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): **February 27, 2020**

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-31812**	**58-2301143**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

210 Main Street West **Baudette, Minnesota**	**56623**
(Address of principal executive offices)	(Zip Code)

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

(Former name or former address, if changed since last report)

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	ANIP	Nasdaq Stock Market

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 February 27, 2020, ANI Pharmaceuticals, Inc. ("ANI") issued a press release announcing its financial and operating results for the three months and year ended December 31, 2019. 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

No.	Description
99.1	Press release, dated February 27, 2020, 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: February 27, 2020

Exhibit 99.1

ANI Pharmaceuticals Reports Full Year and Fourth Quarter 2019 Results, Provides 2020 Guidance and Remains on Track to Submit Cortrophin® Gel sNDA to FDA in March 2020

For the full year ended December 31, 2019:

- **Record net revenues of $206.5 million, an increase of 2.5% versus 2018**
- **GAAP net income of $6.1 million and diluted GAAP earnings per share of $0.50**
- **Adjusted non-GAAP EBITDA of $83.2 million**
- **Adjusted non-GAAP diluted earnings per share of $5.06**

For the fourth quarter 2019:

- **Net revenues of $48.0 million versus $57.1 million in 2018**
- **GAAP net loss of $4.8 million and diluted GAAP loss per share of $0.41**
- **Adjusted non-GAAP EBITDA of $17.4 million**
- **Adjusted non-GAAP diluted earnings per share of $1.08**

Guidance for 2020:

- **Net revenues of $213 million to $223 million**
- **Adjusted non-GAAP EBITDA of $80 million to $86 million**
- **Adjusted non-GAAP diluted earnings per share of $4.46 to $4.86**

Baudette, Minnesota (February 27, 2020) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three and twelve months ended December 31, 2019 and provided its 2020 financial guidance. The Company will host its earnings conference call this morning, February 27, 2020, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 4783883.

Financial Summary

(in thousands, except per share data)	Q4 2019	Q4 2018	2019[a]	2018[a]
Net revenues	$ 47,966	$ 57,122	$ 206,547	$ 201,576
Net (loss)/income	$ (4,835)	$ 5,430	$ 6,094	$ 15,494
GAAP (loss)/earnings per diluted share	$ (0.41)	$ 0.46	$ 0.50	$ 1.30
Adjusted non-GAAP EBITDA[b]	$ 17,383	$ 22,184	$ 83,158	$ 84,401
Adjusted non-GAAP diluted earnings per share[c]	$ 1.08	$ 1.32	$ 5.06	$ 5.07

[a] See ANI's Form 10-K filed February 27, 2020 for discussion of year-to-date results.
[b] See Table 3 for US GAAP reconciliation.
[c] See Table 4 for US GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

> "ANI generated record net revenues and non-GAAP gross profit in 2019 while continuing to diversify its commercial product offering and pipeline opportunities. While revenues and non-GAAP gross profit for three of our important generic products were negatively impacted in recent periods, overall our business remains resilient, and we look forward to leveraging important recent launches such as Vancomycin Oral Solution and Bretylium Tosylate Injection as well as the recently acquired Amerigen portfolio in 2020. During 2019, we launched several new products, entered into collaborative arrangements with strategic partners and acquired both previously approved and development stage products we plan to launch in the future. We have utilized strong operating cash flows for asset acquisitions and investment into our portfolio of pipeline products and expect to continue to do so in the future.

During the fourth quarter, we successfully completed our fourth commercial scale batch of both Corticotropin API and the Cortrophin® Gel drug product, and importantly, remain on track to submit our supplemental NDA filing in March 2020."

2020 Financial Guidance

For the twelve months ending December 31, 2020, ANI is providing guidance on net revenue, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted earnings per share. The following table summarizes 2020 guidance as compared to 2019 actual results:

($ in millions except per share data)	**2019**	**2020 Guidance Range**			**% Change from Prior Year**		
	Actual	**Low**	**Mid**	**High**	**Low**	**Mid**	**High**
Net Revenues	$ 206.5	$ 213.0	$ 218.0	$ 223.0	3%	6%	8%
Adjusted non-GAAP EBITDA	$ 83.2	$ 80.0	$ 83.0	$ 86.0	-4%	0%	3%
Adjusted non-GAAP diluted earnings per share	$ 5.06	$ 4.46	$ 4.66	$ 4.86	-12%	-8%	-4%

In addition, we expect that adjusted non-GAAP gross margin, defined as the result of Net Revenues less Cost of Sales (excluding depreciation and amortization) as a percentage of Net Revenues, will decline from approximately 71% in 2019 to the mid 60% range in 2020, driven by the impact of negative price and product mix. Year over year changes of our Adjusted non-GAAP diluted earnings per share metric differ from our Adjusted non-GAAP EBITDA metric due to a projected increase in cash interest expense resulting from the refinancing of our convertible debt to bank debt.

