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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

**Current Report  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

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Date of Report (Date of earliest event reported): **May 8, 2018**

**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.

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**Item 2.02 Results of Operations and Financial Condition.**

On May 8, 2018, ANI Pharmaceuticals, Inc. (“ANI”) issued a press release announcing its financial and operating results for the three months ended March 31, 2018. 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

<b>No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press release, dated May 8, 2018, issued by ANI</a>

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**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: May 8, 2018

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BAUDETTE, Minn., May 8, 2018 /PRNewswire/ --

**For the first quarter 2018:**

- **Net revenues of \$46.5 million, an increase of 27% as compared to the same period in 2017**
- **GAAP net income of \$2.3 million and diluted GAAP earnings per share of \$0.19**
- **Adjusted non-GAAP EBITDA of \$21.8 million**
- **Adjusted non-GAAP diluted earnings per share of \$1.32**

**ANI Pharmaceuticals, Inc. ("ANI")** (NASDAQ: ANIP) today reported its financial results for the three months ended March 31, 2018 and reaffirmed its 2018 financial guidance. The Company will host its earnings conference call this morning, May 8, 2018, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 2059819.

**Financial Summary**

<i>(in thousands, except per share data)</i>	<u><b>Q1 2018</b></u>	<u><b>Q1 2017</b></u>
<b>Net revenues</b>	\$ 46,483	\$ 36,628
<b>Net income</b>	\$ 2,250	\$ 1,152
<b>GAAP earnings per diluted share</b>	\$ 0.19	\$ 0.10
<b>Adjusted non-GAAP EBITDA<sup>(a)</sup></b>	\$ 21,754	\$ 14,729
<b>Adjusted non-GAAP diluted earnings per share<sup>(b)</sup></b>	\$ 1.32	\$ 0.74

<sup>(a)</sup> See Table 3 for U.S. GAAP reconciliation.  
<sup>(b)</sup> See Table 4 for U.S. GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

"The first quarter of 2018 was a strong quarter, with increases in net revenues, Adjusted non-GAAP EBITDA, and Adjusted non-GAAP diluted earnings per share of 27%, 48%, and 78%, respectively, as compared with the first quarter of 2017. As expected, 2018 has been an active year for business development efforts at ANI. In the first five months, we have successfully strengthened our generic product portfolio via the acquisition of 23 generic products from IDT, by executing a new license and supply agreement for a generic product that will be filed in the coming months, and, most recently, adding seven products, including three commercial products, to our generic portfolio from an acquisition related to the Amneal/Impax combination. In addition, we are pleased with the initial results of our four-product brand acquisition that was completed in December of last year. We expect to complete the tech transfer of these four brands to our Baudette manufacturing facility and launch under the ANI label in 2018; this will serve to further increase our branded product portfolio."

**ANI Reaffirms Guidance for the Full Year 2018**

ANI's estimates are based upon actual results for the three months ending March 31, 2018 and projected results for the remaining nine months of the year. ANI's full year 2018 guidance reflects management's current assumptions regarding customer relationships, product pricing, prescription trends, competition, inventory levels, cost of sales, operating costs, timing of research and development spend, taxes, and the anticipated timing of future product launches, integration and contribution of recent acquisitions and other key events. For the twelve months ending December 31, 2018, ANI is providing guidance on net revenue, adjusted non-GAAP EBITDA and adjusted non-GAAP diluted earnings per share.

The following table summarizes 2018 guidance:

<i>(in millions, except per share data and percentages)</i>	<u><b>2018 Guidance</b></u>
Net revenues	\$212 to \$228
Adjusted non-GAAP EBITDA	\$90 to \$100
Adjusted non-GAAP diluted earnings per share	\$5.43 to \$6.08

**Cortrophin® Gel Re-commercialization Update**

In the first quarter of 2018, ANI has continued to advance the manufacture of Corticotropin active pharmaceutical ingredient ("API"). ANI has ordered and is in the process of installing and qualifying the capital equipment necessary for commercial scale API manufacturing. We plan to initiate commercial-scale API manufacturing in the second quarter of 2018 and are still on track to initiate API process validation and registration batch manufacturing by the end of 2018. ANI has also continued to manufacture batches of Cortrophin® gel drug product and is still on track to manufacture commercial scale drug product batches before the end of 2018.

