
**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**

March 20, 2019

Date of Report (date of earliest event reported)

**Establishment Labs Holdings Inc.
(Exact name of registrant as specified in its charter)**

**British Virgin Islands
(State or other jurisdiction of
incorporation or organization)**

**001-38593
(Commission File No.)**

**Not applicable
(I.R.S. Employer
Identification Number)**

**Building B15 and 25
Coyol Free Zone
Alajuela
Costa Rica**

(Address of principal executive offices) (Zip Code)

+506 2434 2400

(Registrant's telephone number, including area code)

N/A

(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))
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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.

Item 2.02. Results of Operations and Financial Condition.

On March 20, 2019, Establishment Labs Holdings Inc. (the “Company”) issued a press release announcing the Company’s financial results for the three and twelve months ended December 31, 2018 and recent corporate highlights. A copy of the press release is furnished herewith as Exhibit 99.1.*

* The information in Item 2.02 of this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 [Press Release of Establishment Labs Holdings Inc. dated March 20, 2019.](#)

SIGNATURES

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

ESTABLISHMENT LABS HOLDINGS INC.

Dated: March 20, 2019

By: /s/ Renee M. Gaeta

Name: Renee M. Gaeta

Title: Chief Financial Officer



Establishment Labs Reports Fourth Quarter and Full Year 2018 Financial Results

NEW YORK, Mar. 20, 2019 (GLOBE NEWSWIRE) – Establishment Labs Holdings Inc. (NASDAQ: ESTA), a medical technology company focused on women’s health, initially in the breast aesthetics and reconstruction market, today announced its financial results for the fourth quarter and full year ended December 31, 2018.

Business Highlights

- Full year 2018 worldwide sales of \$61.2 million, representing a 76.5% increase year-over-year.
- Fourth quarter 2018 worldwide sales of \$16.4 million, a 38.8% increase year-over-year.
- Ongoing revenue growth fueled by strong adoption of the Company’s Motiva Implants across addressable markets.
- Well positioned to continue capturing share in existing and new markets; poised to launch in Thailand and Taiwan in 2019.
- Reached IDE study-defined enrollment targets for the aesthetic cohorts, including primary augmentation and revision.
- Submitted the Company’s smooth anatomical tissue expander and the latest version of Motiva Ergonomix for CE Mark registration, which signal expansion into breast reconstruction and minimally invasive surgeries within breast aesthetics, respectively.

“2018 was an outstanding year for Establishment Labs as we continued to execute on our strategy of bringing our Motiva Implants to more women worldwide,” said Juan José Chacón-Quirós, Chief Executive Officer of Establishment Labs. “Our performance is the result of our clearly differentiated, innovative product portfolio and the trust physicians and patients are placing in us and our technology. With the momentum we are carrying into 2019, we should continue to deliver top line growth.”

Fourth Quarter and Full Year 2018 Financial Results

Revenues increased \$4.6 million, or 38.8%, to \$16.4 million for the fourth quarter of 2018, as compared to \$11.8 million in the same period in 2017. Revenues for the full year ended December 31, 2018 increased \$26.5 million, or 76.5%, to \$61.2 million, as compared to \$34.7 million for the full year ended December 31, 2017. Increased sales of Motiva Implants® were primarily driven by the continued volume growth across all addressable markets, alongside the improved business performance driven by the Company’s direct market strategies in Brazil and Europe.

Gross profit for the fourth quarter of 2018 was \$9.9 million, or 60.2% of revenues, compared to gross profit of \$6.6 million, or 55.6% of revenues in the same period in 2017. Gross profit for the full year ended December 31, 2018 was \$36.1 million, or 59.0% of revenues, as compared to gross profit of \$17.7 million, or 51.0% of revenues, in the same period in 2017. The increase in gross margin was primarily due to an increase in production volume and continued contribution of direct markets revenues with generally higher average selling prices.

Total operating expenses for the fourth quarter of 2018 increased \$7.3 million, or 65.9%, to \$18.5 million, as compared to \$11.2 million in the same period in 2017.

