UTMD profit margins in 2Q 2016 and 1H 2016 compared to 2Q 2015 and 1H 2015 follow:

	2Q	2Q			1H	
	2016	2015	1H 2016	)	2015	
Gross Profit Margin (gross profit/ sales):	59.6 %	58.7 %	60.0	%	59.2	%
Operating Income Margin (operating income/ sales):	41.1 %	38.2 %	41.5	%	38.0	%
EBT Margin (profit before income taxes/ sales):	41.7 %	37.7 %	42.3	%	36.8	%
Net Income Margin (profit after taxes/ sales):	31.1 %	28.1 %	31.1	%	27.1	%

UTMD's 2Q and 1H 2016 Gross Profit Margins (GPMs) improved as a result of continued manufacturing cost improvements and better absorption of fixed costs with higher sales.

UTMD's Operating Income Margins (OIMs) in 2016 benefited from the suspension of the Medical Device Excise Tax in the U.S. and the favorable FX impact of converting UK and Australia operating expenses of UTMD's subsidiaries in those countries, in addition to the higher GPMs.

In addition to the higher OIMs, the EBT Margins (EBTMs) were further leveraged by a gain in remeasured value of EUR cash balances in the UK in 1H 2016 compared to a loss in 1H 2015, and the lack of any interest expense in 2016.

The Net Income Margins (NIMs) improved in proportion to the EBTM improvement, as income tax provision rates were comparable for the same periods in both years.

Earnings Per Share (EPS) for the most recent twelve months ending June 30, 2016 (TTM) were \$3.38.

Excluding the noncash effects of depreciation, amortization of intangible assets and stock option expense, TTM consolidated earnings before taxes, excluding the remeasured bank balance currency loss or gain and interest expense, were \$19,686.

Compared to the end of June a year earlier, UTMD's cash balances increased \$10.2 million. June 30, 2016 cash balances increased \$6.1 million from December 31, 2015. UTMD's current ratio as of June 30, 2016 was 7.6, compared to 5.6 a year earlier and 8.1 at year-end 2015. The balance of Intangible Assets declined \$7.6 million from a year earlier due to amortization and a 16% weaker GBP FX rate. Intangible assets were 43% of total assets on June 30, 2016 compared to 53% a year earlier, and 49% at year-end 2015.

#### b) Revenues

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 med/surg 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 U.S. 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. Except on rare occasions such as when customers do not meet prepayment 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.

Total 2Q 2016 consolidated sales were \$93 (+1%) higher than in 2Q 2015, and \$161 (+1%) higher in 1H 2016 than in 1H 2015. Constant FX consolidated sales in 2Q 2016 were another \$103 higher, and 1H 2016 constant FX sales were an additional \$235 higher. As a result, constant FX sales in 2Q 2016 and 1H 2016 were up 2%. Comparing 2Q 2016 to 2Q 2015, total U.S. domestic sales were 9% lower and outside the U.S. (OUS) sales were 11% higher. First half 2016 U.S. domestic sales were 5% lower than in 1H 2015 and OUS sales in 1H 2016 were 7% higher than in 1H 2015.

U.S. domestic sales, which are obviously not affected by FX rate volatility, were 9% (\$492) lower in 2Q 2016 than in 2Q 2015, and 5% (\$574) lower in 1H 2016 than in 1H 2015. The components of domestic sales include 1) "direct sales" of UTMD's medical devices to user facilities (and med/surg stocking distributors for hospitals), 2) "OEM sales" of components and other products manufactured by UTMD for other medical device and non-medical device companies, and 3) sales of Filshie Clip System devices by UTMD's UK subsidiary, Femcare-Nikomed Ltd, to CooperSurgical Inc. (CSI) for distribution in the U.S. under an exclusive distribution agreement between CSI and Femcare executed prior to UTMD's acquisition of Femcare in 2011.