ANI requested a Type C meeting with the FDA in the fourth quarter of 2017 to provide the regulatory plan for re-commercialization of Cortrophin® gel. The FDA granted the Type C meeting and provided an initial response in March 2018, with further communications expected during the second quarter of 2018.

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

## Vancocin® Oral Solution Update

ANI is currently advancing a commercialization effort for Vancocin® oral solution. Following completion of ongoing formulation and manufacturing optimization, ANI intends to file a prior approval supplement ("PAS") in the second half of 2018. This product will be manufactured at ANI's site in Baudette, MN and will compete in a market that currently exceeds \$450 million annually.

### First Quarter Results

Net Revenues (in thousands)	Three Months Ended March 31,		Change	% Change
	2018	2017		
Generic pharmaceutical products	\$ 23,227	\$ 26,572	\$ (3,345)	(13)%
Branded pharmaceutical products	16,595	8,039	8,556	106%
Royalty and other income	5,716	224	5,492	NM <sup>(1)</sup>
Contract manufacturing	945	1,793	(848)	(47)%
Total net revenues	<u>\$ 46,483</u>	<u>\$ 36,628</u>	<u>\$ 9,855</u>	<u>27%</u>

(1) Not Meaningful

For the three months ended March 31, 2018, ANI reported net revenues of \$46.5 million, an increase of 27% from \$36.6 million in the prior year period, driven by the following factors:

- Revenues from sales of branded pharmaceuticals increased 106%, to \$16.6 million from \$8.0 million in the prior period, primarily due to sales of Inderal® XL and InnoPran XL®, both of which were acquired in Q1 2017 and re-launched in ANI's own label in Q1 2018, as well as increased sales of Inderal® LA.
- Royalty and other income increased to \$5.7 million from \$0.2 million, primarily due to the royalties received on sales of Atacand®, Atacand HCT®, Arimidex®, and Casodex®.
- Revenues from sales of generic pharmaceuticals decreased 13% to \$23.2 million from \$26.6 million in the prior period, primarily due to volume decreases for Fenofibrate and sales decreases for Propranolol ER driven by price, tempered by the impact of the second quarter 2017 launch of Diphenoxylate Hydrochloride and Atropine Sulfate.
- Contract manufacturing revenue decreased by 47% to \$0.9 million from \$1.8 million in the prior year period, primarily as a result of the timing and volume of customer orders.

Operating expenses increased to \$39.9 million for the three months ended March 31, 2018, from \$32.0 million in the prior year period. The increase was primarily due to a \$4.3 million increase in cost of sales as compared with the prior period, and \$5.6 million of costs of sales related to the inventory step up on Inderal® XL and InnoPran XL® inventory and the write-off of remaining inventory acquired as part of the acquisition when ANI launched the products under its own label during the quarter. In addition, selling, general, and administrative expense increased by \$1.7 million due to increased personnel costs, and depreciation and amortization increased by \$1.5 million due to the amortization of the product rights for Atacand®, Atacand HCT®, Arimidex®, and Casodex®, which were acquired in December 2017.

Excluding the \$5.6 million of net inventory step-up related to the sales and write off Inderal® XL and InnoPran XL® in the first quarter of 2018 and \$1.5 million of net inventory step-up related to sales of Inderal® LA, Inderal® XL, and InnoPran XL® in the first quarter of 2017, cost of sales decreased to 32% from 41% of net revenues driven by the significant increase in royalty income.

