

# COGENTIX MEDICAL INC /DE/

## **FORM 8-K** (Current report filing)

Filed 08/01/17 for the Period Ending 08/01/17

Address	5420 FELTL ROAD MINNETONKA, MN 55343
Telephone	(952) 426-6140
CIK	0000894237
Symbol	CGNT
SIC Code	3845 - Electromedical and Electrotherapeutic Apparatus
Industry	Advanced Medical Equipment & Technology
Sector	Healthcare
Fiscal Year	12/31

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

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**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

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Date of Report (Date of earliest event reported): **August 1, 2017**

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**COGENTIX MEDICAL, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation)

**000-20970**  
(Commission File Number)

**13-3430173**  
(I.R.S. Employer Identification No.)

**5420 Feltl Road**  
**Minnetonka, Minnesota**  
(Address of principal executive offices)

**55343**  
(Zip Code)

**(952) 426-6140**  
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02. Results of Operations and Financial Condition**

On August 1, 2017, Cogentix Medical, Inc. (the “Company”) issued a press release providing information regarding its results of operations and financial condition for the fiscal quarter ended June 30, 2017.

The Company is furnishing the information contained in this report, including Exhibit 99.1, pursuant to Item 2.02 of Form 8-K promulgated by the Securities and Exchange Commission (the “SEC”). This information shall not be deemed to be “filed” with the SEC for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits* .

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release of Cogentix Medical, Inc. dated August 1, 2017 (furnished herewith)

**SIGNATURES**

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

Dated: August 1, 2017

**COGENTIX MEDICAL, INC.**

By: /s/ Brett Reynolds  
Name: Brett Reynolds  
Title: Sr. Vice President, Chief Financial Officer and  
Corporate Secretary

**COGENTIX MEDICAL, INC.  
CURRENT REPORT ON FORM 8-K  
EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>	<b>Method of Filing</b>
<a href="#">99.1</a>	Press release of Cogentix Medical, Inc. dated August 1, 2017	Furnished herewith

# Cogentix Medical

## **Cogentix Medical Reports Strong Second Quarter Operating Results with 11% Urology Revenue Growth; Recently Executed Business Development Transactions Expected to Add Approximately 10 Points of Urology Revenue Growth in 2018**

*Conference Call Today at 4:30 p.m. ET*

**MINNEAPOLIS, MN, August 1, 2017** – Cogentix Medical, Inc. (NASDAQ: CGNT), a global medical device company focused on providing the Urology, Uro/Gyn and Gynecology markets with innovative and proprietary products, today reported financial results for the second quarter ended June 30, 2017.

### **Second Quarter and Business Development Highlights**

- Second quarter revenue was \$14.1 million, including \$12.3 million in Urology product revenue. Urology product revenue, representing 87% of total revenue, increased 11% over last year's second quarter and 12% on a constant currency basis. Total Company revenue for the second quarter increased 8% over the prior year period and 9% on a constant currency basis.
- Gross profit was \$9.4 million or 66.9%, a \$0.5 million increase over the prior year period.
- GAAP operating income was \$0.4 million in the second quarter, compared to a GAAP operating loss of \$2.3 million in the year ago quarter.
- Cash operating profit, a non-GAAP financial measure that excludes non-cash items, was \$1.5 million in the second quarter, an increase of \$0.7 million when compared to the cash operating profit of \$0.8 million in the second quarter of 2016.
- The Company continues to evaluate strategic alternatives for its non-core Industrial and Airway Management product lines.
- In July, the Company announced completion of two business development transactions expected to add approximately 10 points of urology products revenue growth in 2018.

“Cogentix achieved another quarter of double-digit organic revenue growth from our core Urology business,” said Darin Hammers, President and CEO. “This growth was driven by impressive results from our PrimeSight™ product line, which grew 48% in the quarter, as our physician customers continue to embrace the always ready, always sterile value proposition PrimeSight offers. Unit sales of our Urgent® PC product line grew 5% in the United States during the second quarter, and the average selling price was consistent with the last several quarters. Our sales and marketing team continues to perform at a high level, and we have decided to expand our US sales force by five territories during the third quarter. As a result, we anticipate second half 2017 revenue growth for our Urology business will be above the 11% growth we generated in the first half of the year. Additionally, the two business development agreements we recently executed should add approximately 10 points of growth to urology products revenue in 2018 as these agreements leverage our strong sales and marketing organization. With \$27 approximately million in cash and investments, and no debt on our balance sheet, we are continuing to evaluate other business development opportunities so that we can further enhance our growth profile while building value for shareholders.”