The reason for the lower domestic sales was lower sales of Femcare's Filshie Clip System devices to CSI. Sales to CSI were \$457 (36%) lower in 2Q 2016 compared to 2Q 2015, and \$716 (26%) lower in 1H 2016 compared to 1H 2015. Femcare's Filshie Clip System sales to CSI were 17% of total domestic sales in 2Q 2016 compared to 24% in 2Q 2015, and 20% in 1H 2016 compared to 26% in 1H 2015. On the other hand, domestic OEM sales, representing 14% of total domestic sales in both 2Q and 1H 2016, were \$107 (+18%) higher in 2Q 2016 than in 2Q 2015, and were \$227 (+19%) higher in 1H 2016 than in 1H 2015. Domestic direct sales were \$141 (4%) lower in 2Q 2016 than in 2Q 2015, and were \$85 (1%) lower in 1H 2016 than in 1H 2015. Domestic sales were 46% of total consolidated sales in 2Q 2016 compared to 51% in 2Q 2015, and 48% in 1H 2016 compared to 52% in 1H 2015.

OUS sales in 2Q 2016 were \$584 (+11%) higher than in 2Q 2015, and 1H 2016 sales were \$735 (+7%) higher than in 1H 2015, despite the fact that both the GBP and AUD FX rates were 6% lower in 1H 2016. Transaction-weighted 2Q 2016 OUS sales invoiced in foreign currencies, which represented 29.7% of total consolidated sales when converted to USD, were reduced 3.2% as a result of the lower 2016 FX rates detailed in the table above. Transaction-weighted 1H 2016 OUS sales invoiced in foreign currencies, which represented 29.0% of total consolidated sales when converted to USD, were reduced 3.7% as a result of the lower 2016 FX rates detailed in the table above.

Ireland subsidiary shipments, including trade sales to international third parties as well as intercompany sales, were EUR 2,227 in 2Q 2016 compared to EUR 1,542 in 2Q 2015, and EUR 3,906 in 1H 2016 compared to 3,269 in 1H 2015. UTMD's Ireland subsidiary manufactures and distributes UTMD devices, including all single-patient use Sterishot Filshie Clip System kits, to international distributors, including UTMD subsidiaries in the UK and Australia for direct distribution to clinical end-user facilities within their local markets. The increases represent higher OUS sales for all products manufactured by Ireland, but also reflect period-to-period fluctuations from the fact that international distributors tend to order less frequently in larger quantities to minimize transportation, duties/customs and other administrative costs. UTMD Ireland 1H 2016 direct sales to Ireland domestic clinical facilities were 2%

#### higher in EUR.

Shipments by UTMD's UK subsidiary, Femcare-Nikomed Ltd ("Femcare UK"), were GBP 1,538 in 2Q 2016 compared to GBP 1,738 in 2Q 2015, and GBP 3,332 in 1H 2016 compared to GBP 3,867 in 1H 2015. Included in the Femcare UK sales were the sales of Filshie Clip System devices to CSI. Femcare UK sales to CSI are invoiced in fixed USD, so GBP sales declined less than in USD terms due to the lower GBP FX rate in 2016. In GBP terms, sales to CSI were GBP 261 (31%) lower in 2Q 2016 compared to 2Q 2015, and GBP 385 (21%) lower in 1H 2016 compared to 1H 2015. Femcare UK direct sales to UK domestic clinical facilities in 1H 2016 were 9% higher in GBP.

Sales by UTMD's Australia subsidiary ("Femcare Australia") to Australia end-user clinical facilities in 2Q 2016 were AUD 850 in 2Q 2016 compared to AUD 881 in 2Q 2015, and AUD 1,574 in 1H 2016 compared to AUD 1,636 in 1H 2015. UTMD believes that the 4% lower sales in 2016 are due to more difficult economic conditions for patients in Australia.

