

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Apollo Endosurgery, Inc.

Form: 8-K

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**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): **May 4, 2020**

Apollo Endosurgery, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-35706
(Commission File Number)

16-1630142
(IRS Employer Identification No.)

**1120 S. Capital of Texas Highway
Building 1, Suite #300
Austin, Texas 78746**
(Address of principal executive offices) (Zip Code)
(512) 279-5100
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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 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.

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value per share	APEN	The Nasdaq Global Market

Item 2.02 Results of Operations and Financial Condition.

On May 4, 2020, the Company issued a press release reporting its financial results for the fiscal quarter ended March 31, 2020. A copy of the Company's press release is attached hereto as Exhibit 99.1.

The press release attached hereto as Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description of Document
99.1	<u>Press release, issued by Apollo Endosurgery, Inc., dated May 4, 2020.</u>

SIGNATURE

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.

APOLLO ENDOSURGERY, INC.

Dated: May 4, 2020

By: /s/ Todd Newton

Name: Todd Newton

Title: Chief Executive Officer

APOLLO ENDOSURGERY, INC. REPORTS FIRST QUARTER 2020 RESULTS**Conference Call to Discuss Results Today at 3:30 p.m. CT / 4:30 p.m. ET**

AUSTIN, Texas (May 4, 2020) - Apollo Endosurgery, Inc. ("Apollo") (Nasdaq: APEN), a global leader in less invasive medical devices for gastrointestinal and bariatric procedures, today announced financial results for the first quarter ended March 31, 2020.

First Quarter 2020 and Recent Highlights

- First quarter U.S. OverStitch™ Endoscopic Suturing System ("ESS") sales increased 25% to \$3.8 million
- Implemented cost reduction initiatives to preserve liquidity in response to the COVID-19 pandemic, which are expected to save more than \$7 million in cash during the second quarter

Todd Newton, CEO of Apollo, said, "The first two months of 2020 started very well for Apollo, particularly in respect of ESS demand in our direct markets. However, the COVID-19 pandemic and resulting actions brought an unprecedented decline in the allocation of global healthcare resources for elective or deferrable medical procedures, including those that use our products, and the impact on our March sales was significant. We expect the second quarter of 2020 will continue to be very challenging. In response, we have implemented aggressive cost reduction measures for the second quarter to preserve capital to the maximum extent possible, while maintaining the flexibility to respond to demand signals and positioning the Company to thrive again as procedures return."

U.S. ESS product sales increased 25% to \$3.8 million for the first quarter of 2020. Outside the US ("OUS"), ESS product sales decreased 12% (8% in constant currency) to \$3.1 million for the first quarter of 2020 primarily due to the onset of the COVID-19 pandemic delaying distributor orders scheduled to ship in March. OUS ESS product sales in direct markets, excluding Brazil which we transitioned from a direct market to a distributor market in early March, increased 11% (15% in constant currency). Worldwide, ESS product sales increased 5% (8% in constant currency) to \$6.8 million for the first quarter of 2020.

U.S. IGB sales decreased by \$0.6 million for the first quarter of 2020 and OUS IGB product sales decreased \$0.2 million, or 8% (5% in constant currency), for the first quarter of 2020 primarily due to the COVID-19 impact in our direct markets which offset an increase in IGB distributor orders.

In total, U.S. Endoscopy sales increased 4% to \$4.7 million for the first quarter of 2020. Worldwide Endoscopy product sales decreased 4% (2% in constant currency) to \$10.4 million for the first quarter of 2020. ESS product sales represented 66% of total Endoscopy sales for the first quarter of 2020, compared with 60% for the first quarter of 2019.

Total GAAP revenue reported in the first quarter of 2019 included \$2.3 million related to transition services that we rendered in that period related to the Surgical product line that we divested in December of 2018 compared to \$0.2 million in the first quarter of 2020. As a result, total GAAP revenue reported for the first quarter of 2020 declined by \$2.5 million compared to the first quarter of 2019.

Gross margin for the first quarter of 2020 was 53%, compared to 55% for the first quarter of 2019 when we realized gross margin on the continuing transition services rendered on the Surgical product line. Gross margin realized on our Endoscopy products increased 124 basis points in the first quarter of 2020 compared to the first quarter of 2019.

