
**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): **August 3, 2017**

ANI PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-31812
(Commission File Number)

58-2301143
(I.R.S. Employer
Identification Number)

**210 Main Street West
Baudette, Minnesota**
(Address of principal executive offices)

56623
(Zip Code)

Registrant's telephone number, including area code: **(218) 634-3500**

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 3, 2017, ANI Pharmaceuticals, Inc. (“ANI”) issued a press release announcing its financial and operating results for the three and six months ended June 30, 2017. A copy of the press release is furnished as Exhibit 99.1 to this report.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>No.</u>	<u>Description</u>
99.1	Press release, dated August 3, 2017, issued by ANI

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.

ANI PHARMACEUTICALS, INC.

By: /s/ Stephen P. Carey
Stephen P. Carey
Vice President, Finance and Chief Financial Officer

Dated: August 3, 2017

BAUDETTE, Minn., Aug. 3, 2017 /PRNewswire/ --

For the second quarter 2017:

- **Net revenues of \$44.8 million, an increase of 43% as compared to the same period in 2016**
- **GAAP net income of \$2.7 million and diluted GAAP earnings per share of \$0.23**
- **Adjusted non-GAAP EBITDA of \$19.1 million**
- **Adjusted non-GAAP diluted earnings per share of \$0.98**

ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three and six months ended June 30, 2017, and reaffirmed its 2017 financial guidance. The Company will host its earnings conference call this morning, August 3, 2017, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 51622970.

Financial Summary

<i>(in thousands, except per share data)</i>	<u>Q2 2017</u>	<u>Q2 2016</u>	<u>YTD 2017</u>	<u>YTD 2016</u>
Net revenues	\$ 44,764	\$ 31,337	\$ 81,392	\$ 51,892
Net income	\$ 2,681	\$ 1,125	\$ 3,833	\$ 2,471
GAAP earnings per diluted share	\$ 0.23	\$ 0.10	\$ 0.33	\$ 0.21
Adjusted non-GAAP EBITDA^(a)	\$ 19,112	\$ 15,445	\$ 33,841	\$ 26,825
Adjusted non-GAAP diluted earnings per share^(b)	\$ 0.98	\$ 0.75	\$ 1.72	\$ 1.28

(a) See Table 3 for US GAAP reconciliation.
 (b) See Table 4 for US GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

"This was a record quarter for ANI, with revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted earnings per share increasing 43%, 24%, and 31%, respectively, as compared to the prior year. These increases are the direct result of the launches of InnoPran XL® and Inderal® XL in February 2017, as well as the continued impact of products launched in the second and third quarter of 2016. In addition to our record results, we launched three products in the second quarter, two from the ANDA baskets acquired in 2014 and 2015, as well as the first product launch from our partnership with IDT."

ANI Reaffirms Guidance for the Full Year 2017

ANI's estimates are based on projected results for the twelve months ending December 31, 2017 and reflect management's current beliefs about product pricing, prescription trends, inventory levels, cost of sales, operating costs, taxes, and the anticipated timing of future product launches and events.

- Net revenues for 2017 to be between \$181 million and \$190 million.
- Cost of sales as a percent of revenues, excluding impact of inventory step-up, to be between 42% and 44%.
- Adjusted non-GAAP EBITDA to be between \$73.1 million and \$77.2 million.
- Adjusted non-GAAP diluted earnings per share to be between \$3.58 and \$3.94.

Corticotropin Re-commercialization Update

In the second quarter of 2017, ANI's active pharmaceutical ingredient ("API") manufacturer initiated manufacturing of an intermediate scale batch of Corticotropin API, which it expects to complete in the third quarter of 2017. Shortly after completing the first intermediate scale batch of API, the Company intends to manufacture a second intermediate scale batch, starting the third quarter of 2017. ANI has identified a finished dosage form contract manufacturer and intends to initiate Corticotropin finished dosage form manufacturing in the third quarter of 2017. ANI intends to meet and present its Regulatory Filing Plan to the FDA in the second half of 2017.

For further details, please see ANI's Corticotropin Re-commercialization Milestone Update in Table 5.