The following table provides USD denominated sales divided into general product categories for total sales, and the subset of OUS sales:

Global revenues by product category:

	2Q	2Q		
	2016	2015	1H 2016	1H 2015
Obstetrics	\$1,092	\$1,174	\$2,200	\$2,309
Gynecology/ Electrosurgery/ Urology	5,465	5,758	11,192	11,712
Neonatal	1,518	1,680	3,172	3,213
Blood Pressure Monitoring and Accessories*	2,415	1,785	4,227	3,396
Total:	\$10,490	\$10,397	\$20,791	\$20,630

OUS revenues by product category:

	2Q	2Q		
	2016	2015	1H 2016	1H 2015
Obstetrics	\$132	\$197	\$313	\$382
Gynecology/ Electrosurgery/ Urology	3,474	3,325	6,827	6,736
Neonatal	576	565	1,189	1,020
Blood Pressure Monitoring and Accessories*	1,522	1,033	2,382	1,838
Total:	\$5,704	\$5,120	\$10,711	\$9,976

<sup>\*</sup>includes molded components sold to OEM customers.

Large 2Q 2016 OUS distributor orders for BPM kits from China and South America offset the substantially lower sales of Filshie Clip System devices to CSI in the U.S. OUS sales of Filshie Clip System devices, however, helped increase Gynecology product sales in 2Q 2016.

Looking forward, sales in 3Q 2016 may be \$800 lower than in either 1Q or 2Q 2016. CSI's fixed order for 3Q 2016 is less than half that of 3Q 2015 (\$420 lower). The GBP FX rate in late 2Q 2016 due to BREXIT is about 14% lower than the GBP FX rate in 3Q 2015. The incremental 8% negative FX rate impact on GBP sales may lead to about \$100 in additional lower 3Q 2016 consolidated USD sales. The distributor orders in 2Q 2016 for BPM kits represented about a \$400 blip over normal. Because the Company focused on meeting the increased international distributor BPM demand in 2Q 2016, it did not timely meet demand from its direct domestic business as a result of production capacity limitations, particularly in Utah. Because the resulting \$200 ending backlog for fast turnaround direct domestic orders carried over to 3Q 2016, with improved production capacity planning, we expect higher 3Q 2016 domestic direct sales compared to 2Q 2016. OEM sales, which are also included in the BPM category, are expected to continue to grow in the second half of the year.

#### c) Gross Profit (GP)

GP results from subtracting the cost of manufacturing products (direct materials, direct labor and manufacturing overhead), or the purchase price of finished products which are resold, from revenues. At UTMD, manufacturing overhead costs fully absorb indirect costs including depreciation on manufacturing equipment and facilities, quality assurance, materials requirements planning and purchasing, manufacturing engineering, production supervision,

shipping, royalties paid to other entities and health plan benefits for both direct and indirect manufacturing personnel. GP in 2Q 2016 was \$6,252 (59.6% GPM) compared to \$6,099 (58.7% GPM) in 2Q 2015. In 1H 2016, GP was \$12,475 (60.0% GPM) compared to \$12,211 (59.2% GPM) in1H 2015. UTMD's Ireland manufacturing subsidiary, in particular, continued improving its productivity with 1H 2016 manufactured product shipments up 18% while direct labor and manufacturing overhead costs were only up 11%.

#### d) Operating Income (OI)

OI is the profit remaining after subtracting operating expenses from GP. Operating expenses (OE) include sales and marketing (S&M) expenses, product development (R&D) expenses and general and administrative (G&A) expenses. OI in 2Q 2016 was \$4,315 (41.1% OIM) compared to \$3,967 (38.2% OIM) in 2Q 2015, and \$8,627 (41.5% OIM) in 1H 2016 compared to \$7,844 (38.0% OIM) in 1H 2015.

Consolidated USD-denominated 2Q 2016 OE were \$1,937 (18.5% of consolidated revenues) compared to \$2,132 in 2Q 2015 (20.5% of consolidated revenues). Consolidated OE were \$3,848 in 1H 2016 (18.5% of revenues) compared to \$4,367 in 1H 2015 (21.2% of revenues). In contrast to Revenues, in the case of OE, the lower FX rates were accretive to financial results. OE of UTMD's foreign subsidiaries in the aggregate in 2Q 2016 and 1H 2016 would have been \$60 and \$113 higher, respectively, with constant FX.

