UTAH MEDICAL PRODUCTS INC

Form 10-Q

November 04, 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: September 30, 2016 Commission File No. <u>001-12575</u>

#### 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 November 3, 2016: 3,761,300.

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#### PART I - FINANCIAL INFORMATION

Item 1. Financial Statements
UTAH MEDICAL PRODUCTS, INC. AND SUBSIDIARIES
CONSOLIDATED CONDENSED BALANCE SHEETS AS OF
SEPTEMBER 30, 2016 AND DECEMBER 31, 2015
(in thousands)

	(unaudited) SEPTEMBER	(audited) DECEMBER	
ASSETS	30, 2016	31, 2015	
Current assets:	20, 2010	01, 2010	
Cash	\$ 31,556	\$ 23,278	
Investments, available-for-sale	51	55	
Accounts & other receivables, net	5,029	4,563	
Inventories	4,529	4,196	
Other current assets	738	781	
Total current assets	41,903	32,873	
Property and equipment, net	7,301	7,369	
Goodwill	13,831	14,725	
Other intangible assets	33,572	37,772	
Other intangible assets - accumulated amortization	(13,791	(13,564)	
Other intangible assets, net	19,781	24,208	
Total assets	\$ 82,816	\$ 79,175	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$ 943	\$ 649	
Accrued expenses	4,585	3,417	
Total current liabilities	5,528	4,066	
Deferred tax liability - intangible assets	3,612	4,452	
Deferred income taxes	1,004	1,009	
Total liabilities	10,144	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 - September 30,			
2016, 3,761 shares and December 31, 2015, 3,751 shares	38	38	
Accumulated other comprehensive income (loss)	(9,820	(5,961)	
Additional paid-in capital	3,114	2,710	
Retained earnings	79,340	72,861	
Total stockholders' equity	72,672	69,648	
Total liabilities and stockholders' equity	\$ 82,816	\$ 79,175	

# UTAH MEDICAL PRODUCTS, INC. AND SUBSIDIARIES CONSOLIDATED CONDENSED STATEMENTS OF INCOME FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2016 AND SEPTEMBER 30, 2015 (in thousands, except per share amounts - unaudited)

	THREE MONTI ENDED SEPTE	HS )	NINE MONTHS ENDED		
	30,		SEPTEMBER 30,		
Calar mad	2016	2015	2016	2015	
Sales, net	\$9,655	\$9,945	\$30,446	\$30,575	
Cost of goods sold	3,880	3,866	12,196	12,285	
Gross profit	5,775	6,079	18,250	18,290	
Operating expense					
Selling, general and administrative	1,701	1,969	5,320	6,039	
Research & development	135	110	364	406	
Total operating expense	1,836	2,079	5,684	6,445	
Operating income	3,939	4,000	12,566	11,845	
Other income (expense)	41	127	206	(126 )	
Income before provision for income taxes	3,980	4,127	12,772	11,719	
•					
Provision for income taxes	1,045	1,080	3,361	3,086	
Net income	\$2,935	\$3,047	\$9,411	\$8,633	
Earnings per common share (basic)	\$0.78	\$0.81	\$2.50	\$2.30	
Earnings per common share (diluted)	\$0.78	\$0.81	\$2.49	\$2.29	
Shares outstanding - basic	3,761	3,753	3,757	3,753	
Shares outstanding - diluted	3,778	3,768	3,775	3,772	
Other comprehensive income (loss):	¢(420 )	φ(1. <b>5</b> 2.6)		φ(1. <b>7</b> 11.)	
Foreign currency translation net of taxes of \$0 in all periods				\$(1,711)	
Unrealized gain (loss) on investments net of taxes of \$2, (\$2), (\$2) and (\$2) Total comprehensive income	3	(4 ) \$1,507	(3 ) \$5,552	(3 ) \$6,919	
Total comprehensive income	\$2,308	\$1,307	\$3,332	\$0,919	
see notes to consolidated condensed financial statements 2					

#### UTAH MEDICAL PRODUCTS, INC. AND SUBSIDIARIES CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2016 AND SEPTEMBER 30, 2015 (in thousands - unaudited)

