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

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FORM 8-K

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

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November 13, 2018

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**Date of Report (date of earliest event  
reported)**

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

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**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)**

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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.

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

On November 13, 2018, Establishment Labs Holdings Inc. (the “Company”) issued a press release announcing the Company’s financial results for the three and nine months ended September 30, 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 November 13, 2018.](#)

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**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: November 13, 2018

By: /s/ Renee Gaeta

Name: Renee Gaeta

Title: Chief Financial Officer




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## Establishment Labs Reports Third-Quarter 2018 Financial Results

**NEW YORK, November 13, 2018 (GLOBE NEWSWIRE)**– Establishment Labs Holdings Inc. (NASDAQ: ESTA), a medical technology company focused on improving patient safety and aesthetic outcomes, initially in the breast aesthetics and reconstruction market, today announced its financial results for the third quarter ended September 30, 2018.

### **Business Highlights**

- Third-quarter 2018 revenue of \$16.3 million, representing an increase of 122.4% year-over-year.
- Increase in revenue driven by the continued adoption of Motiva Implants® across addressable markets.
- Continued improvement in gross margins in the third quarter of 62.1%, an increase of 26.2% year-over-year.
- Launching a targeted expansion of direct sales in the fourth quarter in the United Kingdom, Germany and Spain to meet the growing demands in those markets.

“We are pleased to report a record quarterly performance, which was driven by the continued adoption of Motiva Implants® across our addressable markets,” said Juan José Chacón-Quirós, Founder and Chief Executive Officer of Establishment Labs. “While we remained focused on executing against our commercial strategy during the quarter, we continued to take important steps to position ourselves for long-term, sustainable growth. We invested in direct sales forces in Europe, enhanced our infrastructure and manufacturing facilities, and continued key clinical and R&D programs, which will allow us to continue to bring differentiated products to market.”

### **Third-Quarter 2018 and Year-to-Date Financial Results**

Revenues increased \$9.0 million, or 122.4%, to \$16.3 million for the three months ended September 30, 2018, as compared to \$7.3 million for the three months ended September 30, 2017. Revenues for the nine months ended September 30, 2018 increased \$21.9 million, or 95.9%, to \$44.8 million, as compared to \$22.9 million for the nine months ended September 30, 2017. The increase in revenue in the third quarter was driven by the increased sales of Motiva Implants®, expansion of the Company’s direct sales force across key markets, and the continued strong performance of our distributors worldwide.

Gross profit for the third quarter of 2018 was \$10.1 million, or 62.1% of revenues, compared to gross profit of \$3.6 million, or 49.2% of revenues, in the same period in 2017. Gross profit for the nine months ended September 30, 2018 was \$26.2 million, or 58.6% of revenues, as compared to gross profit of \$11.1 million, or 48.7% of revenues, in the same period in 2017.

The increase in gross margin was primarily due to an increase in production volume, improved production efficiencies and the addition of direct market revenues with generally higher average selling prices.

Total operating expenses for the third quarter of 2018 were \$16.2 million, compared to operating expenses of \$9.6 million in the same period in 2017. Sales, general and administrative expenses increased \$4.8 million, or 59.5%, to \$13.0 million due to the hiring of additional sales and administrative employees, an increase in consulting and audit fees and an increase in stock compensation expense.

Research and development expenses increased \$1.7 million, or 121.0%, to \$3.2 million due to investments related to the Company’s FDA clinical trial in the United States and enhancing the Company’s product pipeline and infrastructure.

Total operating expenses for the nine months ended September 30, 2018 were \$41.5 million, compared to operating expenses of \$26.5 million in the same period in 2017. While this reflects a 56.4% year over year increase, it is not attributable to our direct sales force transitions.

Net income for the third quarter was \$1.3 million up from net loss of \$10.7 million in the same period in 2017, while net losses for the nine months ended September 30, 2018 decreased to \$10.6 million from \$27.8 million in the same

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period in 2017. The significant decrease in net losses is due to change in fair value of derivatives related to the fair value of Madryn derivatives embedded in the credit agreement we entered into in August 2017.