ANI's full year 2020 financial 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 and other key events.

Cortrophin® Gel Re-commercialization Update

Product	**Required Filing**	**Expected Filing Date**	**Total Annual Market[(d)]**
Cortrophin® Gel	sNDA	March 2020	$1.0 billion

[(d)] Based on data from IQVIA

We continue to successfully progress our Cortrophin® Gel re-commercialization program. Significant accomplishments since the third quarter 2019 press release (dated November 6, 2019) include:

- ANI successfully completed API process validation by completing the fourth commercial scale batch of Corticotropin API. ANI also completed manufacturing for a fifth commercial scale batch of Corticotropin API. All five commercial scale batches were analytically consistent with each other and met all API release specifications. ANI expects to have 6 months stability on all API registration batches prior to the sNDA filing and by the end of first quarter 2020.

- ANI successfully completed drug product process validation in the fourth quarter of 2019. ANI also completed manufacturing of a fourth commercial scale batch of Cortrophin® Gel. This batch was analytically consistent with previously manufactured batches and met all drug product release specifications. ANI had already completed manufacturing for three commercial scale registration stability batches of Cortrophin® Gel and expects to have 6 months stability on each prior to the sNDA filing and by the end of first quarter 2020.

ANI is on track to file the sNDA as planned by March 2020.

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

Fourth Quarter Results

Net Revenues (in thousands)	**Three Months Ended December 31,**			
	2019	**2018**	**Change**	**% Change**
Generic pharmaceutical products	$ 29,121	$ 33,735	$ (4,614)	(14)%
Branded pharmaceutical products	15,624	18,840	(3,216)	(17)%
Contract manufacturing	2,640	3,669	(1,029)	(28)%
Royalty and other income	581	878	(297)	(34)%
Total net revenues	$ 47,966	$ 57,122	$ (9,156)	(16)%

Generic Pharmaceutical Products

Fourth Quarter Net Revenues - Results and Update

Net revenues from sales of generic pharmaceuticals decreased 14% to $29.1 million from $33.7 million in the prior period, primarily due to decreases in sales of Esterified Estrogen with Methlytestosterone ("EEMT"), Erythromycin Ethylsuccinate ("EES"), Propafenone, and Fenofibrate. These decreases were tempered by the September 2019 launch of Vancomycin HCl for Oral Solution as well as increased unit sales of Vancomycin tablets.

Branded Pharmaceutical Products

Fourth Quarter Net Revenues - Results and Update

Net revenues from sales of branded pharmaceuticals decreased 17% to $15.6 million from $18.8 million in the prior period, primarily due to decrease in sales of Inderal® LA, Atacand® and Atacand HCT®. These decreases were tempered by increased sales of InnoPran XL®.

Contract Manufacturing

Fourth Quarter Net Revenues - Results and Update

Contract manufacturing revenues decreased 28% to $2.6 million from $3.7 million in the prior year period, due to the timing and volume of orders from contract manufacturing customers in the period.

Royalty and Other

Fourth Quarter Net Revenues - Result and Update

Royalty and Other decreased 34% to $0.6 million from $0.9 million, primarily due to the timing and volume of product development and laboratory services revenue earned by ANI Canada.

Operating Expenses

Operating expenses increased to $52.6 million for the three months ended December 31, 2019, from $45.7 million in the prior year period. The increase was primarily due to the following:

- $6.5 million in the build of Cortrophin pre-launch commercial inventories (which are expensed for US GAAP); there were no such activities in 2018,
- $1.2 million increase in research and development expense, primarily due to Q4 2019 development-based milestone payments earned by collaborative partners, and
- $0.9 million increase in depreciation and amortization expense, primarily due to additional amortization expense associated with a March 2019 asset acquisition and a January 2019 royalty buyout payment related to a prior period asset acquisition.

