UTAH MEDICAL PRODUCTS INC Form 10-Q August 09, 2018

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, 2018 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 August 7, 2018: 3,733,000.

#### <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, 2018 and December 31, 2017	1
	Consolidated Condensed Statements of Income for the three and six months ended June $30, 2018$ and June $30, 2017$	2
	Consolidated Condensed Statements of Cash Flows for six months ended June 30, 2018 and June 30, 2017	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	14
Item 4.	Controls and Procedures	14
PART II	– OTHER INFORMATION	
Item 1.	Legal Proceedings	15
Item 1A.	Risk Factors	15
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	16
Item 6.	Exhibits	17
SIGNAT	TURES	18

#### PART I - FINANCIAL INFORMATION

Item 1. Financial Statements UTAH MEDICAL PRODUCTS, INC. AND SUBSIDIARIES CONSOLIDATED CONDENSED BALANCE SHEETS AS OF JUNE 30, 2018 AND DECEMBER 31, 2017 (in thousands)

	(unaudited)	(audited) DECEMBE	R
	JUNE 30,	31,	
<u>ASSETS</u>	2018	2017	
Current assets:			
Cash	\$ 45,873	\$ 39,875	
Investments, available-for-sale	0	80	
Accounts & other receivables, net	4,532	3,623	
Inventories	5,228	5,244	
Other current assets	363	366	
Total current assets	55,996	49,188	
Property and equipment, net	10,769	11,621	
Goodwill	13,925	14,092	
Other intangible assets	34,018	34,805	
Other intangible assets - accumulated amortization	(17,664	(16,961	)
Other intangible assets, net	16,354	17,844	
Total assets	\$ 97,044	\$ 92,745	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$ 979	\$ 934	
Accrued expenses	4,269	4,346	
Total current liabilities	5,248	5,280	
Deferred tax liability - intangible assets	2,827	3,102	
Other long term liabilities	5,168	5,785	
Deferred income taxes	439	456	
Total liabilities	13,682	14,623	
Stockholders' equity:			
Preferred stock - \$.01 par value; authorized - 5,000shares; no shares issued or outstanding	_	_	
Common stock - \$.01 par value; authorized - 50,000 shares; issued - June 30, 2018, 3,732			
shares and December 31, 2017, 3,721 shares	37	37	
Accumulated other comprehensive income (loss)	(9,876		)
Additional paid-in capital	1,197	809	,
Retained earnings	92,004	85,617	
Total stockholders' equity	83,362	78,122	
Total liabilities and stockholders' equity	\$ 97,044	\$ 92,745	

see notes to consolidated condensed financial statements

UTAH MEDICAL PRODUCTS, INC. AND SUBSIDIARIES CONSOLIDATED CONDENSED STATEMENTS OF INCOME FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2018 AND JUNE 30, 2017 (in thousands, except per share amounts - unaudited)

	Three Months		Six Mont	hs
	Ended		Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Sales, net	\$10,965	\$10,829	\$21,852	\$21,088
Cost of goods sold	3,981	3,936	7,946	7,660
Gross profit	6,984	6,893	13,906	13,428
Operating expense				
Selling, general and administrative	1,811	1,740	3,649	3,432
Research & development	117	119	230	238
Total operating expenses	1,928	1,859	3,879	3,670
Operating income	5,056	5,034	10,027	9,758
Other income (expense)	500	23	538	49
Income before provision for income taxes	5,556	5,057	10,565	9,807
Provision for income taxes	1,248	1,187	2,165	2,402
Net income	\$4,308	\$3,870	\$8,400	\$7,405
Earnings per common share (basic)	\$1.15	\$1.04	\$2.25	\$1.99
Earnings per common share (diluted)	\$1.15	\$1.04	\$2.24	\$1.98
Shares outstanding - basic	3,731	3,716	3,728	3,715
Shares outstanding - diluted	3,754	3,732	3,751	3,732
Other comprehensive income (loss): Foreign currency translation net of taxes of \$0 in all periods Total comprehensive income	\$(2,836) \$1,472	\$1,680 \$5,550	\$(1,535) \$6,865	\$2,336 \$9,741

see notes to consolidated condensed financial statements

# UTAH MEDICAL PRODUCTS, INC. AND SUBSIDIARIES CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS FOR THE SIX MONTHS ENDED JUNE 30, 2018 AND JUNE 30, 2017 (in thousands - unaudited)

	Six Moi June 30		ns Ende	d
	2018		2017	
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net income	\$8,400		\$7,405	,
Adjustments to reconcile net income to net cash provided by operating act	tivities			
Depreciation	395		330	
Amortization	1,128		1,031	
Gain on Investments	(32	)	0	
Provision for (recovery of) losses on accounts receivable	1		(1	)
(Gain) loss on disposal of assets	(418	)	-	
Deferred income taxes	(225	)	(182	)
Stock-based compensation expense	42		69	
Tax benefit attributable to exercise of stock options	39		21	
Changes in operating assets and liabilities:				
Accounts receivable	(992	)	(1,15)	7)
Accrued interest and other receivables	0		(5	)
Inventories	(45	)	(100	)
Prepaid expenses and other current assets	(3	)	60	
Accounts payable	51		68	
Accrued expenses	(594	)	203	
Total adjustments	(653	)	337	
Net cash provided by operating activities	7,747		7,742	!
CASH FLOWS FROM INVESTING ACTIVITIES:				
Capital expenditures for:				
Property and equipment	(201	)	(114	)
Intangible assets	-		_	
Purchases of investments	-		_	
Proceeds from sale of investments	74			
Proceeds from sale of property and equipment	862		_	
Net cash provided by (used in) investing activities	735		(114	)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from issuance of common stock - options	347		168	
Payment of dividends	(2,011	)		)
Net cash provided by (used in) financing activities	(1,664		-	)
Effect of exchange rate changes on cash		)	629	
Net increase (decrease) in cash and cash equivalents	5,998		7,441	
Cash at beginning of period	39,875		26,29	
Cash at end of period	\$45,873	3	\$33,73	,7
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:				
Cash paid during the period for income taxes	\$3,016		\$2,676	)
Cash paid during the period for interest	0		0	

