

COGENTIX MEDICAL INC /DE/

FORM 8-K (Current report filing)

Filed 11/07/17 for the Period Ending 11/07/17

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

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

FORM 8-K

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

Date of Report (Date of earliest event reported): **November 7, 2017**

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 Felfl 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 12n-2 of the Securities Exchange Act of 1034 (§240.12n-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.

Item 2.02. Results of Operations and Financial Condition

On November 7, 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 September 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* .

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Cogentix Medical, Inc. dated November 7, 2017 (furnished herewith)

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

EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
99.1	Press release of Cogentix Medical, Inc. dated November 7, 2017	Furnished herewith



Cogentix Medical Reports Third Quarter Results; Second Highest Quarterly Revenue in Company History

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

MINNEAPOLIS, MN, November 7, 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 third quarter ended September 30, 2017.

Third Quarter and Business Development Highlights

- Third quarter revenue was \$13.8 million, an increase of 3% over the third quarter of 2016.
- Revenue from Urology products totaled \$11.9 million, an increase of 4% over the third quarter of 2016.
- Gross profit was \$9.4 million or 68.3% of revenue, up \$0.4 million or 90 basis points over the year ago quarter.
- GAAP operating loss of \$0.2 million, compared to GAAP operating income of \$0.5 million in the same period last year.
- Cash operating profit, a non-GAAP financial measure that excludes non-cash items from GAAP operating income, was \$1.0 million in the third quarter as compared to cash operating profit of \$1.4 million in the year ago quarter.
- Earnings per share of break even, consistent with the prior year quarter.
- In September, the Company announced a \$2 million investment in Vensica Medical, a privately-held Israeli company. Vensica is developing an ultrasound based, needle-free drug delivery system with an initial indication for botulinum toxin (such as Botox® or Dysport®) to treat overactive bladder (OAB).

“We achieved the second highest quarterly revenue in the company’s history despite some short-term volatility in the timing of capital orders for our PrimeSight™ product line and reduced urology procedures as a result of practice closures due to hurricanes in Texas and the Southeast,” said Darin Hammers, President & CEO. “Our Urology business grew four percent in the third quarter, and we believe that this business will have a very strong finish to the year as several large capital orders for PrimeSight that were initially expected in the third quarter are now expected to close in the fourth quarter. We continue to execute our plan to build on our leadership position in the urology market and we are in the process of increasing our U.S. urology sales force to 51 territory managers, up from 46 at the end of the second quarter. Also in the third quarter, we completed our agreement with Vensica, which allows Cogentix to acquire, with a modest investment, a potentially revolutionary approach to administering botulinum toxin to treat overactive bladder and other possible indications. We are well positioned as we look forward to 2018 and beyond”.

Financial Results for the Third Quarter Ended September 30, 2017

For the quarter ended September 30, 2017, the Company achieved total revenue of \$13.8 million compared to \$13.4 million in the year ago quarter. The \$0.4 million increase in reported revenue is entirely attributable to the increase in Urology revenue, as non-core Industrial and Airway Management revenue remained stable at approximately \$1.9 million for this quarter and the year ago quarter. Revenue from PrimeSight totaled \$4.3 million, down \$0.1 million due to quarterly variability in the timing of capital orders. Urgent PC revenue totaled \$5.4 million compared to \$5.2 million in the year ago period. The \$0.2 million increase in Urgent PC revenue represents the first year over year increase in revenue since the third quarter of 2016, following the entrance of a large competitor in the PTNS market. Revenue from Macroplastique[®] and other urology products in the quarter totaled \$2.3 million, an increase of approximately \$0.4 million compared to the prior year period that is primarily attributable to our acquisition of Genesis Medical LTD (“Genesis”), a privately held U.K. company that distributes a variety of products to urologists, in July 2017.

Gross margin for the quarter ended September 30, 2017 was 68.3% compared with 67.4% in the year-ago period with the 90 basis point increase due to product mix. Operating expenses in the quarter totaled \$9.6 million compared to \$8.5 million in the same period of the prior year. The increase in operating expenses is attributable to approximately \$0.3 million of business development related expenses in the current quarter, an increase in sales and marketing expenses of \$0.4 million due to the increase in the number of sales representative for our Urology business, higher non-cash stock based compensation and the inclusion of the operating costs of Genesis since our acquisition in July 2017.

Operating loss for the quarter was \$0.2 million compared to an operating profit of \$0.5 million in the year ago period. Cash operating profit, a non-GAAP financial measure that is operating profit excluding all non-cash items, was \$1.0 million for the quarter ended September 30, 2017 compared to a cash operating profit of \$1.4 million (excluding one-time charges) in the year-ago quarter. Earnings per share was breakeven in both the current quarter and the year ago quarter.