These increases were partially offset by a $2.3 million decrease in cost of sales as a result of the previously mentioned royalty buyout in January 2019 and a decrease in sales over the comparable periods, tempered by Q4 2019 inventory reserve charges of $4.6 million primarily related to the Company's exit from the Methylphenidate Extended Release market.

Cost of sales as a percentage of net revenues increased to 37% during the three months ended December 31, 2019, from 35% during same period in 2018. The increase was primarily due to the inventory reserve charges recognized in the fourth quarter 2019 and negative price, which were tempered by reductions related to the 2019 royalty buyout.

Net Loss and Diluted Loss per Share

Net loss was $4.8 million for the three months ended December 31, 2019, as compared to net income of $5.4 million in the prior year period. The net loss was driven by the previously mentioned $6.5 million build of Cortrophin pre-launch commercial inventories and $4.6 million of inventory reserve charges. The effective consolidated tax benefit rate for the three months ended December 31, 2019 was 37%.

Diluted loss per share for the three months ended December 31, 2019 was $0.41, based on 11,886 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.46 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.08, as compared to adjusted non-GAAP diluted earnings per share of $1.32 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.

ANI Product Development Pipeline

ANI's pipeline consists of 118 products, addressing a total annual market size of $7.0 billion, based on data from IQVIA. Of these, ANI expects that at least 52 can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

Non-GAAP Financial Measures

The Company's fiscal 2019 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, expense from acquired in-process research and development, gains, losses, and expenses related to the repurchase of convertible debt, expenses related to debt financing, transaction and integration expenses, non-cash impairment charges, Cortrophin pre-launch charges, other income / expense and certain other items, including expensed milestone payments and inventory reserve charges, that vary in frequency and impact on ANI's results of operations. 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, non-cash impairment charges, Cortrophin pre-launch charges and certain other items, including expensed milestone payments and inventory reserve charges, that vary in frequency and impact on ANI's results of operations. 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, transaction and integration expenses, gains, losses, and expenses related to the repurchase of convertible debt, expenses related to debt financing, non-cash interest expense, depreciation and amortization expense, expense from acquired in-process research and development, non-cash impairment charges, Cortrophin pre-launch charges and certain other items, including expensed milestone payments and inventory reserve charges, that vary in frequency and impact on ANI's results of operations, 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, non-cash impairment charges, Cortrophin pre-launch charges and certain other items, including expensed milestone payments and inventory reserve charges, that vary in frequency and impact on ANI's results of operations.

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, as adjusted for the dilutive effect of the convertible debt notes (in 2019), when applicable. 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; 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@anipharmaceuticals.com

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Net Revenues	$ 47,966	$ 57,122	$ 206,547	$ 201,576
Operating Expenses				
Cost of sales (excl. depreciation and amortization)	17,795	20,133	63,154	73,024
Research and development	4,678	3,482	19,806	15,388
Selling, general, and administrative	14,014	13,376	55,843	44,063
Depreciation and amortization	9,564	8,686	44,612	33,742
Cortrophin pre-launch charges	6,511	-	6,706	-
Intangible asset impairment charge	75	-	75	-
Total Operating Expenses	52,637	45,677	190,196	166,217
Operating (Loss)/Income	(4,671)	11,445	16,351	35,359
Other Expense, Net				
Interest expense, net	(2,870)	(3,626)	(12,966)	(14,758)
Other expense, net	(111)	(479)	(228)	(550)
(Loss)/Income Before Benefit/(Provision) for Income Taxes	(7,652)	7,340	3,157	20,051
Benefit/(Provision) for Income Taxes	2,817	(1,910)	2,937	(4,557)
Net (Loss)/Income	$ (4,835)	$ 5,430	$ 6,094	$ 15,494
(Loss)/Earnings Per Share				
Basic (Loss)/Earnings Per Share	$ (0.41)	$ 0.46	$ 0.51	$ 1.31
Diluted (Loss)/Earnings Per Share	$ (0.41)	$ 0.46	$ 0.50	$ 1.30
Basic Weighted-Average Shares Outstanding	11,886	11,730	11,841	11,677
Diluted Weighted-Average Shares Outstanding	11,886	11,785	12,040	11,772