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, 2017. 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 May 2014, new accounting guidance (ASU 2014-09) 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. UTMD adopted this new standard on January 1, 2018, using a modified retrospective approach. In accordance with ASU 2014-09, UTMD's revenue recognition is based on standard terms & conditions of sale for like customers in addition to contracts and the performance obligations identified in them. With very insignificant and limited exceptions, the Company's performance obligation is met when it ships a physical product to a customer. The basis on which UTMD recognizes revenue was updated on January 1, 2018, but it did not result in a change to the process and timing of revenue recognition, because the previous revenue recognition method complies with ASU 2014-09. Therefore, the adoption of ASU 2014-09 did not have an impact on UTMD's financial statements. In accordance with this adoption disaggregated revenue is presented in Note 7.

In February 2016, new accounting guidance was issued which requires recording most leases on the balance sheet. The new lease standard requires disclosure of key information about lease arrangements and aligns many of the underlying principles of this new model with those in the new revenue recognition standard noted above. This guidance becomes effective for annual reporting periods beginning after December 15, 2018, with early adoption permitted. UTMD has yet to assess the impact that this standard will have on its consolidated financial statements when it is adopted. The only significant lease the Company anticipates it will have at that time is for the parking lot at its Utah facility.

(3) Inventories at June 30, 2018 and December 31, 2017 consisted of the following:

June	December
30,	31,
2018	2017
\$1,307	\$ 1,313
ess1,342	1,270
2,579	2,661
\$5,228	\$ 5,244
	30, 2018 \$1,307 ess1,342 2,579

(4) Stock-Based Compensation. At June 30, 2018, 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, Compensation - 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, 2018 and 2017, the Company recognized \$11 and \$33, respectively, in stock based compensation cost. In the six months ended June 30, 2018 and 2017, the Company recognized \$42 and \$69, 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, 2017 or June 30, 2018.

(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, 2018:

Fair Value Measurements Using Quoted **Prices** in Active Markets for Significant Total Fair IdentiOther Significant Value Asset@bservable Unobservable **Inputs** (LevelInputs at Description 6/30/2018 1) (Level 2) (Level 3) \$ \$ **Equities** \$ 0 \$0 0 0

(7) Global revenues (USD) by product category:

		Outside	
	Domestic	US	Total
Obstetrics	\$ 891	\$204	\$1,095
Gynecology/Electrosurgery/Urology	2,378	3,695	6,073
Neonatal	1,031	704	1,735
Blood Pressure Monitoring and Accessories	1,181	881	2,062
Total	\$ 5,481	\$5,484	\$10,965

(8) 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

Utah Medical Products, Inc. (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, 2017 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 or six month period in comparison with a previous three or six 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; A\$ or AUD = Australia Dollars; £ or GBP = UK Pound Sterling; C\$ or CAD = Canadian Dollars; and € or EUR = Euros.

#### Analysis of Results of Operations

#### a) Overview

In the second calendar quarter (2Q) and first half (1H) of 2018, UTMD achieved results which reflect that the Company remains on target to achieve beginning of year goals for 2018.

Income statement results in 2Q and 1H 2018 compared to the same periods of 2017 were as follows:

	2Q	2Q				
	2018	2017	change	1H 2018	1H 2017	change
Net Sales	\$10,965	\$10,829	+1.3 %	\$21,852	\$21,088	+3.6 %
Gross Profit	6,984	6,893	+1.3 %	13,906	13,428	+3.6 %
Operating Income	5,056	5,034	+0.4 %	10,027	9,758	+2.7 %
Income Before Tax	5,556	5,057	+9.9 %	10,565	9,807	+7.7 %
Net Income	4,308	3,870	+11.3 %	8,400	7,405	+13.4 %
Earnings per Diluted Share	1.148	1.037	+10.7 %	2.239	1.985	+12.8 %

Because 32% of 1H 2018 consolidated sales and 53% of 1H 2018 consolidated operating expenses are in foreign currencies, the volatility of foreign currency exchange (FX) rates for sales and expenses outside the U.S. (OUS) continued to have an impact on period-to-period relative financial results. FX rates for income statement purposes are transaction-weighted averages. The average rates from the applicable foreign currency to USD during 2Q 2018 and 1H 2018 compared to the same periods in 2017 follow:

					1H	
	2Q 18	2Q 17	Change	1H 18	17	Change
GBP	1.359	1.279	+6.3 %	1.375	1.259	+ 9.2 %
EUR	1.192	1.108	+7.5 %	1.209	1.085	+11.4 %
AUD	0.756	0.750	+0.8 %	0.771	0.755	+ 2.1 %
CAD	0.775	0.743	+4.2 %	0.783	0.749	+ 4.5 %

UTMD's revenues invoiced in the above foreign currencies represented 31.3% of total consolidated USD sales in 2Q 2018 and 32.2% in 1H 2018.