The Company's cash balance as of September 30, 2018 was \$65.6 million.

#### **Conference Call**

Establishment Labs will host a conference call and webcast today at 8:30 a.m. Eastern Time to discuss its financial results. The dial-in number to access the call is U.S./Canada (877) 376-9925, International (629) 228-0732, and the conference ID is 5096498. A live webcast of the conference call will be available on the Investor Relations section of the Company's website at [www.establishmentlabs.com](http://www.establishmentlabs.com).

A replay of the call will be available starting on November 13, 2018 at 11:30 a.m. Eastern Time, through December 12, 2018 at 11:59 p.m. Eastern Time. To access the replay, dial (855) 859-2056 for domestic callers and (404) 537-3406 for international callers and use the replay conference ID 5096498. 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 improving patient safety and aesthetic outcomes, 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, Puregraft and MotivaImagine® Centers. Please visit the website for additional information: <https://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 U.S. 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, 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*

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*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.*

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	\$ 16,286	\$ 7,324	\$ 44,811	\$ 22,870
Cost of revenue	6,173	3,720	18,566	11,731
Gross profit	10,113	3,604	26,245	11,139
Operating expenses:				
Sales, general and administrative	12,985	8,139	32,462	22,114
Research and development	3,174	1,436	9,026	4,420
Total operating expenses	16,159	9,575	41,488	26,534
Loss from operations	(6,046)	(5,971)	(15,243)	(15,395)
Interest income	5	3	9	9
Interest expense	(2,204)	(6,691)	(6,548)	(8,632)
Change in fair value of derivative instruments	11,420	2,095	15,945	(2,104)
Change in fair value of contingent consideration	(694)	—	(1,446)	—
Initial public offering expenses	—	—	—	(1,585)
Other income (expense), net	(1,274)	(79)	(3,238)	(21)
Income (loss) before income taxes	1,207	(10,643)	(10,521)	(27,728)
Benefit (provision) for income taxes	99	(31)	(63)	(36)
Net income (loss)	\$ 1,306	\$ (10,674)	\$ (10,584)	\$ (27,764)
Basic net income (loss) per share	\$ 0.07	\$ (1.21)	\$ (0.66)	\$ (3.15)
Diluted net income (loss) per share	0.06	(1.21)	(0.66)	(3.15)
Weighted average outstanding shares used for basic net income (loss) per share	19,152,995	8,824,807	16,146,675	8,824,807
Weighted average outstanding shares used for diluted net income (loss) per share	20,123,297	8,824,807	16,146,675	8,824,807

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

	September 30, 2018	December 31, 2017
<b>Assets</b>		
Current assets:		
Cash	\$ 65,577	\$ 10,864
Accounts receivable, net of allowance for doubtful accounts of \$1,488 and \$1,512	18,248	13,108
Inventory	15,365	13,173
Prepaid expenses and other current assets	5,597	2,237
Total current assets	104,787	39,382
Long-term assets:		
Property and equipment, net of accumulated depreciation of \$4,637 and \$3,179	12,892	13,500
Goodwill	465	465
Intangible assets, net of accumulated amortization of \$1,038 and \$573	2,970	3,401
Restricted cash	75	75
Other non-current assets	283	272
Total assets	\$ 121,472	\$ 57,095
<b>Liabilities and shareholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 5,492	\$ 9,131
Accrued liabilities	5,861	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	3,498	1,228
Total current liabilities	14,851	57,435
Long-term liabilities:		
Note payable, Madryn, net of debt discount and issuance costs	21,486	—
Madryn put option	4,717	—
Madryn call option	—	—
Other liabilities, long term	3,431	4,673
Total liabilities	44,485	62,108
Shareholders' equity (deficit):		
Total shareholders' equity (deficit)	76,987	(5,013)
Total liabilities and shareholders' equity (deficit)	\$ 121,472	\$ 57,095

**Investor Relations Contact**

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