

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): **March 26, 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))

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

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:

Item 2.02 Results of Operations and Financial Condition.

On March 26, 2020, the Company issued a press release reporting its financial results for the fiscal quarter and fiscal year ended December 31, 2019. 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	Press release, issued by Apollo Endosurgery, Inc., dated March 26, 2020.

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: March 26, 2020

By: /s/ Todd Newton

Name: Todd Newton

Title: Chief Executive Officer

APOLLO ENDOSURGERY, INC. REPORTS FOURTH QUARTER AND FULL YEAR 2019 RESULTS

Conference Call to Discuss Results Today at 3:30 p.m. CT / 4:30 p.m. ET

AUSTIN, Texas (March 26, 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 fourth quarter and year ended December 31, 2019. The Company will hold a conference call today at 3:30 p.m. CT / 4:30 p.m. ET to discuss its results.

Highlights

- Fourth quarter U.S. OverStitch™ Endoscopic Suturing System ("ESS") sales increased 33% to \$4.4 million
- Fourth quarter U.S. Endoscopy sales increased 31% to \$5.6 million
- Worldwide ESS sales for the full year 2019 increased 21% (23% in constant currency) to \$28.3 million, representing 63% of our Endoscopy sales
- Fourth quarter Orbera® IntraGastric Balloon System ("IGB") sales increased 23% in the U.S. and 11% (13% in constant currency) worldwide

Todd Newton, CEO of Apollo, said, "The Endoscopic Suturing market developed rapidly in 2019 as evidenced by Apollo's 36% revenue growth for ESS products in the U.S. and 21% growth worldwide. Clinical publications providing evidence of the many applications for our ESS technology continued to expand during 2019, and Apollo's new single channel OverStitch device introduced in November 2018 is taking our technology to a broader group of physicians and locations. Our strategy in the near term is to withstand the unprecedented challenges presented by the COVID-19 pandemic, and then return our focus as swiftly as possible to increasing the user base of our technology and to improve our operating efficiency as we continue to scale the business."

Due to unprecedented global economic conditions and uncertainty resulting from the COVID-19 pandemic, the Company will not be providing an outlook for 2020 at this time. We are closely monitoring the global impact to the health systems where we conduct business and the slowdown in business activity related to COVID-19, and hope to provide better clarity about our outlook for 2020 on our first quarter results call. In response to the rapidly changing conditions resulting from the COVID-19 pandemic, we have taken steps to limit business activities, to limit spending and maintain only key business functions in order to continue to fulfill product orders and support our customers while also taking proactive measures to protect the health and safety of our employees and their families consistent with local guidelines.

U.S. ESS product sales increased 33% to \$4.4 million in the fourth quarter of 2019 and 36% to \$14.9 million in the full year of 2019. Outside the U.S. ("OUS") ESS product sales decreased 15% (13% in constant currency) to \$3.0 million for the fourth quarter of 2019 due primarily to the timing of distributor orders, while increasing 8% (13% in constant currency) to \$13.4 million in the full year of 2019. Worldwide, ESS product sales increased 8% (9% in constant currency) and 21% (23% in constant currency) for the fourth quarter and full year of 2019, respectively.

U.S. IGB sales increased 23% to \$1.2 million for the fourth quarter of 2019 and decreased 4% to \$5.2 million for the full year of 2019. OUS IGB product sales increased 7% (9% in constant currency) to \$3.1 million and decreased 5% (2% in constant currency) to \$11.7 million for the fourth quarter and full year of 2019, respectively. Our efforts to expand IGB therapy in the U.S. market and advance twelve-month therapy OUS improved in the fourth quarter leading to reported growth in both regions and lifting our full year results close to break even with the prior year. Worldwide, IGB sales increased 11% (13% in constant currency) and decreased 5% (3% in constant currency) for the fourth quarter and full year of 2019, respectively.

Worldwide Endoscopy product sales increased 9% (10% in constant currency) and 10% (12% in constant currency) for the fourth quarter and full year of 2019, respectively. ESS product sales represented 64% and 63% of total Endoscopy sales for the fourth quarter and full year of 2019, respectively. In the U.S., Endoscopy sales increased 31% to \$5.6 million and 22% to \$20.1 million for the fourth quarter and full year of 2019, respectively.

The divestiture of our Surgical products in December of 2018 reduced total revenues by \$4.1 million and \$13.7 million for the fourth quarter and full year of 2019, respectively. We divested the Surgical products line in order to strengthen Apollo's focus on our Endoscopy products, which we believe have high growth potential.

Gross margin for the fourth quarter of 2019 was 49%, compared to 47% for the fourth quarter of 2018. Gross margin for the full year of 2019 decreased to 51% compared to 55% for the full year of 2018 as a result of a greater proportion of our overall product sales coming from our ESS products, which realize a lower gross margin than our other products. Management has previously discussed its ongoing gross margin improvement initiative.

Total operating expenses decreased \$11.2 million to \$12.7 million for the fourth quarter of 2019 and decreased \$24.1 million to \$49.2 million for the full year of 2019 compared to the same periods of 2018. Excluding the one-time \$7.8 million loss on divestiture of our Surgical products in December of 2018, the subsequent reduction in intangible asset amortization expense of \$1.2 million and \$5.0 million for the fourth quarter and full year of 2019, respectively resulting from this divestiture and a one-time \$5.6 million settlement gain reported in the first quarter of 2019, total operating expenses decreased \$2.3 million and \$5.7 million for the fourth quarter and full year of 2019, respectively. This reduction in recurring operating expenses was the result of lower U.S. direct to consumer advertising and lower clinical trial costs as enrollment or other milestones were reached on the clinical studies that the Company is funding.