The weighted average positive impact on GBP, EUR, AUD and CAD currency revenues in 2Q 2018 compared to 2Q 2017 was 5.4%, increasing reported USD sales by \$177. The weighted average positive impact on GBP, EUR, AUD and CAD currency sales in 1H 2018 compared to 1H 2017 was 7.9%, increasing reported USD sales by \$518. With

the same FX rates as in 2017 (constant currency terms), total consolidated 2Q 2018 sales were down 0.4%, and 1H 2018 sales were up 1.2%.

UTMD's consolidated Gross Profit Margin (GPM), Gross Profit (GP) divided by sales, was consistent with the prior year's periods. Consolidated Operating Expenses (OE) were \$69 higher in 2Q 2018 compared to 2Q 2017, and \$210 higher in 1H 2018 compared to 1H 2017. Eighty-three percent of the increase in 2Q 2018 OE was due to the change in FX rates. Seventy-eight percent of the increase in 1H 2018 OE was due to the change in FX rates. The combination of 3.6% higher revenues, the same GPM but higher OE resulted in a 2.7% increase in 1H 2018 Operating Income (OI). The 13.4% higher UTMD Net Income (NI) in 1H 2018 was primarily a result of the higher OI plus 1) non-operating income from the sale of a no longer needed storage facility in Utah, and 2) a lower U.S. income tax provision rate.

Earnings Per Diluted Share (EPS) in 1H 2018 were up only 12.8% compared to the 13.4% higher NI, because of employee option exercises and a higher dilution calculation resulting from a higher share market price.

EPS for the most recent twelve months (TTM) were \$2.53 per U.S. GAAP. This includes the 4Q 2017 recognition of a \$6,288 one-time U.S. and Utah repatriation tax (REPAT) on foreign subsidiary cash and cumulative earnings (E&P) resulting from the "Tax Cuts and Jobs Act" enacted in December 2017. Excluding the REPAT tax, TTM EPS were \$4.15.

UTMD profit margins in 2Q 2018 and 1H 2018 compared to 2Q 2017 and 1H 2017 follow:

	2Q 2018		2Q 2017	7	1H 201	8	1H 201	7
	(Apr-Jun	ı)	(Apr-Jui	n)	(Jan-Ju	n)	(Jan-Ju	n)
Gross Profit Margin (gross profit/ sales):	63.7	%	63.7	%	63.6	%	63.7	%
Operating Income Margin (operating income/ sales):	46.1	%	46.5	%	45.9	%	46.3	%
EBT Margin (profit before income taxes/ sales):	50.7	%	46.7	%	48.3	%	46.5	%
Net Income Margin (profit after taxes/ sales):	39.3	%	35.7	%	38.4	%	35.1	%

In summary, comparing the profit margins in 2018 time periods with 2017 periods, GPM were about the same, OIM were squeezed by higher FX rates on foreign OE, the EBTM benefited from the gain from one-time sale of unneeded assets, and the NIM benefited from the higher EBTM combined with lower U.S. income tax rates.

UTMD's Balance Sheet continued to strengthen. June 30, 2018 ending Cash and Investments were up \$5.9 million and Stockholders' Equity was up \$5.2 million from December 31, 2017. 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 2018 and the end of December 2017 follow:

	June	December		
	30,	31,		
	2018	2017	change	9
GBP	1.320	1.352	(2.4	%)
EUR	1.168	1.202	(2.9)	%)
AUD	0.740	0.781	(5.3	%)
CAD	0.761	0.799	(4.7	%)

#### b) Revenues

Beginning on January 1, 2018, the Company adopted ASU 2014-09, the new revenue recognition accounting standard. Management completed an extensive assessment and implementation of the standard, including UTMD's various contracts with customers and associated performance obligations and the Company's conclusions regarding its revenue recognition practices and procedures. Other items like commissions and rights of return were also evaluated by the Company. Management is confident that the Company has properly evaluated the standard's requirements and has arrived at appropriate conclusions in recognizing revenue in accordance with the new standard. Those practices and procedures the Company will use to recognize revenue under the new standard are not significantly different than the methods used previously since UTMD has traditionally recognized revenue upon shipping a physical product to a customer, which is also when the Company has met its performance obligations under contracts it has with its customers that represent over 99% of its revenue. While the Company's revenue not associated with shipping a physical product is immaterial, management believes the Company's practices in recognizing that revenue is also in accordance with ASU 2014-09.

Terms of sale are established in advance of UTMD's acceptance of customer orders. In the U.S., Ireland, UK and Australia prior to 2017, UTMD generally accepted orders directly from and shipped directly to end user clinical

facilities, as well as third party medical/surgical distributors, under UTMD's Standard Terms and Conditions (T&C) of Sale. The same was true in 2017 with the addition of direct shipments to end user facilities in Canada and France. About 14% of UTMD's domestic end user sales, excluding Femcare's Filshie Clip System sales to its exclusive U.S. distributor, CooperSurgical Inc. (CSI), go through third party med/surg distributors which contract separately with clinical facilities to provide purchasing, storage and scheduled delivery functions for the applicable facility. UTMD's T&C of Sale to end user facilities are substantially the same in the U.S., Canada, Ireland, UK, France and Australia.