Consolidated S&M expenses in 2Q 2016 were \$457 (4.4% of sales) compared to \$552 (5.3% of sales) in 2Q 2015. Consolidated S&M expenses in 1H 2016 were \$862 (4.1% of sales) compared to \$1,125 (5.5% of sales) in 1H 2015. The U.S. Medical Device Excise Tax (MDET), initially imposed as a component of the Patient Protection and Affordable Care Act (Obamacare), levied in 2015 as 2.3% of domestic sales of medical devices, was suspended by Congress for the years 2016 and 2017. The MDET included in S&M expenses in 2Q and 1H 2015 was \$70 and \$138, respectively.

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 have agreements in the U.S. and UK under which it agrees to provide hospital members inservice and clinical training as required and reasonably requested.

UTMD promises prospective customers that it will provide, at no charge in reasonable quantities, copies of instruction materials developed for the use of its products. UTMD provides customer support from offices in the U.S., UK, Ireland and Australia by telephone, and employed representatives on a geographically dispersed basis, 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 inservice and training expenses are routinely expensed as they occur. All of these services are allocated from S&M overhead costs included in OE. Historically, marginal consulting costs have been immaterial to financial results.

R&D expenses were \$119 (1.1% of sales) in 2Q 2016 compared to \$140 (1.4% of sales) in 2Q 2015, and \$229 (1.1% of sales) in 1H 2016 compared to \$296 (1.4% of sales) in 1H 2015. R&D expenses were lower after the completion of internal development of a new L&D device, the CVX-Ripe<sup>TM</sup>, designed to provide a mechanical means of ripening the cervix at term gestation that will reduce the time needed to allow induction of labor, and to reduce the total time of active labor needed to achieve a successful vaginal delivery. The CVX-Ripe catheter was commercially introduced in fourth quarter 2015 after gaining U.S. FDA concurrence with UTMD's 510-K submission.

Consolidated G&A expenses in 2Q 2016 were \$1,361 (13.0% of sales) compared to \$1,439 (13.8% of sales) in 2Q 2015, and \$2,757 (13.3% of sales) in 1H 2016 compared to \$2,946 (14.3% of sales) in 1H 2015. Consolidated G&A expenses included non-cash expense from the amortization of identifiable intangible assets (IIA) resulting from the Femcare acquisition of \$572 (5.4% of consolidated revenues) in 2Q 2016 and \$1,148 (5.5% of consolidated revenues) in 1H 2016, compared to \$618 (5.9% of consolidated revenues) in 2Q 2015 and \$1,230 (6.0% of consolidated revenues) in 1H 2015. The period to period differences in IIA amortization expense were predominantly FX-related since the IIA amortization expense was GBP 802 in 1H 2016 compared to GBP 808 in 1H 2015.

In addition to IIA amortization, G&A expenses also include the cost of outside financial auditors and corporate governance activities related to the implementation of SEC rules resulting from the Sarbanes-Oxley and Dodd-Frank Acts, as well as estimated stock-based compensation cost, a noncash expense. Option compensation expense included in G&A expenses was \$21 in 2Q 2016 compared to \$22 in 2Q 2015, and \$42 in 1H 2016 compared to \$44 in 1H 2015.