Second Quarter Results

Net Revenues <i>(in thousands)</i>	Three Months Ended June 30,			
	<u>2017</u>	<u>2016</u>	<u>Change</u>	<u>% Change</u>
Generic pharmaceutical products	\$ 31,490	\$ 22,463	\$ 9,027	40%
Branded pharmaceutical products	11,671	7,488	4,183	56%
Contract manufacturing	1,529	1,166	363	31%
Contract services and other income	74	220	(146)	(66)%
Total net revenues	\$ 44,764	\$ 31,337	\$ 13,427	43%

For the three months ended June 30, 2017, ANI reported net revenues of \$44.8 million, an increase of 43% from \$31.3 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 40%, to \$31.5 million from \$22.5 million in the prior period, primarily due to sales of the generic products launched during 2016.
- Revenues from sales of branded pharmaceuticals increased 56%, to \$11.7 million from \$7.5 million in the prior period, primarily due to sales of Inderal® XL and InnoPran XL®, both of which were launched in Q1 2017.
- Contract manufacturing revenue increased by 31% to \$1.5 million from \$1.2 million in the prior year period, primarily as a result of the timing and volume of customer orders.
- Contract services and other income decreased by 66%, to \$0.1 million from \$0.2 million, primarily because sales of Fenofibrate in the ANI label have replaced the royalties previously received on the product.

Operating expenses increased to \$37.8 million for the three months ended June 30, 2017, from \$26.1 million in the prior year period. The increase was primarily due to a \$9.3 million increase in cost of sales as compared with the prior period, as a result of higher sales of products sold with profit-sharing arrangements, increased volume, and \$3.2 million of cost of sales related to the net inventory step-up on Inderal® XL, InnoPran XL®, and Inderal® LA inventory. In addition, depreciation and amortization increased by \$1.1 million as compared with the prior period, driven by amortization of a higher intangible asset base.

Excluding the \$3.2 million of net inventory step-up costs related to sales of Inderal® XL, InnoPran XL®, and Inderal® LA in the second quarter of 2017 and the \$2.1 million of net inventory step-up costs related to sales of Inderal® LA and Propranolol ER in the second quarter of 2016, cost of sales increased as a percentage of net revenues to 40% from 31%, primarily as a result of increased sales of products with profit-sharing arrangements.

Net income was \$2.7 million for the three months ended June 30, 2017, as compared to net income of \$1.1 million in the prior year period. The effective tax rate for the three months ended June 30, 2017 was 32%.

Diluted earnings per share for the three months ended June 30, 2017 was \$0.23, based on 11,667 thousand diluted shares outstanding, as compared to diluted earnings per share of \$0.10 in the prior year period. Adjusted non-GAAP diluted earnings per share was \$0.98, as compared to adjusted non-GAAP diluted earnings per share of \$0.75 in the prior year period. For a reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure, please see Table 4.

Results for Six Months Ended June 30, 2017

Net Revenues (in thousands)	Six Months Ended June 30,		Change	% Change
	2017	2016		
Generic pharmaceutical products	\$ 58,061	\$ 35,715	\$ 22,346	63%
Branded pharmaceutical products	19,711	13,084	6,627	51%
Contract manufacturing	3,322	2,550	772	30%
Contract services and other income	298	543	(245)	(45)%
Total net revenues	<u>\$ 81,392</u>	<u>\$ 51,892</u>	<u>\$ 29,500</u>	57%

For the six months ended June 30, 2017, ANI reported net revenues of \$81.4 million, an increase of 57% from \$51.9 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 63%, to \$58.1 million from \$35.7 million in the prior period, primarily due to sales of the generic products launched during 2016.
- Revenues from sales of branded pharmaceuticals increased 51%, to \$19.7 million from \$13.1 million in the prior period, primarily due to sales of Inderal® XL and InnoPran XL®, both of which were launched in Q1 2017, as well as sales of Inderal® LA, which launched in Q2 2017.
- Contract manufacturing revenue increased by 30% to \$3.3 million from \$2.6 million in the prior year period, primarily as a result of the timing and volume of customer orders.
- Contract services and other income decreased by 45%, to \$0.3 million from \$0.5 million, primarily because sales of Fenofibrate in the ANI label have replaced the royalties previously received on the product.