Net loss for the fourth quarter of 2019 was \$7.2 million compared to \$18.4 million for the fourth quarter 2018. For the full year, net loss was \$27.4 million in 2019 compared to \$45.8 million in 2018.

Cash, cash equivalents and restricted cash were \$30.9 million as of December 31, 2019.

Conference Call

Apollo will host a conference call on March 26, 2020 at 3:30 p.m. Central Time / 4:30 p.m. Eastern Time to discuss Apollo's operating results for the fourth quarter and year ended December 31, 2019.

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 remain available on Apollo's website, www.apolloendo.com, following the call.

Non-GAAP Financial Measures

To supplement our financial results, we are providing a non-GAAP financial measure, percentage revenue change in constant currency, which removes the impact of changes in foreign currency exchange rates that affect the comparability and trend of revenues compared to the same period of the prior year. Percentage revenue 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 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. 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
	(Unaudited)	(Unaudited)		
Revenues ⁽¹⁾	\$ 11,989	\$ 15,182	\$ 50,713	\$ 60,854
Cost of sales	6,154	8,100	25,038	27,660
Gross margin	5,835	7,082	25,675	33,194
Operating expenses:				
Sales and marketing	6,735	7,753	28,730	32,831
General and administrative	3,369	3,847	13,588	13,436
Research and development	2,139	2,895	10,384	12,176
Amortization of intangible assets	504	1,663	2,095	7,074
Settlement gain	—	—	(5,609)	—
Loss on divestiture	—	7,770	—	7,770
Total operating expenses	12,747	23,928	49,188	73,287
Loss from operations	(6,912)	(16,846)	(23,513)	(40,093)
Other expenses:				
Interest expense, net	1,203	1,083	4,052	4,063
Other (income) expense	(1,063)	355	(408)	1,440
Net loss before income taxes	(7,052)	(18,284)	(27,157)	(45,596)
Income tax expense	144	69	275	191
Net loss	\$ (7,196)	\$ (18,353)	\$ (27,432)	\$ (45,787)
Net loss per share, basic and diluted	\$ (0.34)	\$ (0.84)	\$ (1.27)	\$ (2.31)
Shares used in computing net loss per share, basic and diluted ⁽²⁾	20,946,035	21,895,133	21,542,284	19,789,867

⁽¹⁾ Revenue between periods declined \$4.1 million for the three months ended December 31, 2019 and \$13.7 million for the year ended December 31, 2019 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.

⁽²⁾ In June 2018, 4.3 million common shares were issued upon completion of a public offering. In August 2019, 1.0 million outstanding common shares were exchanged for a pre-funded warrant.

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

	Three Months Ended December 31, 2019			Three Months Ended December 31, 2018			% Increase / (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
ESS	\$ 4,446	\$ 3,026	\$ 7,472	\$ 3,353	\$ 3,571	\$ 6,924	32.6 %	(15.3)%	7.9 %
IGB	1,157	3,126	4,283	939	2,914	3,853	23.2 %	7.3 %	11.2 %
Total Endoscopy	5,603	6,152	11,755	4,292	6,485	10,777	30.5 %	(5.1)%	9.1 %
% Endoscopy	47.7 %	52.3 %		39.8 %	60.2 %				
Surgical	—	42	42	2,436	1,703	4,139	(100.0)%	(97.5)%	(99.0) %
Other	183	9	192	260	6	266	(29.6)%	50.0 %	(27.8) %
Total revenues	\$ 5,786	\$ 6,203	\$ 11,989	\$ 6,988	\$ 8,194	\$ 15,182	(17.2)%	(24.3)%	(21.0) %

	Year Ended December 31, 2019			Year Ended December 31, 2018			% Increase / (Decrease)		
	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues	U.S.	OUS	Total Revenues
ESS	\$ 14,944	\$ 13,365	\$ 28,309	\$ 11,016	\$ 12,364	\$ 23,380	35.7 %	8.1 %	21.1 %
IGB	5,162	11,678	16,840	5,400	12,339	17,739	(4.4)%	(5.4)%	(5.1) %
Total Endoscopy	20,106	25,043	45,149	16,416	24,703	41,119	22.5 %	1.4 %	9.8 %
% Endoscopy	44.5 %	55.5 %		39.9 %	60.1 %				
Surgical	—	3,712	3,712	10,795	7,913	18,708	(100.0)%	(53.1)%	(80.2) %
Other ⁽¹⁾	1,815	37	1,852	995	32	1,027	82.4 %	15.6 %	80.3 %
Total revenues	\$ 21,921	\$ 28,792	\$ 50,713	\$ 28,206	\$ 32,648	\$ 60,854	(22.3)%	(11.8)%	(16.7) %

⁽¹⁾Other U.S. revenue includes \$1.3 million of transition and manufacturing services provided to ReShape for the year ended December 31, 2019.

Product sales percentage change in constant currency were as follows:

	Three Months Ended December 31, 2019		Year Ended December 31, 2019	
	% Increase/Decrease in Constant Currency		% Increase/Decrease in Constant Currency	
	OUS	Total Revenues	OUS	Total Revenues
ESS	(13.1)%	9.1 %	12.5 %	23.4 %
IGB	9.2 %	12.6 %	(1.6)%	(2.5) %
Total Endoscopy	(3.1)%	10.3 %	5.5 %	12.3 %
Surgical	(97.5)%	(99.0) %	(50.2)%	(79.0) %
Other	33.8 %	(27.2) %	23.9 %	80.6 %
Total revenues	(22.7)%	(20.1) %	(8.0)%	(14.6) %