	SEPTEM	BER 30,
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	\$9,411	\$8,633
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	452	461
Amortization	1,714	1,898
Provision for (recovery of) losses on accounts receivable	-	(9)
(Gain) loss on disposal of assets	5	1
Deferred income taxes	(351)	(359)
Stock-based compensation expense	62	66
Changes in operating assets and liabilities:		
Accounts receivable - trade	(510)	(791)
Accrued interest and other receivables	(35)	(83)
Inventories	(222)	151
Prepaid expenses and other current assets	36	76
Accounts payable	316	31
Accrued expenses	228	(180)
Total adjustments	1,695	1,262
Net cash provided by operating activities	11,106	9,895
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital expenditures for:		
Property and equipment	(237)	(151)
Intangible assets	(9)	
Net cash (used in) provided by investing activities	(246)	
The cash (asea in) provided by investing activities	(2.0)	(200 )
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock - options	306	298
Common stock purchased and retired	-	(683)
Payment of taxes for exchange of stock options	-	(42)
Tax benefit attributable to exercise of stock options	37	110
Repayments of notes payable	-	(4,778)
Payment of dividends	(1,954)	
Net cash (used in) provided by financing activities	(1,611)	(7,009)
Effect of exchange rate changes on cash	(971)	(332)
Net increase in cash and cash equivalents	8,278	2,348
Cash at beginning of period	23,278	19,274
Cash at end of period	\$31,556	\$21,622

#### SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:

Cash paid during the period for income taxes
Cash paid during the period for interest

\$3,342 \$4,030
- 65

see notes to consolidated condensed financial statements

## <u>UTAH MEDICAL PRODUCTS, INC.</u> <u>NOTES TO CONSOLIDATED CONDENSED FINANCIAL STATEMENTS</u> (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, 2017 and early adoption is permitted for 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 September 30, 2016 and December 31, 2015 consisted of the following:

	September	December
	30,	31,
	2016	2015
Finished goods	\$ 1 244	\$ 1,715
Work in proce		961
Raw materials	2,130	1,520
Total	<u>\$</u> 4,529	<u>\$</u> 4,196

(4) Stock-Based Compensation. At September 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 September 30, 2016 and 2015, the Company recognized \$20 and \$22,

respectively, in stock based compensation cost. In the nine months ended September 30, 2016 and 2015, the Company recognized \$62 and \$66, respectively, in stock based compensation cost.

(5) 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 September 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 September 30, 2016:

Fair Value Measurements Using Quoted Prices in Active Markets Total for Significant Fair Identi@ther Significant AssetsObservable Unobservable Value (Level Inputs Inputs (Level 2) (Level 3) Description 9/30/2016 1) Equities \$ 51 \$51 \$ 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 third calendar quarter (3Q) and first nine months (9M) of 2016, UTMD continued to achieve financial results consistent with its beginning of year projections for 2016.

Income statement results in 3Q and 9M 2016 compared to the same periods of 2015 follow:

	3Q	3Q				
	2016	2015	change	9M 2016	9M 2015	change
Net Sales	\$9,655	\$9,945	(2.9 %)	\$30,446	\$30,575	(0.4 %)
Gross Profit (GP)	5,775	6,079	(5.0 %)	18,250	18,290	(0.2 %)
Operating Income (OI)	3,939	4,000	(1.5 %)	12,566	11,845	+6.1 %
Income Before Tax (EBT)	3,980	4,127	(3.6 %)	12,772	11,719	+9.0 %
Net Income (NI)	2,935	3,047	(3.7 %)	9,411	8,633	+9.0 %
Earnings per Diluted Share (EPS)	.777	.809	(3.9 %)	2.493	2.289	+8.9 %

Except for the expected continued negative effect of a stronger USD on sales invoiced in foreign currencies, the lower consolidated 3Q income statement numbers resulted from just one component of UTMD's revenues: Femcare sales of the Filshie Clip System to UTMD's U.S. distributor, Cooper Surgical Inc. (CSI). For the year-to-date, consolidated sales were almost the same as in 2015 despite the fact that 9M 2016 Femcare sales to CSI were \$1,114 lower and the effect of a stronger USD reduced foreign currency sales another \$405, together representing a 5% reduction in consolidated sales. But the Company to date in 2016 has achieved essentially the same revenues and gross profits, while increasing profit margins in all income statement categories shown in the table above yielding operating income 6% higher, and net income and earnings per share 9% higher.

In constant currency terms, 3Q 2016 consolidated sales were only 1% lower, and 9M 2016 sales were 1% higher than in the same periods in 2015, where "constant currency" means using the same foreign currency exchange (FX) rates as in the previous year when converting sales invoiced in foreign currencies to USD. Though less of a negative impact than in the prior year, the stronger USD in 2016 has continued to reduce UTMD total consolidated sales by about 1.3%. In 3Q 2016, the major negative FX impact, reducing UTMD consolidated sales \$197 by itself, was a much weaker GBP following the June Brexit referendum.