Sales, general and administrative expenses for the fourth quarter of 2018 increased \$6.1 million, or 70.4%, to \$14.8 million, as compared to \$8.7 million in the same period in 2017, due to the hiring of additional sales and administrative employees, an increase in consulting and audit fees and higher insurance costs.

Research and development expenses for the fourth quarter of 2018 increased \$1.2 million, or 49.8%, to \$3.7 million, as compared to \$2.4 million in the same period in 2017, primarily due to investments related to the Company’s pivotal clinical trial in the United States that is required to obtain FDA approval for Motiva.

Net loss for the fourth quarter of 2018 was \$10.5 million, as compared to a net loss of \$7.1 million in the same period in 2017, a result of the Company's continued growth and investments in operations to support its expected business needs.

For the full year ended December 31, 2018, net loss was \$21.1 million, a decrease of \$13.8 million, or 39.5%, as compared to a net loss of \$34.9 million in the same period in 2017. The decrease in net loss for the full year 2018 is due to change in fair value of derivatives related to the fair value of derivatives embedded in a credit agreement entered in August 2017 with Madryn Health Partners, LP.

Total operating expenses for the full year ended December 31, 2018 were \$60.0 million, an increase of \$22.3 million, as compared to operating expenses of \$37.7 million in the same period in 2017. The year-over-year increase in operating expenses of 59.1% is primarily attributable to the initiation of the Company's pivotal clinical trial in the United States, the ongoing expansion of its operations costs and the associated costs of operating as a public company.

The Company's cash balance as of December 31, 2018 was \$52.6 million.

Conference Call

Establishment Labs will host a conference call and webcast today at 4:30 p.m. Eastern Time to discuss its financial results. The conference call can be accessed by dialing (877) 376-9925 (U.S. and Canada) or (629) 228-0732 (international), and using the conference ID: 9089791. In addition, the webcast will be available on the Investor Relations section of the Company's website at www.establishmentlabs.com.

A replay of the call will be available starting on March 20, 2019 at 7:30 p.m. Eastern Time, through April 19, 2019 at 7:30 p.m. Eastern Time. To access the replay, dial (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international) and use the replay conference ID: 9089791. The webcast will be available on the Investor Relations section of the Company's website for 30 days following the completion of the call.

About Establishment Labs

Establishment Labs Holdings Inc. (NASDAQ: ESTA) is a global medical technology company focused on women's health, initially in the breast aesthetics and reconstruction market, by designing, developing, manufacturing and marketing an innovative portfolio of silicone gel-filled breast implants, branded as Motiva Implants®, the centerpiece of the MotivaImagine® platform. Motiva Implants® are produced at our two manufacturing sites that are compliant with ISO13485:2016, FDA 21 CFR 820 under the MDSAP program, and are currently sold in over 60 countries through exclusive distributors or the Company's direct salesforce. In March 2018, Establishment Labs received approval for an investigational device exemption (IDE) from the FDA and initiated the Motiva Implant® clinical trial in the United States in April 2018. In addition to Motiva Implants®, Establishment Labs' product and technologies portfolio includes the Divina® 3D Simulation System, MotivaImagine® Centers and other products and services. Please visit the website for additional information: www.establishmentlabs.com.

Forward – Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). You can find many (but not all) of these statements by looking for words such as "approximates," "believes," "expects," "anticipates," "estimates," "intends," "plans," "would," "may" or other similar expressions in this press release, and includes statements related to the expected growth in sales of Motiva Implants, product development and the PMA clinical trial currently being conducted to obtain approval of Motiva Implants in the United States. Any statements that refer to projections of our future financial or operating performance, anticipated trends in our business, our goals, strategies, focus and plans, and other characterizations of future events or circumstances, including statements expressing general optimism about future operating results, are forward-looking statements. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995. We caution investors that any forward-looking statements presented in this report, or that we may make orally or in writing from time to time, are expressions of our beliefs and expectations based on currently available information at the time such statements are made. Such statements are based on assumptions, and the actual outcome will be affected by known and unknown