Summary comparison of (USD) consolidated operating expenses:

	2Q	2Q		
	2016	2015	1H 2016	1H 2015
S&M Expense	\$457	\$552	\$862	\$1,125
R&D Expense	119	140	229	296
G&A Expense	1,361	1,439	2,757	2,946
Total Operating Expenses:	\$1,937	\$2,132	\$3,848	\$4,367

#### e) Non-operating expense (NOE)/ Non-operating income (NOI)

NOE/NOI includes the combination of 1) expenses from loan interest and bank fees; 2) expenses or income from losses or gains from remeasuring the value of EUR cash bank balances in the UK and GBP cash balances in Ireland in USD terms; and 3) income from rent of underutilized property, investment income and royalties received from licensing the Company's technology. Net NOI in 2Q 2016 was \$64 compared to net \$43 NOE in 2Q 2015. In other words, total net NOE was \$107 lower in 2Q 2016 compared to 2Q 2015. Net NOI in 1H 2016 was \$165 compared to \$252 NOE in 1H 2015. In other words, total NOE was \$417 lower in 1H 2016 compared to 1H 2015. Two key components follow: Interest expense in 2Q and 1H 2016 was zero. The loans obtained to help finance the acquisition of Femcare in 1Q 2011 were fully repaid in 1Q 2015 at an expense of \$65 including accrued interest and bank fees. The total gain on remeasured foreign currency balances in 2Q 2016 was \$38 compared to a loss of \$61 in 2Q 2015, contributing a \$99 lower net NOE. In 1H 2016, the total gain on remeasured foreign currency balances was \$111 compared to a loss of \$229 in 1H 2015, contributing a \$340 lower net NOE.

#### f) Income Before Tax (EBT)

Income before taxes (EBT) results from subtracting net NOE from, or adding net NOI to, as applicable, OI. Consolidated 2Q 2016 EBT was \$4,379 (41.7% EBTM) compared to \$3,924 (37.7% EBTM) in 2Q 2015. Consolidated 1H 2016 EBT was \$8,792 (42.3% EBTM) compared to \$7,592 (36.8% EBTM) in 1H 2015. The \$1,200 higher 1H 2016 EBT was due to \$783 higher OI coupled with \$65 lower interest expense and a remeasured foreign currency bank balance gain of \$111 in 1H 2016 compared to a loss of \$229 in 1H 2015.

The EBT of Utah Medical Products Ltd. (Ireland) was EUR 1,600 in 1H 2016 compared to EUR 1,272 in 1H 2015. The EBT of Femcare Group Ltd (Femcare-Nikomed, Ltd., UK and Femcare Australia) was GBP 1,808 in 1H 2016 compared to GBP 1,709 in 1H 2015.

Excluding the noncash effects of depreciation, amortization of intangible assets and stock option expense, 2Q 2016 consolidated EBT excluding the remeasured bank balance currency gain or loss and interest expense ("adjusted consolidated EBITDA") were \$5,098 compared to \$4,793 in 2Q 2015. The \$305 higher 2Q 2016 adjusted consolidated EBITDA resulted primarily from the combination of \$454 higher EBT, \$99 lower loss on remeasured foreign currency and \$47 lower IIA amortization expense. Adjusted consolidated EBITDA in 1H 2016 were \$10,200 compared to \$9,491 in 1H 2015. The \$709 higher 1H 2016 EBITDA resulted from the combination of \$1,200 higher EBT, \$340 lower loss on remeasured foreign currency balances and \$82 lower IIA amortization expense.

#### g) Net Income (NI)

NI is EBT minus a provision for income taxes. UTMD's consolidated NI in 2Q 2016 of \$3,259 was 12% (\$341) higher than the NI of \$2,918 in 2Q 2015. The consolidated income tax provision rates in both periods were 25.6%. NI in 1H 2016 of \$6,476 was 16% (\$890) higher than the NI of \$5,586 in 1H 2015. The consolidated income tax provision rates were 26.3% in 1H 2016 and 26.4% in 1H 2015. UTMD's income tax provision is trued-up each quarter for cumulative year-to-date estimated income tax liability. UTMD's NIM was 31.1% in both 2Q 2016 and 1H 2016. The NIMs for 2Q 2015 and 1H 2015 were 28.1% and 27.1% respectively.