Profit margins in 3Q 2016 and 9M 2016 compared to 3Q 2015 and 9M	30	30	9M		9M	
	- (	2015	2016		2015	
2015 were as follows:	2016		_010			
Gross Profit Margin (gross profit/ sales):	59.8 %	61.1 %	59.9	%	59.8	%
Operating Income Margin (operating profit/ sales):	40.8 %	40.2 %	41.3	%	38.7	%
EBT Margin (profit before income taxes/ sales):	41.2 %	41.5 %	42.0	%	38.3	%

Net Income Margin (profit after taxes/ sales):

30.4 % 30.6 % 30.9 % 28.2

%

UTMD's FX rates for income statement purposes are transaction-weighted averages. The average rates from the applicable foreign currency to USD during 3Q 2016 and 9M 2016 compared to the same periods in 2015 follow:

	3Q	3Q				
	2016	2015	change	9M 2016	9M 2015	change
GBP	1.314	1.546	(15.0 %)	1.393	1.530	(9.0 %)
EUR	1.118	1.121	(0.3 %)	1.116	1.117	(0.1 %)
AUD	0.759	0.723	+5.0 %	0.744	0.760	(2.2 %)
Sales	Weighte	ed				
Avera	ige:		(5.9 %)			(4.4 %)

3Q 2016 and 9M 2016 sales invoiced in foreign currencies would have been \$173 and \$405 higher, respectively, using 2015 FX rates (constant currency). UTMD estimates that the negative impact of 2016 FX rates compared to 2015 FX rates will be about \$600 lower sales, causing a 1.5% decline in 2016 total consolidated USD sales compared to 2015 sales.

Domestic sales in 3Q 2016 were \$61 (1%) lower compared to 3Q 2015, as Femcare sales to CSI, which were \$398 (50%) lower, are included in the domestic sales category. Outside the U.S. (OUS) sales in 3Q were \$229 (5%) lower, primarily from the lower GBP FX rate. GBP constant currency sales were \$197 higher. For 9M 2016 compared to 9M 2015, domestic sales were \$635 lower (4%) which includes \$1,114 (31%) lower sales to CSI, and outside the U.S. (OUS) sales were \$506 (+3%) higher despite a negative FX impact of \$405. Excluding CSI sales, 9M 2016 domestic sales were \$479 (+4%) higher.

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 September 2016 and the end of December 2015 follow:

	Sept	Dec	
	30,	31,	
	2016	2015	change
GBP	1.301	1.476	(11.9 %)
EUR	1.124	1.087	+3.4 %
AUD	0.767	0.729	+5.1 %

The lower 3Q 2016 Gross Profit Margin (GPM) was the combined result of product mix and lower total sales. For 9M 2016 compared to 9M 2015, there was no significant consolidated GP difference as UTMD was able to maintain its GPM as planned on approximately the same level of sales.

UTMD's Operating Income Margin (OIM) in 2016 has benefited from the favorable FX impact of converting operating expenses in the UK to the USD, particularly the noncash amortization expense of identifiable intangible assets (IIA) resulting from the acquisition of Femcare in 2011. Suspension of the Medical Device Excise Tax in the U.S. also helped the OIM.

The difference in Net Income Margins (NIMs) were primarily the result of differences in non-operating income, more specifically, gains or losses in remeasured USD value of foreign currency bank balances, as the consolidated income tax provision rates were about the same in both years. Non-operating income in 3Q 2016 was \$41 compared to \$127 in 3Q 2015. Non-operating income in 9M 2016 was \$206 compared to a non-operating loss of \$126 in 9M 2015.

EPS for the most recent twelve months (TTM) were \$3.35. Please recall that this includes a 4Q 2015 one-time \$.09 EPS gain from the adjustment in UTMD's deferred tax balance from a reduction in future corporate income tax rates

enacted in the UK in late 2015.

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 \$19,499.

September 30, 2016 cash balances increased \$8.3 million from December 31, 2015. UTMD's current ratio as of September 30, 2016 was 7.6 compared to 8.1 at year-end 2015. Intangible assets were 41% of total assets on September 30, 2016 compared to 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 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 3Q 2016 consolidated sales were \$290 (3%) lower than in 3Q 2015, and \$129 (0%) lower in 9M 2016 than in 9M 2015. Constant FX consolidated sales in 3Q 2016 were only \$117 (1%) lower than in 3Q 2015, and 9M 2016 constant FX sales were \$275 (+1%) higher than in 9M 2015.