At September 30, 2017, the Company’s cash and investments totaled \$26.8 million, compared to \$26.9 million at June 30, 2017. There were no borrowings under the Company’s \$7.0 million line of credit as of September 30, 2017.

Nine Month Financial Results Ended September 30, 2017

For the nine-month period ended September 30, 2017, total revenue of \$40.8 million represented an increase of 6% over the year ago period. This increase is due to 8% growth in the Urology business, partially offset by a decline in non-core Airway Management and Industrial revenue.

Operating loss for the nine months ended September 30, 2017 was \$1.0 million while cash operating profit (which excludes non-cash items) was \$2.4 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 3769188. To access a live webcast of the call, go to the investor relations section of Cogentix Medical’s website at ir.cogentixmedical.com.

An audio replay will be available for 30 days following the call at 855-859-2056 with the conference ID number 3769188. An archived webcast will also be available at ir.cogentixmedical.com.

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. '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, 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.

COGENTIX MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net sales	\$ 13,765,065	\$ 13,407,611	\$ 40,779,414	\$ 38,618,826
Cost of goods sold	4,370,408	4,369,574	13,522,655	12,257,933
Gross profit	9,394,657	9,038,037	27,256,759	26,360,893
	68.3%	67.4%	66.8%	68.3%
Operating expenses				
General and administrative	2,055,763	1,558,090	6,250,246	5,087,871
Research and development	1,234,468	1,218,669	3,556,977	3,255,603
Selling and marketing	5,697,552	5,203,477	16,699,590	16,272,678
Amortization of intangible assets	601,604	590,858	1,780,803	1,772,574
One-time costs	-	(53,887)	-	2,257,654
	9,589,387	8,517,207	28,287,616	28,646,380
Operating income (loss)	(194,730)	520,830	(1,030,857)	(2,285,487)
Other income (expense)				
Interest income	62,867	124	184,425	529
Interest expense	(6,122)	(380,803)	(19,747)	(1,147,470)
Other income	1,001	-	7,365	-
Foreign currency exchange gain (loss)	3,020	(14,905)	49,213	(40,311)
	60,766	(395,584)	221,256	(1,187,252)
Income (loss) before income taxes	(133,964)	125,246	(809,601)	(3,472,739)
Income tax expense	26,125	18,932	141,276	52,122
Net income (loss)	\$ (160,089)	\$ 106,314	\$ (950,877)	\$ (3,524,861)
Basic net income (loss) per common share	\$ 0.00	\$ 0.00	\$ (0.02)	\$ (0.14)
Diluted net income (loss) per common share	\$ 0.00	\$ 0.00	\$ (0.02)	\$ (0.14)
Weighted average common shares outstanding:				
Basic	60,126,357	25,633,172	59,888,906	25,509,584
Diluted	60,126,357	25,748,844	59,888,906	25,509,584

COGENTIX MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	<u>September 30, 2017</u>	<u>December 31, 2016</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,375,756	\$ 9,369,624
Short-term investments	10,656,566	13,573,057
Accounts receivable, net	7,178,811	6,770,838
Inventories	7,375,504	7,235,043
Other	987,982	571,527
Total current assets	<u>41,574,619</u>	<u>37,520,089</u>
Property, plant, and equipment, net	2,466,344	2,115,316
Goodwill	19,150,849	18,749,888
Other intangible assets, net	7,969,736	9,482,578
Long-term investments	719,417	5,344,004
Investment in equity interest	2,000,000	-
Deferred tax assets and other	160,716	163,427
Total assets	<u>\$ 74,041,681</u>	<u>\$ 73,375,302</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,051,979	\$ 2,689,035
Income tax payable	249,690	113,191
Accrued liabilities:		
Compensation	3,889,783	4,670,640
Deferred revenue	759,786	597,524
Accrued legal fees	56,241	34,667
Accrued foreign and domestic sales tax/VAT	476,355	327,992
Accrued employee expenses	92,134	88,557
Other	1,383,222	387,056
Total current liabilities	<u>8,959,190</u>	<u>8,908,662</u>
Accrued pension liability	244,940	308,918
Deferred rent	600,092	639,019
Other	618,936	278,780
Total liabilities	<u>10,423,158</u>	<u>10,135,379</u>
Total shareholders' equity	<u>63,618,523</u>	<u>63,239,923</u>
Total liabilities and shareholders' equity	<u>\$ 74,041,681</u>	<u>\$ 73,375,302</u>