Operating expenses increased to \$69.8 million for the six months ended June 30, 2017, from \$41.0 million in the prior year period. The increase was primarily due to a \$22.3 million increase in cost of sales as compared with the prior period, as a result of higher sales of products sold with profit-sharing arrangements, increased volume, and \$4.7 million of cost of sales related to the inventory step-up on Inderal® XL, InnoPran XL®, and Inderal® LA inventory. In addition, depreciation and amortization increased by \$3.2 million as compared with the prior period, driven by amortization of a higher intangible asset base.

Excluding the \$4.7 million of net inventory step-up costs related to sales of Inderal® XL, InnoPran XL®, and Inderal® LA in the six months ended June 30, 2017 and \$2.1 million of net inventory step-up costs related to sales of Inderal® LA and Propranolol ER in the six months ended June 30, 2016, cost of sales increased as a percentage of net revenues to 40% from 25%, primarily as a result of increased sales of products with profit-sharing arrangements.

Net income was \$3.8 million for the six months ended June 30, 2017, as compared to net income of \$2.5 million in the prior year period. The effective tax rate for the six months ended June 30, 2017 was 32%.

Diluted earnings per share for the six months ended June 30, 2017 was \$0.33, based on 11,659 thousand diluted shares outstanding, as compared to diluted earnings per share of \$0.21 in the prior year period. Adjusted non-GAAP diluted earnings per share was

\$1.72, as compared to adjusted non-GAAP diluted earnings per share of \$1.28 in the prior year period. For a reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure, please see Table 4.

Selected Balance Sheet Data
(in thousands)

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
Cash	\$ 8,369	\$ 27,365
Accounts receivable, net	\$ 55,513	\$ 45,895
Inventory, net	\$ 42,307	\$ 26,183
Current assets	\$ 112,856	\$ 103,007
Current liabilities	\$ 28,292	\$ 31,948
Non-current debt	\$ 154,381	\$ 120,643

ANI generated \$6.5 million of positive cash flows from operations in the six months ended June 30, 2017. In February 2017, ANI purchased from Cranford Pharmaceuticals, LLC a distribution license, trademark, and certain finished goods inventory for Inderal® XL for \$20.2 million in cash, using cash on hand. In February 2017, ANI purchased from Holmdel Pharmaceuticals, LP the NDA, trademark, and certain finished goods inventory for InnoPran XL®, including a license to an Orange Book listed patent, for \$30.6 million in cash. ANI made the \$30.6 million cash payment using \$30.0 million of funds from its Line of Credit and \$0.6 million of cash on hand.

ANI Product Development Pipeline

ANI's pipeline consists of 76 products, addressing a total annual market size of \$3.7 billion, based on data from IMS Health. Of these 76 products, 52 were acquired and of these acquired products, ANI expects that 45 can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

Non-GAAP Financial Measures

The Company's fiscal 2017 guidance for adjusted non-GAAP EBITDA and adjusted non-GAAP diluted earnings per share is not reconciled to the most comparable GAAP measure. This is due to the inherent difficulty of forecasting the timing or amount of items that would be included in a reconciliation to the most directly comparable forward-looking GAAP financial measures. Because a reconciliation is not available without unreasonable effort, it is not included in this release.

Adjusted non-GAAP EBITDA

ANI's management considers adjusted non-GAAP EBITDA to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by non-cash stock-based compensation and differences in capital structures, tax structures, capital investment cycles, ages of related assets, and compensation structures among otherwise comparable companies. Management uses adjusted non-GAAP EBITDA when analyzing Company performance.

Adjusted non-GAAP EBITDA is defined as net income/(loss), excluding tax expense, interest expense, depreciation, amortization, the excess of fair value over cost of acquired inventory, stock-based compensation expense, costs related to major transactions not consummated, and other income / expense. Adjusted non-GAAP EBITDA should be considered in addition to, but not in lieu of, net income or loss reported under GAAP. A reconciliation of adjusted non-GAAP EBITDA to the most directly comparable GAAP financial measure is provided in Table 3.

Adjusted non-GAAP Net Income

ANI's management considers adjusted non-GAAP net income to be an important financial indicator of ANI's operating performance providing investors and analysts with a useful measure of operating results unaffected by purchase accounting adjustments, non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, and non-cash impairment charges. Management uses adjusted non-GAAP net income when analyzing Company performance.