UTMD may have separate discounted pricing agreements with a specific 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 typically determine the fixed price by part number for the next agreement period of one year. For new customers, the customer's best estimate of volume is usually accepted by UTMD for determining the ensuing fixed prices for the agreement period. 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 that the selling price is fixed prior to the acceptance of a specific customer order.

Total 2Q 2018 consolidated sales were \$136 (1.3%) higher than in 2Q 2017, and in 1H 2018 were \$764 (3.6%) higher than in 1H 2017. Comparing 2Q 2018 to 2Q 2017, total U.S. domestic sales were 4% higher and USD sales outside the U.S. (OUS sales) were 1% lower. Comparing 1H 2018 to 1H 2017, total U.S. domestic sales were 2% higher and OUS sales were 5% higher.

U.S. domestic sales, including direct sales to U.S. clinical facilities, OEM sales of components and finished devices to other companies, and sales of the Filshie Clip System to UTMD's exclusive U.S. distributor, CSI, were overall 4% (+\$186) and 2% (+\$221) higher in 2Q 2018 and 1H 2018, respectively, compared to 2Q 2017 and 1H 2017. U.S. domestic sales are obviously not affected by FX rate fluctuations. U.S. domestic sales were 50% of total consolidated sales in 2Q 2018 compared to 49% in 2Q 2017, and 49% in 1H 2018 compared to 50% in 1H 2017. Sales of Femcare's Filshie Clip System to CooperSurgical Inc. (CSI) for distribution in the U.S. were \$14 higher in 2Q 2018 compared to 2Q 2017, and \$38 lower in 1H 2018 compared to 1H 2017. Femcare's sales to CSI were 22% of total domestic sales in 2Q 2018 compared to 23% in 2Q 2017, and 22% in 1H 2018 compared to 23% in 1H 2017. Domestic OEM sales were 26% (+\$193) higher in 2Q 2018 compared to 2Q 2017, and 21% (+\$324) higher in 1H 2018 compared to 1H 2017. Direct sales to U.S. user facilities were 1% (\$22) lower in 2Q 2018 compared to 2Q 2017, and also 1% (\$64) lower in 1H 2018 compared to 1H 2017.

The 1% lower 2Q 2018 OUS sales was due to variation in order pattern by UTMD's China distributor of BPM kits. Shipments to the China distributor were \$337 lower in 2Q 2018 compared to 2Q 2017. Excluding shipments to the China distributor in both 2Q periods, OUS sales were 6% higher in 2Q 2018.

Trade sales are sales to third parties, excluding sales from one UTMD entity to another (intercompany sales). Ireland subsidiary trade sales were 22% of OUS sales in 2Q 2018 compared to 26% of OUS sales in 2Q 2017. Ireland subsidiary trade sales were 22% of OUS sales in 1H 2018 compared to 25% of OUS sales in 1H 2017. The lower portion of OUS sales by Ireland was due to the fact that BPM kits to UTMD's China distributor are shipped from Ireland.

Trade sales by UTMD's UK subsidiary, Femcare-Nikomed Ltd. (Femcare UK), were 27% of OUS sales in both 2Q and 1H 2018 compared to 24% of OUS sales in both 2Q and 1H 2017. Included in the Femcare UK sales were the direct sales to end users in France which comprised 8% of OUS sales in 2Q 2018 and 9% of OUS sales in 1H 2018. Sales of the Filshie Clip System in Europe (by UK and Ireland subsidiaries) were up about 15%.

Sales by UTMD's Australia subsidiary to Australia end user facilities were 9% of OUS sales in 2Q 2018 compared to 11% in 2Q 2017, and 9% in 1H 2018 compared to 11% in 1H 2017. Filshie Clip System sales were weak, down 20% in 2Q 2018 and 13% in 1H 2018, compared to the same periods in 2017.

Sales by UTMD's Canada subsidiary direct to Canada end user facilities were 13% of OUS sales in both 2Q 2018 and 1H 2018 compared to 15% of OUS sales in both 2Q 2017 and 1H 2017. Canada Filshie Clip System sales were also weak, down 14% in 2Q 2018 and 9% in 1H 2018, compared to the same periods in 2017.

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

Global revenues by product category:

	2Q	2Q		
	2018	2017	1H 2018	1H 2017
Obstetrics	\$1,095	\$1,116	\$2,181	\$2,155
Gynecology/ Electrosurgery/ Urology	6,073	6,106	12,275	11,944
Neonatal	1,735	1,493	3,445	3,063

Blood Pressure Monitoring and Accessories\* 2,062 2,114 3,951 3,926 Total: \$10,965 \$10,829 \$21,852 \$21,088

OUS revenues by product category:

	2Q	2Q		
	2018	2017	1H 2018	1H 2017
Obstetrics	\$204	\$216	\$413	\$360
Gynecology/ Electrosurgery/ Urology	3,695	3,717	7,602	7,276
Neonatal	704	479	1,449	997
Blood Pressure Monitoring and Accessories*	881	1,121	1,652	1,941
Total:	\$5,484	\$5,533	\$11,116	\$10,574

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

Additional comments on the above tables:

1) Year-to-date global sales were up in all product categories.