U.S. domestic sales (obviously in constant USD currency) were \$61 (1%) lower in 3Q 2016 than in 3Q 2015, and \$635 (4%) lower in 9M 2016 than in 9M 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 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 3Q and 9M 2016 domestic sales was lower sales of Femcare's Filshie Clip System devices to CSI, which were \$398 (50%) lower in 3Q 2016 compared to 3Q 2015 and \$1,114 (31%) lower in 9M 2016 compared to 9M 2015. Filshie Clip System sales to CSI were 8% of total domestic sales in 3Q 2016 compared to 16% in 3Q 2015, and 16% in 9M 2016 compared to 23% in 9M 2015. Excluding sales to CSI, U.S. domestic sales were \$338

(+8%) higher in 3Q 2016 than in 3Q 2015, and \$479 (+4%) higher in 9M 2016 than in 9M 2015. Direct sales of UTMD devices to medical facilities were \$201 (+6%) higher in 3Q 2016 compared to 3Q 2015, and \$116 (+1%) higher in 9M 2016 compared to 9M 2015. U.S. domestic OEM sales were \$136 (+21%) higher in 3Q 2016 compared to 3Q 2015, and \$363 (+19%) higher in 9M 2016 compared to 9M 2015.

OUS sales in 3Q 2016 were \$229 (5%) lower than in 3Q 2015, and in 9M 2016 were \$506 (+3%) higher than in 9M 2015. The lower 3Q sales were due primarily to the negative \$197 impact on sales from the lower FX rate of the GBP. Constant currency OUS sales were \$56 (1%) lower in 3Q 2016 than in 3Q 2015, but \$910 (+6%) higher in 9M 2016 compared to 9M 2015. UK subsidiary USD-denominated trade sales were 24% of total OUS sales in 3Q 2016 compared to 28% in 3Q 2015, and 24% in 9M 2016 compared to 30% in 9M 2015, reflecting the weaker GBP. Australia subsidiary sales were 12% of total OUS sales in 3Q 2016 compared to 13% in 3Q 2015, and 11% in 9M 2016 compared to 13% in 9M 2015. FX rates for the AUD were weaker in 9M 2016. Ireland subsidiary trade sales were 37% of total OUS sales in 3Q 2016 compared to 30% in 3Q 2015, and 36% in 9M 2016 compared to 28% in 9M 2015. The transfer of Sterishot to Ireland increased Ireland's share of OUS sales, and the Euro has effectively retained its value relative to the USD in 2016. Consolidated OUS sales were 49% of total consolidated sales in 3Q 2016 compared to 50% in 3Q 2015, and 51% in 9M 2016 compared to 49% in 9M 2015.

Ireland subsidiary shipments, including trade sales to international third parties as well as intercompany sales, were EUR 1,928 in 3Q 2016 compared to EUR 1,487 in 3Q 2015, and EUR 5,834 in 9M 2016 compared to 4,757 in 9M 2015. UTMD's Ireland subsidiary manufactures and distributes UTMD devices, including 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 9M 2016 direct EUR sales to Ireland domestic clinical facilities were the same as in 9M 2015.

Shipments by UTMD's UK subsidiary, Femcare-Nikomed Ltd ("Femcare UK"), were GBP 1,218 in 3Q 2016 compared to GBP 1,447 in 3Q 2015, and GBP 4,549 in 9M 2016 compared to GBP 5,314 in 9M 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 219 (42%) lower in 3Q 2016 compared to 3Q 2015, and GBP 562 (24%) lower in 9M 2016 compared to 9M 2015. Femcare UK direct sales to UK domestic clinical facilities in 9M 2016 were 8% higher in GBP.

Sales by UTMD's Australia subsidiary ("Femcare Australia") to Australia end-user clinical facilities in 3Q 2016 were AUD 778 in 3Q 2016 compared to AUD 898 in 3Q 2015, and AUD 2,353 in 9M 2016 compared to AUD 2,534 in 9M 2015.

OUS trade sales exported from the U.S. invoiced in USD were 26% of total OUS sales in 3Q 2016 compared to 29% 3Q 2015, and were 29% in both 9M 2016 and 9M 2015. Total U.S. OUS sales including intercompany sales were \$1,488 in 3Q 2016 compared to \$1,579 in 3Q 2015, and \$5,141 in 9M 2016 compared to \$4,847 in 9M 2015.