#### h) Earnings Per Share

Earnings per share (EPS) are consolidated 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 stock market value). EPS in 2Q 2016 were \$.863 and in 1H 2016 were \$1.716. Consistent with the percentage increases in EBT and NI, 2Q 2016 EPS increased 12% (9.0 cents) compared to 2Q 2015, and 1H 2016 EPS increased 16% (23.6 cents) compared to 1H 2015. Looking forward, the 2H 2016 is unlikely to match 1H 2016 EPS performance because of the projected lower CSI demand for Filshie Clip System devices, the weaker GBP after BREXIT and the normalization of high 1H international distributor orders for BPM devices. Despite the unexpected CSI and BREXIT negative impacts on 2H 2016, management believes that it will be able to meet or exceed its financial projection for the 2016 year that was provided stockholders at the beginning of the year in the 2015 SEC Form 10-K.

The weighted average number of diluted shares outstanding used to calculate 2Q 2016 EPS were 3,776,304 compared to 3,773,431 in 2Q 2015. The number of shares added as a dilution factor in 2Q 2016 was 17,906 compared to 18,521 in 2Q 2015. Increases and decreases in UTMD's stock price impact EPS as a result of the dilution calculation for unexercised options with exercise prices below the average stock market value during each period. Diluted shares outstanding used to calculate 1H 2016 EPS declined to 3,773,453 from 3,774,964 in 1H 2015. The number of shares added as a dilution factor in 1H 2016 was 17,899 compared to 22,359 in 1H 2015.

Actual outstanding shares at the end of 2Q 2016 were 3,759,670 which included 1H 2016 employee and outside director option exercises of 8,985 shares. The number of shares used for calculating earnings per share was higher than ending shares because of a time-weighted calculation of average outstanding shares plus dilution from unexercised employee and director options. The total number of outstanding unexercised employee and outside director options at June 30, 2016 was 51,861 shares at an average exercise price of \$39.59/ share, including shares awarded but not vested. This compares to 67,719 unexercised option shares outstanding at June 30, 2015 at an average exercise price of \$38.75/ share. No option shares have been awarded to date in 2016.

UTMD has not repurchased any of its shares in the open market to date in 2016. During 1H 2015, UTMD repurchased 4,000 of its shares in the open market at an average cost, including commissions and fees, of \$53.87 per share (\$215 total). UTMD retains its program for repurchasing shares when they seem undervalued.

#### i) Return on Equity (ROE)

ROE is the portion of NI retained by UTMD to internally finance its growth, divided by the average accumulated stockholders' equity for the applicable time period. Annualized ROE in 1H 2016 (before payment of dividends to stockholders) was 18% compared to 17% in 1H 2015. The higher ROE in 1H 2016 was due to the increase in NI. Targeting a high ROE over 20% remains a key financial objective for UTMD management. ROE can be increased by effectively deploying capital to increase NP, or by reducing stockholders' equity by paying cash dividends to stockholders or by repurchasing shares.

#### Liquidity and Capital Resources

#### i) Cash flows

Net cash provided by operating activities, including adjustments for depreciation and amortization and other non-cash expenses along with changes in working capital, totaled \$7,729 in 1H 2016 compared to \$5,733 in 1H 2015. The most significant change in the two periods was the \$890 increase in net income. Other changes include a \$431 benefit to cash from higher accrued expenses, a \$423 benefit from a larger increase in accounts payable, and a \$378 benefit from a smaller increase in accounts receivable in 1H 2016 compared to 1H 2015.

The Company's elimination of its bank loan principal balance in 1Q 2015 was the most significant use of cash in either period. UTMD repaid the remaining \$4,778 principal on its notes in February 2015. UTMD made cash dividend payments to stockholders of \$976 in 1H 2016 compared to \$957 in 1H 2015.

Capital expenditures for property and equipment (PP&E) were \$90 in 1H 2016 compared to \$109 in 1H 2015. Depreciation of PP&E was \$298 in 1H 2016 compared to \$301 in 1H 2015. Capital expenditures required to enhance manufacturing and communications capabilities during 2016 are expected to be higher than in 2015 as a whole.

