
**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**

August 13, 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Shares, No Par Value	ESTA	The NASDAQ Capital Market

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 August 13, 2019, Establishment Labs Holdings Inc. (the “Company”) issued a press release announcing the Company’s financial results for the three and six months ended June 30, 2019 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release of Establishment Labs Holdings Inc. dated August 13, 2019.</u>

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: August 13, 2019

By: /s/ Renee M. Gaeta

Name: Renee M. Gaeta

Title: Chief Financial Officer



Establishment Labs Reports Second Quarter 2019 Financial Results

August 13, 2019

NEW YORK -- 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 second quarter ended June 30, 2019.

Business Highlights

- Reported second quarter 2019 worldwide sales of \$21.7 million, an increase of 58.2% year-over-year.
- Grew revenue through the ongoing strong adoption of Motiva Implants® across addressable markets, with double digit growth in Latin America, Europe, Middle East and Asia Pacific, as well as by the successful transition to a direct sales model in Europe and Brazil.
- To date, Motiva Implants® continue to be unaffected by the recent safety related bans on silicone gel filled breast implants associated with BIA-ALCL from international regulatory bodies.
- Launched Motiva® in Taiwan and Thailand, one of the largest breast aesthetic markets in Asia.
- Continued to progress its U.S. FDA clinical trial, with all surgeries in the primary and revision augmentation cohorts completed and enrollment progressing in the reconstruction cohorts.
- Raised full-year 2019 revenue guidance to a range of \$84.0 to \$86.0 million from \$80.0 to \$84.0 million previously.

"During the second quarter, we continued to prove the strength of our Women's Health story, driving strong sales growth of over 58%, while regulatory agencies worldwide are placing restrictions on the rest of the industry," said Juan José Chacón-Quirós, Chief Executive Officer of Establishment Labs. "We believe this growth trajectory speaks to the clear differentiation and improved safety and aesthetic outcomes of our product portfolio, as well as to the effectiveness of the direct sales force model that we have implemented in Europe and Brazil.

"In parallel with our ongoing research and development activities, our U.S. FDA clinical trial is progressing with all surgeries now complete in the primary and revision augmentation cohorts and enrollment continuing in the reconstruction cohorts. Importantly, we are implementing a bifurcation strategy in the U.S. that will allow us to submit for the aesthetic cohorts sooner while pursuing approval for the reconstruction cohorts separately. I am very pleased with our progress to this point and I look forward to a strong second half of the year," Mr. Chacón-Quirós concluded.

Second Quarter 2019 Financial Results

Revenues increased \$8.0 million, or 58.2 %, to \$21.7 million for the second quarter of 2019, as compared to \$13.7 million in the same period in 2018. The increase was primarily due to increased sales of Motiva Implants®, driven by greater market penetration in existing geographies and commencement of sales in new geographies including certain European direct markets.

Gross profit for the second quarter of 2019 was \$13.0 million, or 60.0 % of revenues, compared to gross profit of \$8.2 million, or 59.9 % of revenues in the same period in 2018.

Total operating expenses for the second quarter of 2019 increased \$7.9 million, or 54.1%, to \$22.4 million, as compared to \$14.5 million in the same period in 2018 driven by continued investment across the company, including the expansion into European direct markets and the related supporting systems required for this growth.

SG&A expense increased \$7.6 million, or 69.9%, to \$18.4 million for the three months ended June 30, 2019, compared to \$10.8 million for the three months ended June 30, 2018. The increase in SG&A was primarily due to a \$3.1 million increase in personnel costs as a result of the hiring of additional sales, marketing and administrative

employees, a \$2.3 million increase in sales and administrative consulting fees, including stock compensation, a \$1.1 million increase in sales commissions and a \$0.7 million increase in marketing expenses.