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

Global GAAP revenues by product category:

	3Q	3Q		
	2016	2015	9M 2016	9M 2015
Obstetrics	\$1,229	\$1,147	\$3,428	\$3,455
Gynecology/ Electrosurgery/ Urology	4,978	5,558	16,170	17,269
Neonatal	1,402	1,584	4,575	4,798
Blood Pressure Monitoring and Accessories*	2,046	1,656	6,273	5,053
Total:	\$9,655	\$9,945	\$30,446	\$30,575

International revenues by product category:

2016 2015 9M 2016 9M 2013
Obstetrics \$185 \$147 \$499 \$528
Gynecology/Electrosurgery/ Urology 3,197 3,564 10,024 10,301
Neonatal 323 471 1,512 1,492
Blood Pressure Monitoring and Accessories* 1,044 796 3,426 2,634
Total: \$4,749 \$4,978 \$15,461 \$14,955

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

#### 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 was \$304 (5%) lower in 3Q 2016 compared to 3Q 2015, and \$41 (almost 0%) lower in 9M 2016 compared to 9M 2015. The lower GP in 3Q 2016 was due to 3% lower sales, some start-up molding costs and less favorable product mix than in 3Q 2015. UTMD's consolidated GPM, GP divided by sales, was close to UTMD's target GPM of 60% in all periods. The GPM was 59.8% in 3Q 2016 compared to 61.1% in 3Q 2015. The GPM in 9M 2016 was 59.9% compared to 59.8% in 9M 2015. For year-to-date 2016, consolidated total manufacturing costs and consolidated total sales were about the same as in the prior year, consistent with UTMD's 2015 SEC Form 10-K projection.

#### 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 was \$61 (2%) lower in 3Q 2016, but \$721 (+6%) higher for 9M 2016, compared to the same periods in 2015. The lower OI in 3Q 2016 was due to the lower GP in 3Q 2016. OI for 9M 2016 was substantially higher because 9M 2016 GP were about the same as in the prior year, but Operating Expenses (OE) were substantially lower, as shown in the OE summary table below.

The lower OE were due in part to FX rates, where a stronger USD was favorable in this instance, as the change in FX rates lowered foreign subsidiaries' OE when converting OE in their native currencies to USD. Constant currency OE were \$130 higher in 3Q 2016, and \$241 higher in 9M 2016. In the 3Q 2016, virtually all of the favorable FX impact on OE resulted from a weaker GBP. The largest contribution came from the amortization of Femcare IIA, a noncash expense included in UK subsidiary G&A expense, which was £399 in 3Q 2016 and £404 in 3Q 2015, only £5 less. In USD, the expense was \$524 in 3Q 2016 and \$625 in 3Q 2015, \$101 less due to the change in the GBP FX rate. Similarly, the IIA amortization expense in 9M 2016 was only £11 less than in 9M 2015, but \$183 less in 9M 2016 than in 9M 2015 due to the weaker GBP.

In addition to the favorable FX impact on OE, UTMD did not have the burden of a Medical Device Tax (MDET) in 2016 that was initially levied as part of Obamacare as an excise tax on U.S. sales of medical devices. The MDET was suspended by Congress for the years 2016 and 2017. The MDET included in 2015 S&M expense was \$74 in 3Q 2015 and \$212 in 9M 2015. The remaining differences in OE were due to continued consolidation of global operating resources on a functional basis.

As a percentage of sales, total consolidated OE were 19.0% in 3Q 2016 compared to 20.9% in 3Q 2015, and 18.7% in 9M 2016 compared to 21.1% in 9M 2015. Excluding the amortization of Femcare IIA, consolidated operating expenses in 3Q 2016 were 13.6% of sales compared to 14.6% in 3Q 2015. Excluding the amortization of Femcare IIA, consolidated operating expenses in 9M 2016 were 13.2% of sales compared to 15.0% in 9M 2015. One of the key metrics that separates UTMD's performance from other companies is that UTMD tightly manages its operating expenses, primarily by having a flat organizational structure which is fully integrated across all subsidiaries on a cross-functional real-time basis. This is allowed by the experience and long term tenure of UTMD's key employees.

UTMD's 3Q and 9M 2016 OIM, OI divided by sales, was 40.8% and 41.3% respectively, compared to 40.2% and 38.7% in the same periods of 2015. The higher 9M 2016 OIM was the result of a slightly higher GPM on about the same consolidated sales, combined with substantially lower OE than in 9M 2015.

