



Establishment Labs Reports Third Quarter 2019 Financial Results

November 12, 2019

NEW YORK, Nov. 12, 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 third quarter ended September 30, 2019.

Business Highlights

- Reported third quarter 2019 worldwide sales of \$22.9 million, an increase of 40% year-over-year, and the fifth consecutive quarter of record performance.
- Continued to advance FDA clinical trial, with enrollment progressing in the reconstruction cohorts.
- Received notice of allowance for a key U.S. patent application covering the company's implant surface technology.
- Announced 510(k) submission for its SmoothSilk® anatomical tissue expander.
- Raised full-year 2019 revenue guidance to a range of \$86.0 to \$87.0 million, from a prior guidance range of \$84.0 to \$86.0 million, reflecting minimum growth of 40% over full-year 2018.
- Operating cash burn is expected to decline in 2020 as the business achieves scale.

"During the third quarter, we sustained our sales momentum globally, generating 40% revenue growth over the prior year and delivering our fifth consecutive quarter of record revenue performance," said Juan José Chacón-Quirós, Chief Executive Officer of Establishment Labs. "Our strong growth in the third quarter was driven by increased awareness of both the safety and aesthetic differentiation of Motiva Implants versus others on the market. This is reflected not only by our science and patient data, but also by the increasing number of surgeons who are providing independent verification, in publications and industry conferences, of the merits of our technology platform.

"Women's health continues to be at the forefront of everything we do, and in parallel with our commercial initiatives, such as the establishment of a highly effective direct sales force in Europe and Brazil, we continue to invest in research and development to both expand our product offerings while reinforcing our position as a leading safety innovator in the field," concluded Mr. Chacón-Quirós.

Third Quarter 2019 Financial Results

Revenues increased \$6.6 million, or 40%, to \$22.9 million for the third quarter of 2019, as compared to \$16.3 million in the same period in 2018. The increase was primarily driven by double digit growth in the company's direct markets, along with strong performance in distributor markets.

Gross profit for the third quarter was \$14.2 million, or 62.3% of revenues, which compares favorably to 60.0% revenues in the second quarter of 2019 and is similar to the third quarter of 2018. The sequential increase in gross margin percentage was driven primarily by increased sales volumes. The company's gross profit percentage was negatively impacted by 2.1% during the quarter due to amortization related to the fair value of inventory recorded from its asset acquisitions from distributors in recent quarters. As the company sells through the remaining acquired inventory, the impact of this amortization dissipates.

Total operating expenses for the third quarter of 2019 were \$23.0 million, an increase of 42.4% compared to \$16.2 million in the third quarter of 2018. This increase was driven by continued investment across the company to support current and future growth, including a comprehensive upgrade of the company's enterprise resource planning system with SAP.

SG&A expenses increased \$6.2 million, or 48.1%, to \$19.2 million. The increase in SG&A was primarily due to (1) a \$3.2 million dollar increase in personnel and related costs as a result of hiring additional sales, marketing and administrative employees, (2) a \$1.2 million dollar increase in legal and consulting costs, (3) a \$0.7 million dollar increase in sales commissions, and (4) a \$0.7 million dollar increase in marketing expenses.

R&D expenses increased approximately 19% to \$3.8 million, from \$3.2 million in the third quarter of 2018. The increase in R&D expenses was primarily due to costs related to the company's FDA clinical study in the United States.

Net loss for the third quarter of 2019 was \$12.8 million dollars, as compared to net income of \$1.3 million dollars in the same period in 2018, due to the required growth in operations to support expected increases in market demand. As a reminder, the third quarter net income in 2018 was affected by a non-cash gain on the fair value of debt related derivatives of \$11.4 million dollars.

The Company's cash balance as of September 30, 2019 was \$42.6 million.

Updated Full Year 2019 Financial Outlook

Reflecting strong revenue growth to date, the company is increasing its full year 2019 revenue guidance to a range of \$86.0 to \$87.0 million from the

previous range of \$84.0 million to \$86.0 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) 407-0792 (U.S. and Canada) or (201) 689-8263 (international) and using the conference ID: 13695591. 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 80 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue	\$ 22,854	\$ 16,286	\$ 65,316	\$ 44,811
Cost of revenue	8,616	6,173	26,814	18,566
Gross profit	14,238	10,113	38,502	26,245
Operating expenses:				
Sales, general and administrative	19,227	12,985	53,677	32,462
Research and development	3,776	3,174	11,361	9,026
Total operating expenses	23,003	16,159	65,038	41,488
Loss from operations	(8,765)	(6,046)	(26,536)	(15,243)
Interest income	3	5	13	9
Interest expense	(1,805)	(2,204)	(6,568)	(6,548)
Change in fair value of derivative instruments	235	11,420	2,843	15,945
Change in fair value of contingent consideration	205	(694)	567	(1,446)

Other income (expense), net	(2,340)	(1,274)	(2,526)	(3,238)
Income (loss) before income taxes	(12,467)	1,207	(32,207)	(10,521)
Benefit (provision) for income taxes	(308)	99	(387)	(63)
Net income (loss)	<u>\$ (12,775)</u>	<u>\$ 1,306</u>	<u>\$ (32,594)</u>	<u>\$ (10,584)</u>
Basic net income (loss) per share	<u>\$ (0.62)</u>	<u>\$ 0.07</u>	<u>\$ (1.59)</u>	<u>\$ (0.66)</u>
Diluted net income (loss) per share	<u>\$ (0.62)</u>	<u>\$ 0.06</u>	<u>\$ (1.59)</u>	<u>\$ (0.66)</u>
Weighted average outstanding shares used for basic net income (loss) per share	<u>20,620,828</u>	<u>19,152,995</u>	<u>20,478,603</u>	<u>16,146,675</u>
Weighted average outstanding shares used for diluted net income (loss) per share	<u>20,620,828</u>	<u>20,123,297</u>	<u>20,478,603</u>	<u>16,146,675</u>

ESTABLISHMENT LABS HOLDINGS INC.

Condensed Consolidated Balance Sheets
(In thousands, except share data)

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
	(Unaudited)	
Assets		
Current assets:		
Cash	\$ 42,559	\$ 52,639
Accounts receivable, net of allowance for doubtful accounts of \$959 and \$926	22,022	17,648
Inventory, net	26,387	24,845
Prepaid expenses and other current assets	6,968	4,303
Total current assets	<u>97,936</u>	<u>99,435</u>
Long-term assets:		
Property and equipment, net of accumulated depreciation	16,650	12,913
Goodwill	465	465
Intangible assets, net of accumulated amortization	2,893	3,445
Other non-current assets	312	315
Total assets	<u>\$ 118,256</u>	<u>\$ 116,573</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 9,383	\$ 6,239
Accrued liabilities	9,866	6,125
Other liabilities, short term	1,097	4,083
Total current liabilities	<u>20,346</u>	<u>16,447</u>
Long-term liabilities:		
Note payable, Madryn, net of debt discount and issuance costs	47,770	22,322
Madryn put option	3,281	4,768
Other liabilities, long term	3,055	3,551
Total liabilities	<u>74,452</u>	<u>47,088</u>
Shareholders' equity:		
Total liabilities and shareholders' equity	<u>\$ 118,256</u>	<u>\$ 116,573</u>

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