Filshie Clip System sales represented 67% of both 2Q and 1H 2018 Gyn/ES/Uro product category sales. With 2Q 2018 U.S. sales of the Filshie Clip System (to UTMD's exclusive distributor, CSI) about the same as in 2Q 2017, 2) the higher Filshie Clip System 2Q 2018 sales in Europe offset the lower sales in Australia and Canada. For 1H 2018, global Filshie Clip System sales were up 4% despite CSI sales, representing 28% of total Filshie Clip System sales, being 2% lower.

The uneven order patterns of OUS distributors is especially evident in neonatal and BPM product categories. For 3)example, UTMD's China distributor for BPM devices ordered \$337 less in 2Q 2018 than in 2Q 2017. UTMD's OUS distributors for neonatal devices ordered \$199 more in 2Q 2018 than in 2Q 2017.

Looking forward, CSI current forecasts indicate \$424 lower 2H 2018 purchases than in 2H 2017, and UTMD's China distributor for BPM devices, which placed an annual fixed order, has no shipments scheduled in 4Q 2018, resulting in 2H 2018 sales another \$402 lower than in 2H 2017. Trump administration trade policies may have negative consequences as direct exports from Utah represent about 14% of total sales, which could be lost if receiving countries increase tariffs on U.S. goods. Further, possible increased tariffs in Ireland, the UK, Australia and Canada on components and finished devices manufactured in Utah and sold on an intercompany basis could substantially increase subsidiary costs and reduce OUS sales made by UTMD's subsidiaries. While the USD was weaker in 1H 2018 than in 1H 2017, which benefited 1H 2018 sales in USD terms on a comparative basis, it presently is stronger than the average foreign FX rates in 2H 2017, which, if it persists, would have a negative effect on 2H 2018 USD sales on a comparative basis.

#### c) Gross Profit (GP)

GP results from subtracting the cost of manufacturing and shipping products to customers (direct materials, direct labor, manufacturing overhead and shipping costs), or the purchase price of distributed finished products manufactured by other companies, from revenues. At UTMD, manufacturing overhead costs fully absorb indirect costs including depreciation of 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. UTMD's consolidated GPM remained consistent in 2Q 2018 despite noticeable increases in variable manufacturing costs – direct labor and materials. Just the expectation of tariffs on metals, for example, caused aluminum and stainless steel component vendors to substantially increase prices for parts used in UTMD's electrosurgical generators and specialty electrodes. The higher variable costs were offset by better absorption of overheads and improved productivity. Higher variable costs in combination with projected lower sales in 2H 2018, leading to lower absorption of manufacturing overheads, leads management to expect GPMs in 2H 2018 will be lower than in 2H 2017.

#### d) Operating Income (OI)

OI is GP minus OE comprised of general and administrative (G&A), sales and marketing (S&M) and product development (R&D) expenses. Consolidated USD-denominated OE were \$1,928 in 2Q 2018 (17.6% of consolidated revenues) compared to \$1,859 in 2Q 2017 (17.2% of consolidated revenues). Consolidated OE were \$3,880 in 1H 2018 (17.8% of revenues) compared to \$3,670 in 1H 2017 (17.4% of revenues). In the case of OE, higher FX rates (weaker USD) for OUS OE reduce OI. The OE of UTMD's foreign subsidiaries in the aggregate in 2Q 2018 and 1H 2018 would have been \$57 and \$163 lower, respectively, in constant currency. In other words, the FX rate impact on OE represented 83% of the total increase in 2Q 2018 OE and 78% of the total increase in 1H 2018 OE.

OI in 2Q 2018 and 1H 2018 was \$5,056 and \$10,027 respectively, compared to \$5,034 and \$9,758 in 2Q 2017 and 1H 2017 respectively. Because of consistent GPMs and continuing tightly controlled OE, UTMD's 2Q and 1H 2018 excellent but slightly FX rate diluted OIM was 46.1% and 45.9% respectively, compared to 46.5% and 46.3% in the same periods of 2017.

Consolidated S&M expenses in 2Q 2018 were \$430 (3.9% of sales) compared to \$409 (3.8% of sales) in 2Q 2017, and were \$839 (3.8% of sales) in 1H 2018 compared to \$790 (3.8% of sales) in 1H 2017. 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., Canada, the 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 in 2Q 2018 were \$117 compared to \$119 in 2Q 2017 (1.1% of sales in both periods), and were \$230 in 1H 2018 compared to \$238 in 1H 2017 (1.1% of sales in both periods).

Consolidated G&A expenses were \$1,382 (12.6% of sales) in 2Q 2018 compared to \$1,330 (12.3% of sales) in 2Q 2017, and were \$2,810 (12.9% of sales) in 1H 2018 compared to \$2,643 (12.5% of sales) in 1H 2017. Consolidated G&A expenses included non-cash expense from the amortization of IIA resulting from the Femcare acquisition of \$542 (4.9% of consolidated revenues) in 2Q 2018 and \$1,097 (5.0% of consolidated revenues) in 1H 2018, compared to \$510 (4.7% of consolidated revenues) in 2Q 2017 and \$1,004 (4.8% of consolidated revenues) in 1H 2017. The IIA amortization expense increases were only due to FX rate changes, since the IIA amortization expense was £399 in both 2O 2018 and 2O 2017, and £798 in both 1H 2018 and 1H 2017.