Consolidated S&M expenses in 3Q 2016 were \$408 (4.2% of sales) compared to \$533 (5.4% of sales) in 3Q 2015. Consolidated S&M expenses in 9M 2016 were \$1,270 (4.2% of sales) compared to \$1,658 (5.4% of sales) in 9M 2015. The MDET was included in S&M expenses in 3Q and 9M 2015. S&M expenses include all customer support costs including training. In general, training is not required for UTMD's devices 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 devices. 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 Operating Expenses. Historically, marginal consulting costs have been immaterial to financial results.

R&D expenses were \$135 (1.4% of sales) in 3Q 2016 compared to \$110 (1.1% of sales) in 3Q 2015, and \$364 (1.2% of sales) in 9M 2016 compared to \$406 (1.3% of sales) in 9M 2015. R&D expenses in 9M 2016 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.

Consolidated G&A expenses in 3Q 2016 were \$1,293 (13.4% of sales) compared to \$1,436 (14.4% of sales) in 3Q 2015, and \$4,050 (13.3% of sales) in 9M 2016 compared to \$4,381 (14.3% of sales) in 9M 2015. Consolidated G&A expenses included non-cash expense from the amortization of IIA resulting from the Femcare acquisition of \$524 (5.4% of consolidated revenues) in 3Q 2016 compared to \$625 (6.3% of consolidated revenues) in 3Q 2015, and \$1,671 (5.5% of consolidated revenues) in 9M 2016 compared to \$1,854 (6.1% of consolidated revenues) in 9M 2015. The period to period differences in IIA amortization expense were predominantly FX-related. In GBP terms, the IIA amortization expense was GBP 399 in 3Q 2016 compared to GBP 404 in 3Q 2015, and GBP 1,201 in 9M 2016 compared to GBP 1,211 in 9M 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 \$20 in 3Q 2016 compared to \$22 in 3Q 2015, and \$62 in 9M 2016 compared to \$66 in 9M 2015.

#### Operating expense summary:

	3Q	3Q		
	2016	2015	9M 2016	9M 2015
S&M Expense	\$408	\$533	\$1,270	\$1,658
R&D Expense	135	110	364	406
G&A Expense	1,293	1,436	4,050	4,382
Total Operating Expenses:	\$1,836	\$2,079	\$5,684	\$6,446

#### 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 3Q 2016 was \$41 compared to net NOI of \$127 in 3Q 2015. Net NOI in 9M 2016 was \$206 compared to \$126 NOE in 9M 2015. In other words, total NOE was \$332 lower in 9M 2016 compared to 9M 2015. There were two primary components of NOE/NOI that explained the difference in 2016 compared to 2015: 1) Interest expense in 3Q and 9M 2016 was zero. Interest expense in 1Q 2015, the final quarter that UTMD had a debt balance, which was related to the acquisition of Femcare in 1Q 2011, was \$65. 2) The gain on remeasured foreign currency balances in 3Q 2016 was \$18 compared to a gain of \$91 in 3Q 2015. In 9M 2016, the gain on remeasured foreign currency balances was \$129 compared to a loss of \$139 in 9M 2015.

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

EBT results from subtracting net NOE from, or adding net NOI to, as applicable, OI. Consolidated 3Q 2016 EBT was \$3,980 (41.2% EBTM) compared to \$4,127 (41.5% EBTM) in 3Q 2015. Consolidated 9M 2016 EBT was \$12,772 (42.0% EBTM) compared to \$11,719 (38.3% EBTM) in 9M 2015. The \$1,053 higher 9M 2016 EBT was due to \$721 higher OI achieved as a result of much lower OE on about the same GP, coupled with \$332 lower NOE (\$332 higher NOI) from the lack of any interest expense and a substantial remeasured foreign currency bank balance gain in 9M

2016 instead of a loss in 9M 2015.

The EBT of Utah Medical Products Ltd. (Ireland) was EUR 2,455 in 9M 2016 compared to EUR 1,843 in 9M 2015. The EBT of Femcare Group Ltd (Femcare-Nikomed, Ltd., UK and Femcare Australia) was GBP 2,374 in 9M 2016 compared to GBP 2,456 in 9M 2015.

Excluding the noncash effects of depreciation, amortization of intangible assets and stock option expense, 3Q 2016 consolidated EBT excluding the remeasured bank balance currency gain or loss and interest expense ("adjusted consolidated EBITDA") were \$4,670 compared to \$4,857 in 3Q 2015. Adjusted consolidated EBITDA in 9M 2016 were \$14,871 compared to \$14,348 in 9M 2015.