### **Financial Results for the Second Quarter Ended June 30, 2017**

For the quarter ended June 30, 2017, the Company achieved total revenue of \$14.1 million compared to \$13.0 million in the year ago quarter. The \$1.1 million increase in reported revenue is attributable to a \$1.2 million increase in Urology revenue, partially offset by a decrease in non-core Industrial and Airway Management revenue. Revenue from PrimeSight totaled \$5.0 million, up \$1.6 million or 48% from the comparable year-ago period. Urgent PC revenue totaled \$5.3 million compared to \$5.4 million in the comparable year ago period, comprised of 5% unit growth in the U.S. offset by lower average selling prices as compared to the year ago quarter. Revenue from Macroplastique<sup>®</sup> and other urology product revenue in the quarter totaled \$2.0 million, a decrease of approximately \$250,000 compared to the prior year period.

Gross margin for the quarter ended June 30, 2017 was 66.9% compared with 68.6% in the year-ago period, with the decrease due to a shift in product mix. Operating expenses in the quarter totaled \$9.0 million, flat with the \$9.0 million of operating expenses, excluding certain one-time charges, in the same period of the prior year.

Operating profit for the quarter was \$0.4 million compared to an operating loss of \$2.3 million (\$0.1 million excluding one-time charges) in the year ago period. Cash operating profit, a non-GAAP financial measure that is operating profit excluding all non-cash items, was \$1.5 million for the quarter ended June 30, 2017 compared to a cash operating profit of \$0.8 million (excluding one-time charges) in the year-ago quarter. Net income was \$0.4 million (\$0.01 per share) in the quarter ended June 30, 2017, compared to a net loss of \$2.7 million (\$0.10 per share) in the comparable year-ago period.

At June 30, 2017, the Company's cash and investments totaled \$26.9 million, compared to \$25.8 million at March 31, 2017. There were no borrowings under the Company's \$7.0 million line of credit as of June 30, 2017.

### **Six Month Financial Results Ended June 30, 2017**

For the six-month period ended June 30, 2017, total revenue of \$27.0 million represented an increase of 7% over the year ago period. This increase is due to 11% growth in the Urology business, partially offset by a decline in non-core Airway Management and Industrial revenue.

Operating loss for the six months ended June 30, 2017 was \$0.8 million while cash operating profit (which excludes non-cash items) was \$1.4 million.

### **Conference Call**

Cogentix Medical will host a conference call and webcast today at 4:30 p.m. Eastern Time (3:30 p.m. Central Time). Darin Hammers, President and Chief Executive Officer, will host the event along with Brett Reynolds, Chief Financial Officer. Individuals wishing to participate in the conference call should dial 877-303-1595 with the conference ID number 57924692. To access a live webcast of the call, go to the investor relations section of Cogentix Medical's website at [ir.cogentixmedical.com](http://ir.cogentixmedical.com).

An audio replay will be available for 30 days following the call at 855-859-2056 with the conference ID number 57924692. An archived webcast will also be available at [ir.cogentixmedical.com](http://ir.cogentixmedical.com).

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## About Cogentix Medical

Cogentix Medical, Inc., headquartered in Minnetonka, Minnesota, with additional operations in New York, Massachusetts, The Netherlands and the United Kingdom, is a global medical device company. We design, develop, manufacture and market products for flexible endoscopy with our unique PrimeSight™ product lines featuring a streamlined visualization system and proprietary sterile disposable microbial barrier providing users with efficient and cost effective endoscope turnover while enhancing patient safety. We also commercialize the Urgent® PC Neuromodulation System, an FDA-cleared device that delivers percutaneous tibial nerve stimulation (PTNS) for the office-based treatment of overactive bladder (OAB). OAB is a chronic condition that affects approximately 42 million U.S. adults. The symptoms include urinary urgency, frequency and urge incontinence. We also offer Macroplastique®, an injectable urethral bulking agent for the treatment of adult female stress urinary incontinence primarily due to intrinsic sphincter deficiency. For more information on Cogentix Medical and our products, please visit us at [www.cogentixmedical.com](http://www.cogentixmedical.com). ‘CGNT-G’