Net income was \$2.3 million for the three months ended March 31, 2018, as compared to net income of \$1.2 million in the prior year period. The effective tax rate for the three months ended March 31, 2018 was 21% as compared to 31% in the prior year period.

Diluted earnings per share for the three months ended March 31, 2018 was \$0.19, based on 11,706 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 \$1.32, as compared to adjusted non-GAAP diluted earnings per share of \$0.74 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)

	March 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 51,970	\$ 31,144
Accounts receivable, net	\$ 54,801	\$ 58,788
Inventory, net	\$ 34,294	\$ 37,727
Current assets	\$ 143,394	\$ 131,605
Current liabilities	\$ 39,650	\$ 39,228
Non-current debt	\$ 198,725	\$ 198,154

ANI generated \$22.9 million of cash flow from operations in the three months ended March 31, 2018. In December 2017, ANI entered into a credit agreement with Citizens Bank, N.A. that included a \$75 million term loan and a \$50 million line of credit. The \$75 million term loan was used to pay down ANI's former \$25.0 million line of credit and to purchase from AstraZeneca AB and AstraZeneca UK Limited the right, title, and interest in the NDAs and the U.S. rights to market Atacand®, Atacand HCT®, Arimidex®, and Casodex®, for \$46.5 million in cash. The \$50 million line of credit currently remains undrawn.

## **ANI Product Development Pipeline**

ANI's pipeline consists of 76 products, addressing a total annual market size of \$4.7 billion, based on data from IMS Health. Of these 76 products, 71 were acquired and of these acquired products, ANI expects that 54 can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

## **Non-GAAP Financial Measures**

The Company's fiscal 2018 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](http://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; regulatory environment; 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@anipharma.com

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

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
Net Revenues	\$46,483	\$36,628
Operating Expenses		
Cost of sales (excl. depreciation and amortization)	20,693	16,386
Research and development	2,102	1,618
Selling, general, and administrative	8,956	7,293
Depreciation and amortization	8,195	6,706
Total Operating Expenses	39,946	32,003
Operating Income	6,537	4,625
Other Expense, Net		
Interest expense, net	(3,634)	(2,932)
Other expense, net	(61)	(18)
Income Before Provision for Income Taxes	2,842	1,675
Provision for Income Taxes	(592)	(523)
Net Income	\$ 2,250	\$ 1,152
<b>Earnings Per Share</b>		
Basic Earnings Per Share	\$ 0.19	\$ 0.10
Diluted Earnings Per Share	\$ 0.19	\$ 0.10
Basic Weighted-Average Shares Outstanding	11,589	11,527
Diluted Weighted-Average Shares Outstanding	11,706	11,653

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

	<b>March 31, 2018</b>	<b>December 31, 2017</b>
Current Assets		
Cash and cash equivalents	\$ 51,970	\$ 31,144
Accounts receivable, net	54,801	58,788
Inventories, net	34,294	37,727
Prepaid income taxes, net	62	1,162
Prepaid expenses and other current assets	2,267	2,784

Total Current Assets	143,394	131,605
Property and equipment, net	21,882	20,403
Restricted cash	5,002	5,006
Deferred tax asset, net of valuation allowance	23,163	22,667
Intangible assets, net	221,917	229,790
Goodwill	1,838	1,838
Other long-term assets	823	829
<b>Total Assets</b>	<b>\$418,019</b>	<b>\$ 412,138</b>
Current Liabilities		
Accounts payable	\$ 4,886	\$ 3,630
Accrued expenses and other	2,612	1,571
Accrued royalties	11,361	12,164
Accrued compensation and related expenses	1,495	2,306
Accrued government rebates	6,471	7,930
Returned goods reserve	9,020	8,274
Current component of long-term borrowing, net of deferred financing costs	3,805	3,353
Total Current Liabilities	39,650	39,228
Long-term borrowing, net of deferred financing costs and current borrowing component	68,569	69,946
Convertible notes, net of discount and deferred financing costs	130,156	128,208
Total Liabilities	238,375	237,382
Stockholders' Equity		
Common stock	1	1
Treasury stock	(250)	(259)
Additional paid-in capital	181,649	179,020
Accumulated deficit	(1,756)	(4,006)
Total Stockholders' Equity	179,644	174,756
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$418,019</b>	<b>\$ 412,138</b>