G&A expenses include the cost of outside financial auditors and corporate governance activities related to the implementation of SEC rules resulting from the Sarbanes-Oxley Act of 2002, as well as estimated stock-based compensation cost, a noncash expense. Option compensation expense included in G&A expenses was \$11 in 2Q 2018 compared to \$33 in 2Q 2017, and \$42 in 1H 2018 compared to \$69 in 1H 2017.

Summary comparison of (USD) consolidated operating expenses:

	2Q	2Q		
	2018	2017	1H 2018	1H 2017
S&M Expense	\$430	\$410	\$839	\$790
R&D Expense	117	119	230	238
G&A Expense	1,382	1,330	2,810	2,642
<b>Total Operating Expenses:</b>	\$1,928	\$1,859	\$3,880	\$3,670

#### 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. Negative NOE is NOI. Net NOI in 2Q 2018 was \$501 compared to \$23 NOI in 2Q 2017. Net NOI in 1H 2018 was \$538 compared to \$49 NOI in 1H 2017. Included in the 2Q 2018 NOI was a one-time \$418 gain on the sale of a storage facility in Utah that is no longer needed, and a \$32 gain on the sale of other investments. The gain on remeasured foreign currency balances in 2Q 2018 was \$10 compared to a loss/gain of

\$0 in 2Q 2017. In 1H 2018, the gain on remeasured foreign currency balances was \$8 compared to a gain of \$1 in 1H 2017. Royalties received were \$19 in 2Q 2018 compared to \$19 in 2Q 2017, and \$41 in 1H 2018 compared to \$42 in 1H 2017.

#### f) Income Before Income Taxes (EBT)

Consolidated EBT results from subtracting net NOE or adding NOI from or to, as applicable, consolidated OI. Consolidated 2Q 2018 EBT was \$5,556 (50.7% of sales) compared to \$5,057 (46.7% of sales) in 2Q 2017. Consolidated 1H 2018 EBT was \$10,565 (48.3% of sales) compared to \$9,807 (46.5% of sales) in 1H 2017. Although not directly related to sales, 2018 EBTMs were enhanced by the one-time NOI gain from sale of assets.

The EBT of Utah Medical Products, Inc. (U.S.) was \$2,885 in 2Q 2018 compared to \$2,233 in 2Q 2017, and \$5,136 in 1H 2018 compared to \$4,484 in 1H 2017. The EBT of Utah Medical Products, Ltd (Ireland) was EUR 943 in 2Q 2018 compared to EUR 875 in 2Q 2017, and EUR 1,740 in 1H 2018 compared to EUR 1,512 in 1H 2017. The EBT of Femcare Group Ltd (Femcare-Nikomed, Ltd., UK and Femcare Australia) was GBP 1,117 in 2Q 2018 compared to GBP 1,146 in 2Q 2017, and GBP 2,180 in 1H 2018 compared to GBP 2,306 in 1H 2017. The 2Q 2018 EBT of Utah Medical Products Canada, Inc. was CAD 446 compared to CAD 567 in 2Q 2017, and CAD 917 in 1H 2018 compared to CAD 1,062 in 1H 2017.

Excluding the noncash effects of depreciation, amortization of intangible assets and stock option expense, 2Q 2018 consolidated EBT excluding the remeasured bank balance currency gain or loss and interest expense (adjusted consolidated EBITDA) were \$6,312 (57.6% of sales) compared to \$5,779 (53.4% of sales) in 2Q 2017. Adjusted consolidated EBITDA in 1H 2018 were \$12,122 (55.5% of sales) compared to \$11,236 (53.3% of sales) in 1H 2017. The increases in adjusted EBITDA were largely due to the one-time 2Q 2018 asset sales. TTM adjusted EBITDA were \$22,864.

#### g) Net Income (NI)

NI is EBT minus a provision for income taxes. In addition to the increase in EBT, NI in 2018 was further leveraged by lower tax provisions in the U.S. (both federal and state). NI in 2Q 2018 of \$4,308 was \$438 (+11.3%) higher than the NI of \$3,870 in 2Q 2017. The consolidated income tax provision rate in 2Q 2018 was 22.5% compared to 23.5% for 2Q 2017. NI in 1H 2018 of \$8,400 was \$995 (+13.4%) higher than the NI of \$7,405 in 1H 2017. The consolidated income tax provision rates were 20.5% in 1H 2018 and 24.5% in 1H 2017. The combined U.S. federal and Utah state income tax rates were 25.95% in 1H 2018 compared to 39% in 1H 2017. For foreign subsidiaries, the tax provision booked in consolidated results is based on taxable income in the applicable sovereignty, not based on U.S. GAAP EBT. In 1H 2017, UTMD held about \$16 million in cash in USD currency in Ireland and UK subsidiary bank accounts, and the USD weakened relative to the applicable native currency, resulting in a translation loss for each subsidiary that created a significant 2017 tax credit for those subsidiaries in their applicable native currencies. This did not recur in 1H 2018, which offset the benefit of the reduction in the U.S. tax rates.

#### 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 market value). Diluted EPS in 2Q 2018 were \$1.148 compared to \$1.037 in 2Q 2017. In 1H 2018, EPS were \$2.239 compared to \$1.985 in 1H 2017. With some hindrance from higher diluted shares outstanding, 2Q 2018 EPS increased 10.7% (11.1 cents) compared to 2Q 2017, and 1H 2018 EPS increased 12.8% (25.4 cents) compared to 1H 2017. Looking forward, management is now projecting 2018 EPS greater than \$4.00.