While total operating expenses, as reported, increased \$2.5 million for the first quarter of 2020 compared to the first quarter of 2019, this is due to a one-time settlement gain of \$5.6 million settlement gain that reduced operating expenses in the first quarter of 2019. Excluding the one-time settlement gain, total operating expenses decreased \$3.1 million for the first quarter of 2020 and our loss from operations decreased by \$1.5 million, or 18%. This reduction in recurring operating expenses was primarily the result of lower direct to consumer advertising, lower selling costs such as compensation and travel, and lower clinical trial costs. Net loss for the first quarter 2020 was \$10.3 million compared to \$2.8 million for the first quarter 2019.

Cash, cash equivalents and restricted cash were \$24.0 million as of March 31, 2020.

COVID-19 Response

As a result of the COVID-19 outbreak, a number of countries, particularly countries in Europe that comprise the majority of our OUS sales and the United States, implemented a variety of public health interventions in March to reduce the risk of disease transmission and conserve healthcare resources for addressing the community health needs of COVID-19. These measures also to a large degree paused patient access to elective or deferrable procedures, including those that use our products.

In response, Apollo has taken several interim actions to preserve cash while maintaining customer support and critical growth projects. We initially reduced 2019 cash bonuses, implemented compensation reductions across our workforce, reduced or delayed inventory purchase commitments, and cut operating expenditures across the company. We took additional actions in mid-April, including the furlough of approximately 90 employees across our global workforce and capping annual compensation rates at \$100,000. The objective of these temporary cost reductions is to keep our cash use during the second quarter of 2020 at the same level we were expecting prior to COVID-19.

While taking these steps, we have maintained sufficient commercial resources in key markets to support essential customer needs and monitor product demand trends. We are also proceeding with critical growth projects, including the MERIT trial and other reimbursement initiatives, new product development efforts for suturing in the lower GI tract, and select projects expected to improve critical aspects of our supply chain.

Conference Call

Apollo will host a conference call on May 4, 2020 at 3:30 p.m. Central Time / 4:30 p.m. Eastern Time to discuss operating results for the first quarter ended March 31, 2020.

To participate in the conference call dial 844-369-8770 for domestic callers and +1-862-298-0840 for international callers. A live webcast of the conference call will be made available on the "Events and Presentations" section of our Investor Relations website: ir.apolloendo.com.

A replay of the webcast will be made available on Apollo's website, www.apolloendo.com following the event.

Non-GAAP Financial Measures

To supplement our financial results, we are providing a non-GAAP financial measure, Endoscopy product sales percentage change in constant currency, which removes the impact of changes in foreign currency exchange rates that affect the comparability and trend of our Endoscopy product sales compared to the same period of the prior year. Endoscopy product sales percentage change in constant currency is calculated by translating current foreign currency sales at last year's exchange rate. This supplemental measure of our performance is not required by, and is not determined in accordance with GAAP.

We believe the non-GAAP financial measure included herein is helpful in understanding our current financial performance. We use this supplemental non-GAAP financial measure internally to understand, manage and evaluate our business, and make operating decisions. We believe that making non-GAAP financial information available to investors, in addition to GAAP financial information, may facilitate more consistent comparisons between the company's performance over time with the performance of other companies in the medical device industry, which may use similar financial measures to supplement their GAAP financial information. However, our non-GAAP financial measure is not meant to be considered in isolation or as a substitute for the comparable GAAP metric.

About Apollo Endosurgery, Inc.

Apollo Endosurgery, Inc. is a medical technology company focused on less invasive therapies to treat various gastrointestinal conditions, ranging from gastrointestinal complications to the treatment of obesity. Apollo's device-based therapies are an alternative to invasive surgical procedures, thus lowering complication rates and reducing total healthcare costs. Apollo's products are offered in over 75 countries today and include the OverStitch™ Endoscopic Suturing System, the OverStitch Sx™ Endoscopic Suturing System, and the ORBERA® IntraGastric Balloon.

Apollo's common stock is traded on the Nasdaq Global Market under the symbol "APEN". For more information regarding Apollo Endosurgery, go to: www.apolloendo.com.