R&D expenses increased \$0.3 million, or 8.0%, to \$4.0 million for the three months ended June 30, 2019, compared to \$3.7 million for the three months ended June 30, 2018. The increase in R&D expenses was primarily due to \$0.5 million increase in R&D personnel costs and \$0.1 million increase in expenditures related to the initiation of our Premarket Approval (PMA) clinical study in the United States, primarily attributable to third parties fees for set-up and management of the clinical trial.

Net losses for the second quarter of 2019 was \$9.0 million, as compared to a net loss of \$5.4 million in the same period in 2018, a result of the Company's continued growth and investments in operations to support the expected increase in market demand.

The Company's cash balance as of June 30, 2019 was \$31.9 million and subsequently the Company has drawn the \$25.0 million remaining from its credit facility on August 12, 2019.

Full Year 2019 Financial Outlook

The Company anticipates full-year 2019 revenues in the range of \$84.0 to \$86.0 million, up from the previous range of \$80.0 million to \$84.0 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 conference call can be accessed by dialing (877) 376-9925 (U.S. and Canada) or (629) 228-0732 (international) and using the conference ID: 1168908. In addition, the webcast will be available on the Investor Relations section of the Company's website at www.establishmentlabs.com.

The webcast will be available for 30 days following the call on the Investor Relations section of the Company's website at www.establishmentlabs.com.

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 commercially available in 75 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 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 annual report on Form 10-K filed on March 20, 2019, 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)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue	\$ 21,684	\$ 13,709	\$ 42,462	\$ 28,525
Cost of revenue	8,672	5,492	18,198	12,393
Gross profit	13,012	8,217	24,264	16,132
Operating expenses:				
Sales, general and administrative	18,394	10,829	34,450	19,477
Research and development	4,001	3,705	7,585	5,852
Total operating expenses	22,395	14,534	42,035	25,329
Loss from operations	(9,383)	(6,317)	(17,771)	(9,197)
Interest income	4	—	10	4
Interest expense	(2,521)	(2,173)	(4,763)	(4,344)
Change in fair value of derivative instruments	2,640	5,830	2,608	4,525
Change in fair value of contingent consideration	137	(389)	362	(752)
Other income (expense), net	118	(2,159)	(186)	(1,964)
Loss before income taxes	(9,005)	(5,208)	(19,740)	(11,728)
Provision for income taxes	(35)	(152)	(79)	(162)
Net loss	\$ (9,040)	\$ (5,360)	\$ (19,819)	\$ (11,890)
Basic and diluted net loss per share	\$ (0.44)	\$ (0.35)	\$ (0.97)	\$ (0.79)
Weighted average outstanding shares used for basic and diluted net loss per share	20,448,643	15,351,899	20,407,912	14,981,070

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

	June 30, 2019	December 31, 2018
	(Unaudited)	
Assets		
Current assets:		
Cash	\$ 31,870	\$ 52,639
Accounts receivable, net of allowance for doubtful accounts of \$902 and \$926	21,312	17,648
Inventory	26,540	24,845
Prepaid expenses and other current assets	4,455	4,303
Total current assets	84,177	99,435
Long-term assets:		
Property and equipment, net of accumulated depreciation	16,708	12,913
Goodwill	465	465
Intangible assets, net of accumulated amortization	3,081	3,445
Other non-current assets	370	315
Total assets	\$ 104,801	\$ 116,573
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 8,531	\$ 6,239
Accrued liabilities	8,718	6,125
Other liabilities, short term	4,137	4,083
Total current liabilities	21,386	16,447
Long-term liabilities:		
Note payable, Madryn, net of debt discount and issuance costs	24,053	22,322
Madryn put option	2,160	4,768
Other liabilities, long term	3,415	3,551
Total liabilities	51,014	47,088
Total shareholders' equity	53,787	69,485
Total liabilities and shareholders' equity	\$ 104,801	\$ 116,573

Investor Relations Contact

Jeremy Feffer
LifeSci Advisors, LLC
212-915-2568
jeremy@lifesciadvisors.com