EPS for the most recent twelve months were \$2.53, which includes the 4Q 2017 recognition of a \$6,288 one-time U.S. and Utah repatriation tax (REPAT) on foreign subsidiary cash and cumulative earnings (E&P) resulting from the "Tax Cuts and Jobs Act" enacted in December 2017. Excluding the REPAT tax, TTM EPS were \$4.15.

Diluted shares outstanding used to calculate 2Q 2018 EPS were 3,753,608 compared to 3,731,859 in 2Q 2017. The number of shares added as a dilution factor in 2Q 2018 was 23,084 compared to 15,686 in 2Q 2017. Diluted shares outstanding used to calculate 1H 2018 EPS were 3,751,072 compared to 3,730,478 in 1H 2017. The number of shares added as a dilution factor in 1H 2018 was 23,326 compared to 15,253 in 1H 2017.

Outstanding shares at the end of 2Q 2018 were 3,731,920 which included 1H 2018 employee and outside director option exercises of 12,927 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, 2018 was 41,413 shares at an average exercise price of \$45.89/ share, including shares awarded but not vested. This compares to 62,324 unexercised option shares outstanding at June 30, 2017 at an average exercise price of \$46.15/ share. No option shares have been awarded to date in 2018. Despite the lower number of outstanding option shares, the dilution factor in 2018 was higher primarily because of a higher share market price.

During both 1H 2018 and 1H 2017, UTMD did not repurchase its shares in the open market. The Company retains the financial ability for repurchasing its 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 (before stockholder dividends) in 1H 2018 was 21% compared to 18% in 1H 2017. The higher ROE in 1H 2018 was due to the increase in NI. Targeting a high ROE of 20% remains a key financial objective for UTMD management. ROE can be increased by increasing NI, or by reducing stockholders' equity by paying cash dividends to stockholders or by repurchasing shares.

#### Liquidity and Capital Resources

#### j) 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 \$7,747 in 1H 2018 compared to \$7,743 in 1H 2017. The most significant differences in the two periods were the \$995 increase in net income, a \$165 benefit to cash from a smaller increase in 1H 2018 trade accounts receivable compared to 1H 2017, a \$798 benefit to cash from an increase in accrued expenses in 1H 2018 resulting from the REPAT tax following a decrease in 1H 2017, and a \$449 use of cash from a gain on investments and disposal of assets 1H 2018 that did not occur in the same period in 2017.

Capital expenditures for property and equipment (PP&E) were \$201 in 1H 2018 compared to \$114 in 1H 2017. Depreciation of PP&E was \$395 in 1H 2018 compared to \$330 in 1H 2017. The difference in depreciation was due primarily to the new facility in the UK put in service in 4Q 2017.

UTMD made cash dividend payments of \$2,011 in 1H 2018 compared to \$984 in 1H 2017. The difference was due to the fact that the 2017 year-end dividend was paid in January 2018, whereas the 2016 year-end dividend was paid in December 2016. The Company did not use cash to repurchase any of its own shares during either 1H 2018 or 1H 2017.

In 1H 2018, UTMD received \$347 and issued 10,488 shares of its stock upon the exercise of employee and director stock options, net of 2,439 shares retired upon employees trading those shares in payment of the stock option exercise price. Option exercises in 1H 2018 were at an average price of \$44.23 per share. In comparison, in 1H 2017 the Company received \$168 and issued 4,860 shares of stock on the exercise of employee and director stock options. Option exercises in 1H 2017 were at an average price of \$34.67 per share.

Management believes that current cash balances, income from operations and effective management of working capital will provide the liquidity needed to finance internal growth plans. The Company may utilize cash not needed to support normal operations in one or a combination of the following: 1) in general, to continue to invest at an opportune time in ways that will enhance future profitability; 2) to make additional investments in new technology and/or processes; and/or 3) to acquire a product line or company that will augment revenue and EPS growth and better utilize UTMD's existing infrastructure. If there are no better strategic uses for UTMD's cash, the Company will continue to return cash to stockholders in the form of dividends and share repurchases when the stock appears undervalued.

#### k) Assets and Liabilities

June 30, 2018 total consolidated assets were \$97,045, an increase of \$4,300 from December 31, 2017. The increase was due to a \$5,918 increase in cash and investments. Other significant changes in assets included a \$909 increase in consolidated net trade receivables, a \$1,656 decrease in net intangible assets, a \$852 decrease in the current USD

value of net property and equipment, a \$617 decrease in L/T taxes payable due to payment of the first installment of the REPAT tax, and a \$275 decrease in the current USD value of the deferred tax liability associated with the amortization of acquired Femcare identifiable intangible assets (IIA). UTMD's Ireland subsidiary EUR-denominated assets and liabilities were translated into USD at an FX rate 2.9% lower (weaker EUR) than the FX rate at the end of 2017. UTMD's UK subsidiary GBP-denominated assets were translated into USD at an FX rate 2.4% lower (weaker GBP) than the FX rate at the end of 2017. UTMD's Australia subsidiary AUD-denominated assets were translated into USD at an FX rate 5.3% lower (weaker AUD) than the FX rate at the end of 2017. UTMD's Canada subsidiary CAD-denominated assets were translated into USD at an FX rate 4.7% lower (weaker CAD) than the FX rate at the end of 2017. The net book value of consolidated property, plant and equipment decreased \$852 at June 30, 2018 from the end of 2017 due to period-ending changed FX rates, \$201 in new asset purchases and \$395 in depreciation.