risks, trends, uncertainties and factors that are beyond our control. Although we believe that our assumptions are reasonable, they are not guarantees of future performance, and some will inevitably prove to be incorrect. As a result, our actual future results may differ from our expectations, and those differences may be material. Factors that could cause or contribute to these differences include, among others, those risks and uncertainties discussed in the Company's Form S-1, quarterly reports on Form 10-Q, and other filings made by the Company with the Securities and Exchange Commission. The risks included in those documents are not exhaustive, and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for us to predict all such risk factors, nor can we assess the impact of all such risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We are not undertaking any obligation to update any forward-looking statements. Accordingly, investors should use caution in relying on past forward-looking statements, which are based on known results and trends at the time they are made, to anticipate future results or trends.

ESTABLISHMENT LABS HOLDINGS INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Revenue	\$ 16,397	\$ 11,811	\$ 61,208	\$ 34,681
Cost of revenue	6,524	5,248	25,090	16,979
Gross profit	9,873	6,563	36,118	17,702
Operating expenses:				
Sales, general and administrative	14,833	8,707	47,295	30,821
Research and development	3,661	2,444	12,687	6,864
Total operating expenses	18,494	11,151	59,982	37,685
Loss from operations	(8,621)	(4,588)	(23,864)	(19,983)
Interest income	7	10	16	19
Interest expense	(2,266)	(1,788)	(8,814)	(10,420)
Change in fair value of derivative instruments	(51)	(324)	15,894	(2,428)
Change in fair value of contingent consideration	(281)	—	(1,727)	—
Initial public offering expenses	—	—	—	(1,585)
Other income (expense), net	850	(374)	(2,388)	(395)
Loss before income taxes	(10,362)	(7,064)	(20,883)	(34,792)
Benefit (provision) for income taxes	(152)	(69)	(215)	(105)
Net loss	\$ (10,514)	\$ (7,133)	\$ (21,098)	\$ (34,897)
Basic and diluted loss per share	\$ (0.52)	\$ (2.00)	\$ (1.22)	\$ (3.41)
Weighted average outstanding shares used for basic and diluted net loss per share	20,286,812	3,563,977	17,350,705	10,230,586

ESTABLISHMENT LABS HOLDINGS INC.
Condensed Consolidated Balance Sheets
(In thousands, except share data)

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash	\$ 52,639	\$ 10,864
Accounts receivable, net of allowance for doubtful accounts of \$926 and \$1,512	17,648	13,108
Inventory, net	24,845	13,173
Prepaid expenses and other current assets	4,303	2,237
Total current assets	99,435	39,382
Long-term assets:		
Property and equipment, net of accumulated depreciation of \$5,230 and \$3,179	12,913	13,500
Goodwill	465	465
Intangible assets, net of accumulated amortization of \$1,213 and \$573	3,445	3,401
Restricted cash	—	75
Other non-current assets	315	272
Total assets	\$ 116,573	\$ 57,095
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 6,239	\$ 9,131
Accrued liabilities	6,125	2,326
Notes payable related party, including accrued interest	—	4,921
Note payable, Madryn, net of debt discount and issuance costs	—	19,167
Madryn put option	—	20,302
Madryn call option	—	360
Other liabilities, short term	4,083	1,228
Total current liabilities	16,447	57,435
Long-term liabilities:		
Note payable, Madryn, net of debt discount and issuance costs	22,322	—
Madryn put option	4,768	—
Madryn call option	—	—
Other liabilities, long term	3,551	4,673
Total liabilities	47,088	62,108
Shareholders' equity (deficit):		
Total shareholders' equity (deficit)	69,485	(5,013)
Total liabilities and shareholders' equity (deficit)	\$ 116,573	\$ 57,095

Investor Relations Contact

Kaitlyn Rawlett
Weber Shandwick
krawlett@webershandwick.com