Adjusted non-GAAP net income is defined as net income/(loss), plus the excess of fair value over cost of acquired inventory, stock-based compensation expense, costs related to major transactions not consummated, non-cash interest expense, depreciation and amortization expense, and non-cash impairment charges, less the tax impact of these adjustments calculated using an estimated statutory tax rate. Management will continually analyze this metric and may include additional adjustments in the calculation in order to provide further understanding of ANI's results. Adjusted non-GAAP net income should be considered in addition to, but not in lieu of, net income reported under GAAP. A reconciliation of adjusted non-GAAP net income to the most directly comparable GAAP financial measure is provided in Table 4.

Adjusted non-GAAP Diluted Earnings per Share

ANI's management considers adjusted non-GAAP diluted earnings per share to be an important financial indicator of ANI's operating performance, providing investors and analysts with a useful measure of operating results unaffected by purchase accounting adjustments, non-cash stock-based compensation, non-cash interest expense, depreciation and amortization, and non-cash impairment charges. Management uses adjusted non-GAAP diluted earnings per share when analyzing Company performance.

Adjusted non-GAAP diluted earnings per share is defined as adjusted non-GAAP net income, as defined above, divided by the diluted weighted average shares outstanding during the period. Management will continually analyze this metric and may include additional adjustments in the calculation in order to provide further understanding of ANI's results. Adjusted non-GAAP diluted earnings per share should be considered in addition to, but not in lieu of, diluted earnings or loss per share reported under GAAP. A

reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure is provided in Table 4.

About ANI

ANI Pharmaceuticals, Inc. (the "Company" or "ANI") is an integrated specialty pharmaceutical company developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include controlled substances, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit the Company's website www.anipharmaceuticals.com.

Forward-Looking Statements

To the extent any statements made in this release deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about price increases, the Company's future operations, products financial position, operating results and prospects, the Company's pipeline or potential markets therefor, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that the Company may face with respect to importing raw materials; increased competition; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approvals from the U.S. Food and Drug Administration; general business and economic conditions; market trends; products development; regulatory and other approvals; and marketing.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

For more information about ANI, please contact:

Investor Relations

IR@anipharmaceuticals.com

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 1: US GAAP Income Statement
(unaudited, in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net Revenues	\$44,764	\$31,337	\$81,392	\$51,892
Operating Expenses				
Cost of sales (excl. depreciation and amortization)	21,122	11,795	37,508	15,205
Research and development	2,167	764	3,785	1,730
Selling, general, and administrative	7,380	7,628	14,673	13,532
Depreciation and amortization	7,101	5,956	13,807	10,565
Total Operating Expenses	37,770	26,143	69,773	41,032
Operating Income	6,994	5,194	11,619	10,860
Other Expense, Net				
Interest expense, net	(3,025)	(2,830)	(5,957)	(5,612)
Other expense, net	(19)	(12)	(37)	(10)
Income Before Provision for Income Taxes	3,950	2,352	5,625	5,238
Provision for Income Taxes	(1,269)	(1,227)	(1,792)	(2,767)
Net Income	\$ 2,681	\$ 1,125	\$ 3,833	\$ 2,471
Earnings Per Share				
Basic Earnings Per Share	\$ 0.23	\$ 0.10	\$ 0.33	\$ 0.22
Diluted Earnings Per Share	\$ 0.23	\$ 0.10	\$ 0.33	\$ 0.21

Basic Weighted-Average Shares Outstanding	11,546	11,402	11,536	11,398
Diluted Weighted-Average Shares Outstanding	11,667	11,541	11,659	11,514

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 2: US GAAP Balance Sheets
(unaudited, in thousands)

	<u>June 30, 2017</u>	<u>December 31, 2016</u>		
Current Assets				
Cash and cash equivalents	\$ 8,369	\$ 27,365		
Accounts receivable, net	55,513	45,895		
Inventories, net	42,307	26,183		
Prepaid income taxes	3,991	-		
Prepaid expenses and other current assets	2,676	3,564		
Total Current Assets	112,856	103,007		
Property and equipment, net	14,966	10,998		
Restricted cash	5,002	5,002		
Deferred tax asset, net of valuation allowance	27,933	26,227		
Intangible assets, net	196,624	175,792		
Goodwill	1,838	1,838		
Total Assets	\$359,219	\$ 322,864		
Current Liabilities				
Accounts payable	\$ 3,153	\$ 3,389		
Accrued expenses and other	1,565	927		
Accrued royalties	11,255	11,956		
Accrued compensation and related expenses	1,227	1,631		
Current income taxes payable	-	2,398		
Accrued government rebates	3,534	5,891		
Returned goods reserve	7,558	5,756		
Total Current Liabilities	28,292	31,948		
Long-term royalties	-	625		
Borrowings on line of credit	30,000	-		
Convertible notes, net of discount and deferred financing costs	124,381	120,643		
Total Liabilities	182,673	153,216		
Stockholders' Equity				
Common stock	1	1		
Treasury stock	(259)	-		
Additional paid-in capital	175,901	172,563		
Retained earnings/(Accumulated deficit)	903	(2,916)		
Total Stockholders' Equity	176,546	169,648		
Total Liabilities and Stockholders' Equity	\$359,219	\$ 322,864		