Working capital (current assets minus current liabilities) was \$50,748 at June 30, 2018 compared to \$43,909 at December 31, 2017. Cash balances were \$45,873 of the working capital. A current asset increase of \$6,808 was led by the \$5,918 increase in cash and investments. Current liabilities were about the same, with a slight \$31 decrease from the end of 2017. UTMD management believes that its working capital remains sufficient to meet normal operating needs, new capital expenditures and projected cash dividend payments to stockholders.

June 30, 2018 intangible assets (goodwill plus other intangible assets) decreased \$1,656 from the end of 2017. The decrease was due to the lower FX rate (stronger USD) for GBP Femcare intangibles as of June 30, 2018 compared to year-end 2017, plus the \$1,097 1H 2018 amortization of Femcare IIA. At June 30, 2018, net intangible assets including goodwill declined to 31% of total consolidated assets compared to 34% at year-end 2017, and 37% at June 30, 2017.

The deferred tax liability balance for Femcare IIA (\$9,084 on the date of the acquisition), was \$2,827 at June 30, 2018 compared to \$3,102 at December 31, 2017 and \$3,178 at June 30, 2017. 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, i.e. as Femcare pays its taxes in the UK without the benefit of a deduction for IIA amortization expense.

UTMD's total debt ratio (total liabilities/ total assets) as of June 30, 2018 was 14% compared to 16% at the end of 2017. UTMD's total debt ratio as of June 30, 2017 was only 10% because it did not include a REPAT tax liability enacted in December 2017. Excluding the REPAT liability for comparison purposes, the June 30, 2018 debt ratio was 8% and the December 31, 2017 debt ratio was 9%.

#### 1) Management's Outlook

As outlined in its December 31, 2017 SEC 10-K report, UTMD's plan for 2018 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
- be vigilant for accretive acquisition opportunities which may be increasingly brought about by difficult burdens on small, innovative companies.

Generally, the Company continues to effectively execute its plan as outlined above. Based on results of 1H 2018, management expects to exceed the financial objectives for the full year of 2018 as stated in the Form SEC 10-K at the beginning of the year.

#### m) Accounting Policy Changes

On January 1, 2018 UTMD adopted ASU 2014-09, Revenue from Contracts with Customers. Refer to Note 2 for further information.

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), in Australia denominated in the Australia Dollar (AUD), and, starting in 2017, in Canada denominated in the Canadian Dollar (CAD). The currencies are subject to exchange rate fluctuations that are beyond the control of UTMD. The exchange rates were .8564, .8319 and .8763 EUR per USD as of June 30, 2018, December 31, 2017 and June 30, 2017, respectively. Exchange rates were .7578, .7395 and .7696 GBP per USD as of June 30, 2018, December 31, 2017 and June 30, 2017, respectively. Exchange rates were 1.3515, 1.2796 and 1.3028 AUD per USD on June 30, 2018, December 31, 2017 and June 30, 2017, respectively. Exchange rates were 1.3141, 1.2519, and 1.2982 CAD per USD on June 30, 2018, December 31, 2017 and June 30, 2017, respectively. UTMD manages its foreign currency risk without separate hedging transactions by either invoicing customers in the local currency where costs of production were incurred, by converting currencies as transactions occur, 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, 2018. Based on this evaluation, the Chief Executive Officer and Principal Financial Officer concluded that, as of June 30, 2018, 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 six months ended June 30, 2018, 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 the outcome of which is expected to be material to financial results.

#### 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, 2017, 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 years of 2016 through 2019. 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 proactively conform with requirements and thrive:

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

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

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. It recently took two and a half years to gain FDA approval of the use of a clearly safer single use Filshie Clip applicator, which had been in use for over seven years OUS, in lieu of a reused applicator approved in the U.S. since 1996, made of substantially equivalent materials for the same intended use applying the same implanted clip.

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

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

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

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

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

An aging population is 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. An 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 USD can result in significant differences in period to period financial results:

Since a significant portion of UTMD's sales are invoiced in foreign currencies and consolidated financial results are reported in USD terms, a stronger USD can have negative revenue effects. Conversely, a weaker USD would increase foreign subsidiary operating costs in USD terms. 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 are reduced, but also gross profits may be reduced because finished distributed products and/or U.S. made raw materials and components are likely being purchased in fixed USD.

## Future increases in sales of the Filshie Clip System due to Bayer stopping sales of the Essure device are uncertain, and may not materialize.

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

UTMD did not purchase any of its own securities during 1H 2018.

Rule 13a-14(a) as adopted pursuant to Section 302 of the
al Officer pursuant to Rule 13a-14(a) as adopted pursuant to y Act of 2002
18 U.S.C. §1350, as Adopted Pursuant to Section 906 of the
al Officer pursuant to 18 U.S.C. §1350, as Adopted Pursuant kley Act of 2002

#### **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: 8/7/18 By: /s/ Kevin L. Cornwell

Kevin L. Cornwell

CEO

Date: 8/7/18 By: /s/ Brian L. Koopman

Brian L. Koopman

Principal Financial Officer