#### g) Net Income (NI)

NI is EBT minus a provision for income taxes. UTMD's consolidated NI in 3Q 2016 of \$2,935 was 4% (\$112) lower than the NI of \$3,047 in 3Q 2015, which is consistent with EBT. The consolidated income tax provision rates in both periods were about 26.2%. NI in 9M 2016 of \$9,411 was 9% (\$778) higher than the NI of \$8,633 in 9M 2015. The consolidated income tax provision rates were 26.3% in both periods. UTMD's income tax provision is trued-up each quarter for cumulative year-to-date estimated income tax liability. UTMD's NIM was 30.4% in 3Q 2016 and 30.9% in 9M 2016. The NIMs for 3Q 2015 and 9M 2015 were 30.6% and 28.2% respectively.

#### h) Earnings Per Share (EPS)

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 3Q 2016 were \$0.777 compared to \$0.809 in 3Q 2015, and \$2.493 in 9M 2016 compared to \$2.289 in 9M 2015. EPS in both periods of 2016 compared to the same periods in 2015 were consistent with the changes in NI because diluted shares used to calculate EPS were only slightly higher in 3Q and 9M 2016 compared to 3Q and 9M 2015.

EPS for the most recent twelve months were \$3.35. The TTM EPS include a 4Q 2015 one-time \$.09 EPS gain from the adjustment in UTMD's deferred tax balance from a reduction in future corporate income tax rates enacted in the UK in late 2015.

The weighted average number of diluted shares outstanding used to calculate 3Q 2016 EPS were 3,777,537 compared to 3,768,148 in 3Q 2015. The number of shares added as a dilution factor in 3Q 2016 was 16,837 compared to 14,649 in 3Q 2015. Diluted shares outstanding used to calculate 9M 2016 EPS were 3,775,166 compared to 3,771,926 in 9M 2015. The number of shares added as a dilution factor in 9M 2016 was 17,885 compared to 19,020 in 9M 2015. Increases and decreases in UTMD's stock market 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.

Actual outstanding shares at the end of 3Q 2016 was 3,761,247 which included 3Q 2016 employee option exercises of 1,938 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 September 30, 2016 was 49,398 shares at an average exercise price of \$39.55/ share, including shares awarded but not vested. This compares to 64,220 option shares outstanding at September 30, 2015 at an average exercise price of \$38.60/ share. No option shares were awarded in 2015 or to date in 2016.

UTMD has not repurchased any of its own shares in the open market to date in 2016. During 9M 2015 UTMD repurchased 13,000 of its shares in the open market at an average cost, including commission and fees, of \$52.54 per share (\$683 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 9M 2016 (before payment of dividends to stockholders) was 18% compared to 17% in 9M 2015. The higher ROE in 9M 2016 was due to the increase in NI. Targeting a high average ROE of 20% remains a key financial objective for UTMD management. ROE can be increased by effectively deploying capital to increase NI, 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 \$11,106 in 9M 2016 compared to \$9,895 in 9M 2015. The most significant change in the two periods was the \$779 increase in NI. Other changes include a \$408 benefit to cash from higher accrued expenses, a \$374 use of cash from a 9M 2016 increase in inventories compared to a 9M 2015 decrease, a \$284 benefit from a larger increase in accounts payable, and a \$281 benefit from a smaller increase in accounts receivable in 9M 2016 compared to 9M 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 \$1,954 in 9M 2016 compared to \$1,914 in 9M 2015.

Capital expenditures for property and equipment (PP&E) were \$237 in 9M 2016 compared to \$151 in 9M 2015. Depreciation of PP&E was \$452 in 9M 2016 compared to \$461 in 9M 2015. Capital expenditures required to enhance manufacturing and communications capabilities during 2016 are expected to be higher than in 2015 as a whole.

In 9M 2016, UTMD received \$306 and issued 10,062 shares of its stock upon the exercise of employee and outside director stock options, net of 861 shares retired upon optionees trading those shares in payment of the stock option exercise price. Option exercises in 9M 2016 were at an average price of \$33.12 per share. In comparison, in 9M 2015 the Company received \$298 from issuing 14,256 shares of stock upon 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 9M 2015 were at an average price of \$29.02 per share.