In 1H 2016, UTMD received \$257 and issued 8,485 shares of its stock upon the exercise of employee and outside director stock options, net of 500 shares retired upon optionees trading those shares in payment of the stock option exercise price. Option exercises in 1H 2016 were at an average price of \$32.06 per share. In comparison, in 1H 2015 the Company received \$203 from issuing 12,825 shares of stock on the exercise of employee and director stock

options, net of 5,794 shares retired upon optionees trading those shares in payment of the stock option exercise price and related taxes. Option exercises in 1H 2015 were at an average price of \$28.36 per share.

UTMD repurchased and retired 4,000 of its own shares during 1H 2015 at a cost of \$215. No shares were repurchased in 1H 2016.

Management believes that current cash balances, income from operations and effective management of working capital will provide the liquidity needed to finance its internal growth plans. In addition, the Company may use cash for marketing or product manufacturing rights to broaden the Company's product offerings; to acquire its own facility in the UK; for continued share repurchases when the price of the stock is undervalued; for cash dividends to stockholders; and if available for a reasonable price, an acquisition that might strategically fit UTMD's business and be accretive to financial performance.

#### k) Assets and Liabilities

June 30, 2016 total consolidated assets of \$81,043 increased \$1,868 from December 31, 2015. The increase was due to a \$6,117 increase in cash from net income and the fact that the stockholder dividend declared in November 2015 was paid in December prior to the end of the year instead of early in 2016, offset by a \$4,305 decrease in net intangible assets. The intangible asset decrease was primarily comprised of amortization of \$1,179 and a decline of \$3,712 due to the weaker GBP. Other balance sheet changes in assets since the end of 2015 include a \$380 increase in net trade receivables (trade A/R) due to higher 1H 2016 sales. Despite the increase, A/R remain very current at an average of 35 days based on the most recent three months' sales activity. A/R over ninety days from invoice date represent 2% of total A/R, and are fully reserved. Consolidated inventories declined \$94, resulting in 4.0 average inventory turns based on 1H 2016 cost of goods sold. Consolidated net property, plant and equipment decreased a net amount of \$178 at June 30, 2016 from the end of 2015 due to changing FX rates noted above, \$90 in new asset purchases and \$298 in depreciation.

Working capital (current assets minus current liabilities) was \$34,040 at June 30, 2016, compared to \$28,807 at December 31, 2015. The increase was due to the increase in cash, which is included in current assets. Seventy-five percent of UTMD's June 30, 2016 current assets of \$39 million was cash. Current liabilities increased \$1,118, including a \$711 increase in accrued liabilities (A/L) and a \$407 increase in accounts payable (A/P). The higher current liability balances on June 30, 2016 were due to a higher income tax accrual due to higher 1H 2016 EBT, the early payment of a stockholder dividend prior to the end of 2015 compared to the quarterly dividend which was included in A/L on June 30, 2016 and seasonally low A/P at the end of the year on December 31, 2015. Typical current liabilities balances at UTMD's current level of operations are about \$5 million plus any applicable accrued stockholder dividends. UTMD management believes that its working capital remains sufficient to meet normal operating needs, new capital investments, projected cash dividend payments to stockholders and opportunistic repurchases of its shares.

June 30, 2016 intangible assets (goodwill plus other intangible assets) declined \$4,305 from the end of 2015. The decrease was due to the lower FX rate for GBP Femcare intangibles as of June 30, 2016 compared to year-end 2015 plus \$1,179 1H 2016 amortization of identifiable intangible Femcare assets. At June 30, 2016, net intangible assets including goodwill were 43% of total consolidated assets, compared to 49% at year-end 2015 and 53% at June 30, 2015.