### For Further Information:

#### Cogentix Medical, Inc.

Brett Reynolds, SVP and CFO  
952-426-6152

#### EVC Group

Brian Moore/Doug Sherk  
310-579-6199/415-652-9100

### Cautionary Statements Related to Forward-Looking Statements

This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as “anticipate,” “expect,” “plan,” “could,” “may,” “will,” “believe,” “estimate,” “forecast,” “goal,” “project,” and other words of similar meaning. Forward-looking statements in this press release include, but are not limited to, statements about expected revenue growth rates; the Company’s expectations regarding operating profit and cash operating profit; and plans, objectives, expectations and intentions with respect to future operations, products and services. Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the effects of industry, economic or political conditions outside of the Company’s control; competitive market factors; actual or contingent liabilities; the adequacy of the Company’s capital resources; and the risks identified under the heading “Risk Factors” in the annual report on Form 10-K, for the year ended December 31, 2016, filed with the Securities and Exchange Commission (“SEC”) on March 30, 2017. Investors are cautioned to not to place considerable reliance on the forward-looking statements contained in this presentation. Investors are encouraged to read the Company’s filings with the SEC, available at [www.sec.gov](http://www.sec.gov), for a discussion of these and other risks and uncertainties. The forward-looking statements in this presentation speak only as of the date of this release, and the Company undertakes no obligation to update or revise any of these statements. The Company’s businesses are subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

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COGENTIX MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net sales	\$ 14,064,216	\$ 13,004,651	\$ 27,014,349	\$ 25,211,215
Cost of goods sold	4,658,334	4,087,165	9,152,247	7,888,359
Gross profit	9,405,882	8,917,486	17,862,102	17,322,856
	66.9%	68.6%	66.1%	68.7%
Operating expenses				
General and administrative	2,058,327	1,867,312	4,194,483	3,529,781
Research and development	1,031,851	1,100,056	2,322,509	2,036,934
Selling and marketing	5,347,078	5,433,439	11,002,038	11,069,201
Amortization of intangibles	588,646	590,858	1,179,199	1,181,716
One-time costs	-	2,177,990	-	2,311,541
	9,025,902	11,169,655	18,698,229	20,129,173
Operating income (loss)	379,980	(2,252,169)	(836,127)	(2,806,317)
Other income (expense)				
Interest income	61,834	170	121,558	405
Interest expense	(130)	(376,363)	(13,625)	(766,667)
Other income	6,192	-	6,364	-
Foreign currency exchange gain (loss)	33,453	(17,844)	46,193	(25,406)
	101,349	(394,037)	160,490	(791,668)
Income (loss) before income taxes	481,329	(2,646,206)	(675,637)	(3,597,985)
Income tax expense	61,700	18,561	115,151	33,190
Net income (loss)	\$ 419,629	\$ (2,664,767)	\$ (790,788)	\$ (3,631,175)
Basic net income (loss) per common share	\$ 0.01	\$ (0.10)	\$ (0.01)	\$ (0.14)
Diluted net income (loss) per common share	\$ 0.01	\$ (0.10)	\$ (0.01)	\$ (0.14)
Weighted average common shares outstanding:				
Basic	59,895,208	25,518,330	59,767,542	25,446,765
Diluted	60,349,439	25,518,330	59,767,542	25,446,765