UTMD repurchased and retired 13,000 of its own shares during 9M 2015 at a cost of \$683. No shares were repurchased in 9M 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 and in Canada; 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

UTMD's September 30, 2016 balance sheet compared with its December 31, 2015 balance sheet demonstrates continued strengthening. UTMD's cash balances continue to grow rapidly. UTMD's financial performance has allowed continuing to pay quarterly cash dividends to shareholders at a current annual rate of \$3.9 million while making capital expenditures required to maintain property and equipment in good working order. In 4Q 2016, UTMD plans to complete purchases of a 38,600 SF facility in Romsey, England and a 4,700 SF facility in Mississauga, Canada. The UK facility will allow for business expansion in the UK, and the Canada facility will allow UTMD's own employees to distribute its devices directly to Canadian medical facilities beginning in 2017, rather than through third party distributors. This is similar to the initiative undertaken by UTMD in Australia near the end of 2013, with similar expected results. After completion of the new facility purchases, UTMD will own all of its facilities in Utah, Ireland, England, Australia and Canada, which will enhance profitability going forward. UTMD's cash position also provides the ability to opportunistically repurchase its shares and acquire other products and/or companies that would be accretive to future performance.

September 30, 2016 total consolidated assets of \$82,816 increased \$3,641 from December 31, 2015. The increase was due to a \$8,278 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 \$4,427 decrease in net other intangible assets. The intangible asset decrease was primarily comprised of amortization of \$1,714 and a decline of \$3,487 due to the weaker GBP. Other balance sheet changes in assets since the end of 2015 include a \$434 increase in net trade receivables (trade A/R). Despite the increase, A/R remain current at an average of 38 days based on the most recent three months' sales activity. A/R over ninety days from invoice date represent less than 1% of total A/R, and are fully reserved. Consolidated inventories increased \$332, resulting in 3.6 average inventory turns based on 9M 2016 cost of goods sold. Consolidated net property, plant and equipment decreased a net amount of \$69 at September 30, 2016 from the end of 2015 due to changing FX rates noted above, \$237 in new asset purchases and \$452 in depreciation.

Working capital (current assets minus current liabilities) was \$36,375 at September 30, 2016, compared to \$28,807 at December 31, 2015, an increase of \$7,568. The increase was due to the increase in cash, which is included in current assets. Seventy-five percent of UTMD's September 30, 2016 current assets of \$42 million was cash. Current liabilities increased \$1,462, including a \$1,168 increase in accrued liabilities (A/L) and a \$294 increase in accounts payable (A/P). The higher current liability balances on September 30, 2016 were due to a higher income tax accrual due to higher 9M 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 September 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.

September 30, 2016 intangible assets (goodwill plus other intangible assets) declined \$5,320 from the end of 2015. The decrease was due to the lower FX rate for GBP Femcare intangibles as of September 30, 2016 compared to year-end 2015 plus \$1,671 9M 2016 amortization of identifiable intangible Femcare assets. At September 30, 2016, net intangible assets including goodwill were 41% of total consolidated assets, compared to 49% at year-end 2015 and 50% at September 30, 2015.

UTMD eliminated all of its remaining bank debt in February 2015. The deferred tax liability balance for Femcare IIA (\$9,084 on the date of the acquisition), was \$3,612 at September 30, 2016 compared to \$4,452 at December 31, 2015 and \$5,039 at September 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 IIA. UTMD's total debt ratio (total liabilities/total assets) as of September 30, 2016 and as of December 31, 2015 was 12%. UTMD's total debt ratio as of September 30, 2015 was 15%.

1) Management's Outlook.

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

- 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;
- 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
- be vigilant for accretive acquisition opportunities which may be increasingly brought about by difficult burdens on small, innovative companies.

Management believes it remains on track after 9M 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 .8897, .9203 and .8958 EUR per USD as of September 30, 2016, December 31, 2015 and September 30, 2015, respectively. Exchange rates were .7685, .6774 and .6616 GBP per USD as of September 30, 2016, December 31, 2015 and September 30, 2015, respectively. Exchange rates were 1.3044, 1.3710 and 1.4241 AUD per USD on September 30, 2016, December 31, 2015 and September 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 September 30, 2016. Based on this evaluation, the Chief Executive Officer and Principal Financial Officer concluded that, as of September 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 September 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.

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

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 3Q 2016.

#### 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: 11/4/16 By: /s/ Kevin L. Cornwell

Kevin L. Cornwell

CEO

Date: 11/4/16 By: /s/ Paul O. Richins

Paul O. Richins

Principal Financial Officer