UTMD eliminated all of its remaining bank debt in February 2015. The deferred tax liability balance for Femcare identifiable intangible assets (\$9,084 on the date of the acquisition), was \$3,784 at June 30, 2016 compared to \$4,452 at December 31, 2015 and \$5,370 at June 30, 2015. Reduction of the deferred tax liability occurs as the book/tax difference of amortization is eliminated over the remaining useful life of the Femcare identifiable intangible assets. UTMD's total debt ratio (total liabilities/total assets) as of June 30, 2016 and as of December 31, 2015 was 12%. UTMD's total debt ratio as of June 30, 2015 was 15%.

#### 1) Management's Outlook.

As outlined in its December 31, 2015 SEC 10-K report, UTMD's plan for 2016 is 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.

Management believes it is on track after 1Q 2016 to accomplish its previously stated objectives for the year 2016.

#### m) Accounting Policy Changes.

None.

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 3. Quantitative and Qualitative Disclosures about Market Risk

UTMD has manufacturing and trading operations, including related assets, in the U.S. denominated in the U.S. Dollar (USD), in Ireland denominated in the Euro (EUR), in England denominated in the British Pound (GBP) and in Australia denominated in the Australia Dollar (AUD). The currencies are subject to exchange rate fluctuations that are beyond the control of UTMD. The exchange rates were .9028, .9203 and .8966 EUR per USD as of June 30, 2016, December 31, 2015 and June 30, 2015, respectively. Exchange rates were .7545, .6774 and .6359 GBP per USD as of June 30, 2016, December 31, 2015 and June 30, 2015, respectively. Exchange rates were 1.3433, 1.3710 and 1.2986 AUD per USD on June 30, 2016, December 31, 2015 and June 30, 2015, respectively. UTMD manages its foreign currency risk without separate hedging transactions by conducting as much business in local currencies as is practicable, and by optimizing global account structures through liquidity management accounts.

#### Item 4. Controls and Procedures

The Company's management, under the supervision and with the participation of the Chief Executive Officer and the Principal Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) as of June 30, 2016. Based on this evaluation, the Chief Executive Officer and Principal Financial Officer concluded that, as of June 30, 2016, the Company's disclosure controls and procedures were effective.

There were no changes in the Company's internal controls over financial reporting that occurred during the quarter ended June 30, 2016, that have materially affected, or are reasonably likely to materially affect, the Company's internal controls over financial reporting.

#### PART II - OTHER INFORMATION

#### Item 1. Legal Proceedings

The Company may be a party from time to time in litigation incidental to its business. Presently, there is no litigation.

#### Item 1A. Risk Factors

In addition to the other information set forth in this report, investors should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in UTMD's Annual Report on Form 10-K for the year ended December 31, 2015, which could materially affect its business, financial condition or future results. The risks described in the Annual Report on Form 10-K are not the only risks facing the Company. Additional risks and uncertainties not currently known to UTMD or currently deemed to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

<u>Legislative healthcare reform in the United States</u>, 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 led 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 the 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.

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

The Company's experience in 2001-2005, when the FDA 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, from new product development and routine quality control management activities, and a tremendous psychological and emotional toll on employees.

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

New premarketing submission 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 their 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. In any other industry, 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.

# 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 being purchased in fixed USD.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

UTMD did not purchase any of its own securities during 2Q 2016.

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#### Item 6. Exhibits

Exhibit #	SEC Reference #	Title of Document
1	31	Certification of CEO pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
2	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
3	32	Certification of CEO pursuant to 18 U.S.C. §1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
4	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
5	101 ins	XBRL Instance
6	101.sch	XBRL Schema
7	101.cal	XBRL Calculation
8	101.def	XBRL Definition
9	101.lab	XBRL Label
10	101.pre	XBRL Presentation

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchanges Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

#### <u>UTAH MEDICAL PRODUCTS, INC.</u> REGISTRANT

Date: 8/8/16 By: /s/ Kevin L. Cornwell

Kevin L. Cornwell

CEO

Date: 8/8/16 By: /s/ Paul O. Richins

Paul O. Richins

Principal Financial Officer