Cautionary Note on Forward-Looking Statements

Certain statements in this press release are forward-looking statements that are subject to risks and uncertainties that could cause results to be materially different than expectations. In addition, there is uncertainty about the spread of the COVID-19 virus and the impact it may have on the Company's operations, the demand for the Company's products, global supply chains and economic activity in general. Important factors that could cause actual results to differ materially include: the advancement of Apollo products; development of enhancements to Apollo's existing products and technologies; market acceptance of Apollo's products; the execution of our gross margin improvement projects; the ability to collect future payments from ReShape; statements relating to the availability of cash for Apollo's future operations; and Apollo's ability to support the adoption of its products and broaden its product portfolio as well as other factors detailed in Apollo's periodic reports filed with the Securities and Exchange Commission, or SEC, including its [Form 10-K for the year ended December 31, 2019](#) and its Form 10-Q for the period ending March 31, 2020. Copies of reports filed with the SEC are posted on Apollo's website and are available from Apollo without charge. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof, and, except as required by law, Apollo disclaims any obligation to update these forward-looking statements to reflect future events or circumstances.

Disclosure Information

Apollo uses the investor relations section of its website as a means of complying with its disclosure obligations under Regulation FD. Accordingly, we recommend that investors should monitor Apollo's investor relations website in addition to following Apollo's press releases, SEC filings, and public conference calls and webcasts.

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APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(In thousands, except for share data)
(unaudited)

Three Months Ended
March 31,

	2020	2019
Revenues ⁽¹⁾	\$ 10,718	\$ 13,211
Cost of sales	5,081	5,970
Gross margin	5,637	7,241
Operating expenses:		
Sales and marketing	6,330	7,697
General and administrative	3,339	3,717
Research and development	2,147	3,428
Amortization of intangible assets	496	553
Settlement gain	—	(5,609)
Total operating expenses	12,312	9,786
Loss from operations	(6,675)	(2,545)
Other expenses:		
Interest expense, net	1,244	959
Other expense (income), net	2,294	(751)
Net loss before income taxes	(10,213)	(2,753)
Income tax expense	43	51
Net loss	\$ (10,256)	\$ (2,804)
Net loss per share, basic and diluted	\$ (0.49)	\$ (0.13)
Shares used in computing net loss per share, basic and diluted	21,117,126	21,907,281

⁽¹⁾ Revenue between periods declined \$2.1 million for the three months ended March 31, 2020 due to the divestiture of the Surgical product line in December 2018. See the product sales table for additional information by product group and geographic market.

APOLLO ENDOSURGERY, INC. AND SUBSIDIARIES
Product Sales by Product Group and Geographic Market
Unaudited (In thousands)

	Three Months Ended March 31, 2020			Three Months Ended March 31, 2019			% Increase / (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
ESS	\$ 3,755	\$ 3,077	\$ 6,832	\$ 3,007	\$ 3,491	\$ 6,498	24.9 %	(11.9)%	5.1 %
IGB	898	2,628	3,526	1,459	2,863	4,322	(38.5)%	(8.2)%	(18.4) %
Total Endoscopy	4,653	5,705	10,358	4,466	6,354	10,820	4.2 %	(10.2)%	(4.3) %
% Endoscopy	44.9 %	55.1 %		41.3 %	58.7 %				
Surgical	—	—	—	—	1,700	1,700	— %	(100.0)%	(100.0) %
Other ⁽¹⁾	327	33	360	683	8	691	(52.1)%	312.5 %	(47.9) %
Total revenues	\$ 4,980	\$ 5,738	\$ 10,718	\$ 5,149	\$ 8,062	\$ 13,211	(3.3)%	(28.8)%	(18.9) %

⁽¹⁾ Other U.S. revenue includes \$0.2 million and \$0.6 million of transition and manufacturing services provided to ReShape for the three months ended March 31, 2020 and 2019, respectively.

Endoscopy product sales percentage change in constant currency were as follows:

	Three Months Ended March 31, 2020	
	% Increase/Decrease in Constant Currency	
	OUS	Total Revenues
ESS	(7.5)%	7.5 %
IGB	(5.2)%	(16.4) %
Total Endoscopy	(6.5)%	(2.1) %