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

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
Net Income	\$ 2,250	\$ 1,152
Add back		
Interest expense, net	3,634	2,932
Other expense, net	61	18
Provision for income taxes	592	523
Depreciation and amortization	8,195	6,706
Add back		
Stock-based compensation	1,377	1,386
Excess of fair value over cost of acquired inventory	5,645	1,535
Expenses related to transaction not consummated	-	477
Adjusted non-GAAP EBITDA	\$21,754	\$14,729

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

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
Net Income	\$ 2,250	\$1,152

Add back

Excess of fair value over cost of acquired inventory	5,645	1,535
Non-cash interest expense	1,914	1,792
Stock-based compensation	1,377	1,386
Depreciation and amortization expense	8,195	6,706
Expenses related to transaction not consummated	-	477
Less		
Tax impact of adjustments	(3,940)	(4,402)
Adjusted non-GAAP Net Income	\$15,441	\$8,646
Diluted Weighted-Average		
Shares Outstanding	11,706	11,653
Adjusted non-GAAP		
Diluted Earnings per Share	\$ 1.32	\$ 0.74

**ANI Pharmaceuticals, Inc. and Subsidiary**  
**Table 5: Cortrophin® Gel Re-Commercialization Milestone Update**

Step	Duration	Status	Additional Details
<b>Manufacture small-scale batch of corticotropin API</b>	4 mos.	Complete	<ul style="list-style-type: none"> <li>Initial batch yields similar to historical yields</li> <li>Analytical method development and testing ongoing</li> </ul>
<b>Select drug product CMO</b>	6 mos.	Complete	<ul style="list-style-type: none"> <li>Drug product CMO has been selected</li> </ul>
<b>Manufacture intermediate-scale batches of corticotropin API</b>	4-6 mos.	Complete	<ul style="list-style-type: none"> <li>Three intermediate-scale batches successfully completed</li> <li>Further refined/modernized analytical methods and process</li> <li>Demonstrated lot-to-lot consistency</li> </ul>
<b>Type C meeting with FDA</b>		Communications with FDA on-going	<ul style="list-style-type: none"> <li>Meeting Request submitted 4Q17; FDA granted as Type C Meeting</li> <li>Information provided on ANI's regulatory plan for re-commercialization</li> <li>Initial FDA response received March 2018 with additional communications expected 2nd Quarter 2018</li> </ul>
<b>Manufacture demo batches of Cortrophin® Gel</b>	TBD	Target Q3 2018	<ul style="list-style-type: none"> <li>Initiate formulation / fill / finish of drug product</li> </ul>
<b>Manufacture commercial-scale batches of corticotropin API</b>	2-3 mos. per batch	Target 1H 2018	<ul style="list-style-type: none"> <li>Scale-up manufacturing process 5x</li> <li>Manufacture API under cGMPs</li> <li>Finalize API manufacturing process in preparation for process validation/registration batches</li> </ul>
<b>Manufacture registration batches of Cortrophin® Gel</b>	2-3 mos. per batch	Target end 2018	<ul style="list-style-type: none"> <li>Process validation</li> <li>Registration / Commercial batches</li> <li>Initiate registration-enabling ICH stability studies</li> </ul>
<b>Initiate registration stability for sNDA</b>	6 mos.	TBD	<ul style="list-style-type: none"> <li>Six months of accelerated stability from drug substance and drug product batches at time of submission</li> </ul>
<b>sNDA submission</b>	TBD	TBD	<ul style="list-style-type: none"> <li>PAS filing - four month PDUFA date</li> </ul>