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 3: Adjusted non-GAAP EBITDA Calculation and US GAAP to Non-GAAP Reconciliation
(unaudited, in thousands)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Net Income	\$ 2,681	\$ 1,125	\$ 3,833	\$ 2,471
Add back				
Interest expense, net	3,025	2,830	5,957	5,612
Other expense, net	19	12	37	10
Provision for income taxes	1,269	1,227	1,792	2,767
Depreciation and amortization	7,101	5,956	13,807	10,565

Add back

Stock-based compensation	1,807	2,217	3,193	3,322
Excess of fair value over cost of acquired inventory	3,210	2,078	4,745	2,078
Expenses related to transaction not consummated	-	-	477	-
Adjusted non-GAAP EBITDA	\$19,112	\$15,445	\$33,841	\$26,825

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 4: Adjusted non-GAAP Net Income and Adjusted non-GAAP Diluted Earnings per Share Reconciliation
(unaudited, in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net Income	\$ 2,681	\$1,125	\$ 3,833	\$ 2,471
Add back				
Non-cash interest expense	1,774	1,757	3,566	3,482
Depreciation and amortization expense	7,101	5,956	13,807	10,565
Stock-based compensation	1,807	2,217	3,193	3,322
Excess of fair value over cost of acquired inventory	3,210	2,078	4,745	2,078
Expenses related to transaction not consummated	-	-	477	-
Less				
Tax impact of adjustments	(5,140)	(4,443)	(9,542)	(7,195)
Adjusted non-GAAP Net Income	\$11,433	\$8,690	\$20,079	\$14,723
Diluted Weighted-Average				
Shares Outstanding	11,667	11,541	11,659	11,514
Adjusted non-GAAP				
Diluted Earnings per Share	\$ 0.98	\$ 0.75	\$ 1.72	\$ 1.28

ANI Pharmaceuticals, Inc. and Subsidiaries
Table 5: Corticotropin Re-Commercialization Milestone Update

Step	Duration	Status	Additional Details
Manufacture small-scale batch of corticotropin API	4 mos.	Complete	<ul style="list-style-type: none"> Initial batch yields similar to historical yields Analytical method development and testing ongoing Initiate stability testing
Select drug product CMO	6 mos.	Ongoing	<ul style="list-style-type: none"> Drug product CMO has been identified
Manufacture intermediate-scale batches of corticotropin API	2-3 mos. per batch	Ongoing	<ul style="list-style-type: none"> Demonstrate lot to lot consistency Further refine/modernize analytical methods and process Establish API specifications
Type C meeting with FDA		Target 2H2017	<ul style="list-style-type: none"> Present re-commercialization plan Preliminary batch characterization and comparability data Updated analytical methods
Manufacture demo batches of Cortrophin Gel	TBD	Target 2H2017	<ul style="list-style-type: none"> Initiate formulation / fill / finish of drug product
Manufacture commercial-scale batches of corticotropin API	2-3 mos. per batch	Not started	<ul style="list-style-type: none"> Process validation Registration / Commercial batches Initiate registration-enabling ICH stability studies
Manufacture registration batches of Cortrophin Gel	TBD	Not started	<ul style="list-style-type: none"> Process validation Registration / Commercial batches Initiate registration-enabling ICH stability studies
Initiate registration stability for sNDA	6 mos.	Not started	<ul style="list-style-type: none"> Six months of accelerated stability from drug substance and drug product batches at time of submission
sNDA submission	TBD	TBD	<ul style="list-style-type: none"> PAS filing - four month PDUFA date