COGENTIX MEDICAL, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (950,877)	\$ (3,524,861)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,336,095	2,364,673
Share-based compensation expense	1,131,482	440,000
Amortization of premium on available-for-sale securities	95,727	-
Deferred rent	(23,840)	6,836
Amortization of discount on related party debt	-	836,288
Proceeds from restricted stock exchanged for taxes	(17,690)	(57,343)
Other	8,003	(59,048)
Changes in operating assets and liabilities:		
Accounts receivable, net	270,965	1,399,070
Inventories	57,344	(1,637,619)
Other current assets	(154,906)	265,395
Accounts payable	(917,289)	394,573
Interest payable	-	261,505
Accrued compensation	(1,035,278)	1,796,568
Accrued liabilities, other	657,950	213,387
Accrued pension liability	(99,389)	(45,463)
Deferred revenue	250,174	220,789
Net cash provided by operating activities	<u>1,608,471</u>	<u>2,874,750</u>
Cash flows from investing activities:		
Proceeds from maturity of available-for-sale securities	9,900,000	-
Purchases of available-for-sale securities	(2,438,322)	-
Purchase of equity method investment	(2,000,000)	-
Purchases of property, plant and equipment	(680,416)	(232,331)
Acquisition of business, net of cash acquired	(178,042)	-
Net cash provided by (used in) investing activities	<u>4,603,220</u>	<u>(232,331)</u>
Cash flows from financing activities:		
Borrowings from line of credit	3,033,385	2,646,500
Repayments of line of credit	(3,033,385)	(2,646,500)
Payments to former Genesis shareholder	(7,354)	-
Repayments of secured borrowings	(180,755)	-
Proceeds from exercise of stock options	9,713	-
Financing costs	-	(375,839)
Net cash used in financing activities	<u>(178,396)</u>	<u>(375,839)</u>
Effect of exchange rates on cash and cash equivalents	<u>(27,163)</u>	<u>(4,949)</u>
Net increase in cash and cash equivalents	6,006,132	2,261,631
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>\$ 15,375,756</u>	<u>\$ 4,238,225</u>
Supplemental disclosure of cash flow information:		
Cash paid during the period for income tax	\$ 152,941	\$ 35,424
Cash paid during the period for interest	\$ 13,741	\$ 47,754

Non-GAAP Financial Measures :

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

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 income / 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.

Q3 Additional Information

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

(dollars in thousands)

Market/Product	2017	2016	\$ Change	% Change
PrimeSight	\$ 4,293	\$ 4,407	\$ (114)	(2.6%)
Urgent PC	5,360	5,210	150	2.9%
Macroplastique	1,715	1,671	44	2.6%
Other	550	208	342	164.4%
Total Urology	11,918	11,496	422	3.7%
Airway Management	762	845	(83)	(9.8%)
Industrial	1,085	1,067	18	1.7%
Total Other	1,847	1,912	(65)	(3.4%)
Combined Revenue	\$ 13,765	\$ 13,408	\$ 357	2.7%

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

(dollars in thousands)

	2017	2016	\$ Change	% Change
Revenue	\$ 13,765	\$ 13,408	\$ 357	2.7%
Gross profit	9,395	9,038	357	3.9%
	68.3%	67.4%		
Operating costs	8,988	7,980	1,008	12.6%
Amortization of intangibles	602	591	11	1.9%
One-time costs	-	(54)	54	n/m
Operating income (loss)	(195)	521	(716)	(137.4%)
Non-cash operating costs	1,220	977	243	24.9%
One-time costs	-	(54)	54	n/m
Cash operating profit, excluding one-time costs	\$ 1,025	\$ 1,444	\$ (419)	(29.0%)

YTD Additional Information

COGENTIX MEDICAL, INC. AND SUBSIDIARIES
REVENUE BY PRODUCT
NINE MONTHS ENDED September 30,

(dollars in thousands)

Market/Product	2017	2016	\$ Change	% Change
PrimeSight	\$ 13,735	\$ 10,885	\$ 2,850	26.2%
Urgent PC	15,602	15,720	(118)	(0.8%)
Macroplastique	5,237	5,510	(273)	(5.0%)
Other	1,071	798	273	34.2%
Total Urology	35,645	32,913	2,732	8.3%
Airway Management	2,235	2,468	(233)	(9.4%)
Industrial	2,899	3,238	(339)	(10.5%)
Total Other	5,134	5,706	(572)	(10.0%)
Combined Revenue	\$ 40,779	\$ 38,619	\$ 2,160	5.6%

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

(dollars in thousands)

	2017	2016	\$ Change	% Change
Revenue	\$ 40,779	\$ 38,619	\$ 2,160	5.6%
Gross profit	27,257	26,361	896	3.4%
	66.8%	68.3%		
Operating costs	26,507	24,616	1,891	7.7%
Amortization of intangibles	1,781	1,773	8	0.5%
One-time costs	-	2,258	(2,258)	n/m
Operating loss	(1,031)	(2,286)	1,255	(54.9%)
Non-cash operating costs	3,468	2,741	727	26.5%
One-time costs	-	2,258	(2,258)	n/m
Cash operating profit, excluding one-time costs	\$ 2,437	\$ 2,713	\$ (276)	(10.2%)