## COGENTIX MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS  
(UNAUDITED)

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 10,431,068	\$ 9,369,624
Short-term investments	14,275,494	13,573,057
Accounts receivable, net	7,313,021	6,770,838
Inventories	7,235,436	7,235,043
Other	616,166	571,527
Total current assets	<u>39,871,185</u>	<u>37,520,089</u>
Property, plant, and equipment, net	2,186,034	2,115,316
Goodwill	18,749,888	18,749,888
Other intangible assets, net	8,303,379	9,482,578
Long-term investments	2,218,233	5,344,004
Deferred tax assets and other	162,034	163,427
Total assets	<u>\$ 71,490,753</u>	<u>\$ 73,375,302</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,644,109	\$ 2,689,035
Income tax payable	90,762	113,191
Accrued liabilities:		
Compensation	3,536,817	4,670,640
Deferred revenue	629,538	597,524
Accrued legal fees	46,627	34,667
Accrued foreign and domestic sales tax/VAT	413,731	327,992
Accrued employee expenses	79,121	88,557
Other	741,564	387,056
Total current liabilities	<u>7,182,269</u>	<u>8,908,662</u>
Accrued pension liability	360,429	308,918
Deferred rent	613,888	639,019
Other	62,426	278,780
Total liabilities	<u>8,219,012</u>	<u>10,135,379</u>
Total shareholders' equity	<u>63,271,741</u>	<u>63,239,923</u>
Total liabilities and shareholders' equity	<u>\$ 71,490,753</u>	<u>\$ 73,375,302</u>

COGENTIX MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(UNAUDITED)

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2017</b>	<b>2016</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (790,788)	\$ (3,631,175)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,544,473	1,590,903
Loss on disposal of equipment	233	-
Share-based compensation expense	703,320	224,999
Amortization of premium on available-for-sale securities	68,829	-
Deferred tax benefit (expense)	6,764	(1,161)
Deferred rent	(14,983)	9,895
Proceeds from restricted stock exchanged for taxes	(17,690)	(57,343)
Amortization of discount on related party debt	-	554,247
Long-term incentive plan	-	(46,870)
Changes in operating assets and liabilities:		
Accounts receivable, net	(402,955)	1,691,231
Inventories	7,333	(1,096,308)
Other current assets	(31,230)	68,790
Accounts payable	(1,050,123)	104,130
Interest payable	-	178,359
Accrued compensation	(1,349,293)	1,059,496
Accrued liabilities, other	384,213	118,912
Accrued pension liability	27,338	42,862
Deferred revenue	24,402	250,679
Net cash provided by (used in) operating activities	<u>(890,157)</u>	<u>1,061,646</u>
<b>Cash flows from investing activities:</b>		
Proceeds from maturity of available-for-sale securities	4,800,000	-
Purchases of available-for-sale securities	(2,438,322)	-
Purchases of property, plant and equipment	(398,426)	(166,976)
Net cash provided by (used in) investing activities	<u>1,963,252</u>	<u>(166,976)</u>
<b>Cash flows from financing activities:</b>		
Borrowings from line of credit	3,033,385	2,646,500
Repayments of line of credit	(3,033,385)	(2,646,500)
Proceeds from exercise of stock options	3,953	-
Net cash provided by financing activities	<u>3,953</u>	<u>-</u>
Effect of exchange rates on cash and cash equivalents	(15,604)	(4,184)
Net increase in cash and cash equivalents	1,061,44	890,486
Cash and cash equivalents at beginning of period	<u>9,369,624</u>	<u>1,976,594</u>
Cash and cash equivalents at end of period	<u>\$ 10,431,068</u>	<u>\$ 2,867,080</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for income tax	\$ 135,936	\$ 19,378
Cash paid during the period for interest	\$ 13,625	\$ 34,061

**Non-GAAP Financial Measures :**

The tables set forth below entitled “Cash Operating Profit (Unaudited)” provide the non-GAAP cash operating profit for the Company for the three and six months ended June 30, 2017 and June 30, 2016. These tables reconcile the Company’s operating income / loss calculated in accordance with GAAP to the Company’s cash operating profit, a non-GAAP financial measure that excludes one-time costs and non-cash charges for share-based compensation, depreciation and amortization.

The non-GAAP financial information used by management and disclosed by us is not a substitute for, nor superior to, financial information and consolidated financial results calculated in accordance with GAAP, and you should carefully evaluate our reconciliations to non-GAAP. We may calculate our non-GAAP financial information differently from similarly titled measures used by other companies. Therefore, our non-GAAP financial information may not be comparable to those used by other companies. We have described the reconciliations of each of our non-GAAP financial information described above to the most directly comparable GAAP financial measures.

We use this non-GAAP financial information, and in particular non-GAAP cash operating profit / loss, for internal managerial purposes because we believe such measures are one important indicator of the strength and the operating performance of our business. Analysts and investors frequently ask us for this information. We believe that they use this information to evaluate the overall operating performance of companies in our industry, including as a means of comparing period-to-period results and as a means of evaluating our results with those of other companies.

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COGENTIX MEDICAL, INC. AND SUBSIDIARIES  
REVENUE BY PRODUCT  
QUARTER ENDED June 30,

(dollars in thousands)

Market/Product	2017	2016	\$ Change	% Change
PrimeSight	\$ 4,983	\$ 3,377	\$ 1,606	47.6%
Urgent PC	5,262	5,403	(141)	(2.6%)
Macroplastique	1,742	1,985	(243)	(12.2%)
Other	284	307	(23)	(7.5%)
Total Urology	12,271	11,072	1,199	10.8%
Airway Management	755	852	(97)	(11.4%)
Industrial	1,038	1,081	(43)	(4.0%)
Total Other	1,793	1,933	(140)	(7.2%)
<b>Combined Revenue</b>	<b>\$ 14,064</b>	<b>\$ 13,005</b>	<b>\$ 1,059</b>	<b>8.1%</b>

COGENTIX MEDICAL, INC. AND SUBSIDIARIES  
CASH OPERATING PROFIT (UNAUDITED)  
(NON-GAAP)  
QUARTER ENDED June 30,

(dollars in thousands)

	2017	2016	\$ Change	% Change
Revenue	\$ 14,064	\$ 13,005	\$ 1,059	8.1%
Gross profit	9,406	8,917	489	5.5%
	66.9%	68.6%		
Operating costs	8,437	8,400	37	0.4%
Amortization of intangibles	589	591	(2)	(0.3%)
One-time costs	-	2,178	(2,178)	n/m
Operating income (loss)	380	(2,252)	2,632	(116.9%)
Non cash operating costs	1,129	901	228	25.3%
One-time costs	-	2,178	(2,178)	n/m
Cash operating profit, excluding non-cash and one-time costs	\$ 1,509	\$ 827	\$ 682	82.5%

YTD Additional Information

COGENTIX MEDICAL, INC. AND SUBSIDIARIES  
REVENUE BY PRODUCT  
SIX MONTHS ENDED June 30,

(dollars in thousands)

<b>Market/Product</b>	<b>2017</b>	<b>2016</b>	<b>\$ Change</b>	<b>% Change</b>
PrimeSight	\$ 9,441	\$ 6,463	\$ 2,978	46.1%
Urgent PC	10,242	10,510	(268)	(2.5%)
Macroplastique	3,522	3,839	(317)	(8.3%)
Other	521	592	(71)	(12.0%)
<b>Total Urology</b>	<b>23,726</b>	<b>21,404</b>	<b>2,322</b>	<b>10.8%</b>
Airway Management	1,474	1,636	(162)	(9.9%)
Industrial	1,814	2,171	(357)	(16.4%)
<b>Total Other</b>	<b>3,288</b>	<b>3,807</b>	<b>(519)</b>	<b>(13.6%)</b>
<b>Combined Revenue</b>	<b>\$ 27,014</b>	<b>\$ 25,211</b>	<b>\$ 1,803</b>	<b>7.2%</b>

COGENTIX MEDICAL, INC. AND SUBSIDIARIES  
CASH OPERATING PROFIT (UNAUDITED)  
(NON-GAAP)  
SIX MONTHS ENDED June 30,

(dollars in thousands)

	<b>2017</b>	<b>2016</b>	<b>\$ Change</b>	<b>% Change</b>
Revenue	\$ 27,014	\$ 25,211	\$ 1,803	7.2%
Gross profit	17,862	17,323	539	3.1%
	66.1%	68.7%		
Operating costs	17,519	16,636	883	5.3%
Amortization of intangibles	1,179	1,182	(3)	(0.3%)
One-time costs	-	2,312	(2,312)	n/m
Operating loss	(836)	(2,807)	1,971	(70.2%)
Non cash operating costs	2,248	1,769	479	27.1%
One-time costs	-	2,312	(2,312)	n/m
Cash operating profit, excluding non-cash and one-time costs	\$ 1,412	\$ 1,274	\$ 138	10.8%