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

	December 31, 2019	December 31, 2018
Current Assets		
Cash and cash equivalents	$ 62,332	$ 43,008
Accounts receivable, net	72,129	64,842
Inventories, net	48,163	40,503
Prepaid income taxes, net	1,076	-
Prepaid expenses and other current assets	3,995	4,524
Total Current Assets	187,695	152,877
Property and equipment, net	40,551	38,090
Restricted cash	5,029	5,021
Deferred tax assets, net of deferred tax liabilities and valuation allowance	38,326	27,964
Intangible assets, net	180,388	201,604
Goodwill	3,580	3,580
Other non-current assets	1,220	1,468
Total Assets	$ 456,789	$ 430,604
Current Liabilities		
Current component of Term Loan and DDTL, net of deferred financing costs	$ 9,941	$ 3,256
Convertible Notes, net of discount and deferred financing costs	-	112,463
Accounts payable	14,606	8,884
Accrued expenses and other	2,362	1,707
Accrued royalties	5,084	8,456
Accrued compensation and related expenses	3,736	3,524
Current income taxes payable, net	-	5,022
Accrued government rebates	8,901	8,974
Returned goods reserve	16,595	12,552
Deferred revenue	451	711
Total Current Liabilities	61,676	165,549
Term Loan and DDTL, net of deferred financing costs and current borrowing component	175,808	67,296
Other non-current long-term liabilities	6,514	496
Total Liabilities	243,998	233,341
Stockholders' Equity		
Common stock	1	1
Treasury stock	(723)	(659)
Additional paid-in capital	200,800	186,812
Retained earnings	17,584	11,488
Accumulated other comprehensive loss, net of tax	(4,871)	(379)
Total Stockholders' Equity	212,791	197,263
Total Liabilities and Stockholders' Equity	$ 456,789	$ 430,604

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Net (Loss)/Income	$ (4,835)	$ 5,430	$ 6,094	$ 15,494
Add/(Subtract):				
Interest expense, net	2,870	3,626	12,966	14,758
Other (income)/expense, net, less loss on and expense on repurchase of convertible debt	111	(90)	228	(19)
(Benefit)/provision for income taxes	(2,817)	1,910	(2,937)	4,557
Depreciation and amortization	9,564	8,686	44,612	33,742
Cortrophin pre-launch charges	6,511	-	6,706	-
Stock-based compensation	2,444	1,828	9,217	6,782
Acquired IPR&D expense	-	-	2,324	1,335
Excess of fair value over cost of acquired inventory	-	-	-	5,689
Loss on and expense on repurchase of convertible debt and expense on debt refinancing	-	691	-	691
Transaction and integration expenses	-	103	84	1,372
Intangible asset impairment charge	75	-	75	-
Expensed FDA approval milestone payment	-	-	329	-
Inventory reserve charges related to market exits	3,460		3,460	-
Adjusted non-GAAP EBITDA	$ 17,383	$ 22,184	$ 83,158	$ 84,401

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 December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Net (Loss)/Income	$ (4,835)	$ 5,430	$ 6,094	$ 15,494
Add back				
Non-cash interest expense	1,308	1,903	6,833	7,741
Depreciation and amortization expense	9,564	8,686	44,612	33,742
Cortrophin pre-launch charges	6,511	-	6,706	-
Expensed FDA approval milestone payment	-	-	329	-
Acquired IPR&D expense	-	-	2,324	1,335
Stock-based compensation	2,444	1,828	9,217	6,782
Inventory reserve charges related to market exits	3,460	-	3,460	-
Intangible asset impairment	75	-	75	-
Excess of fair value over cost of acquired inventory	-	-	-	5,689
Loss on and expense on repurchase of convertible debt and expense on debt refinancing	-	691	-	691
Transaction and integration expenses	-	103	84	1,372
Less				
Tax impact of adjustments	(5,607)	(3,039)	(17,674)	(13,191)
Discrete tax benefit related to ANI Canada transfer pricing agreement	-	-	(1,653)	-
Adjusted non-GAAP Net Income	$ 12,920	$ 15,602	$ 60,407	$ 59,655
Diluted Weighted-Average Shares Outstanding	11,886	11,785	12,040	11,772
Less: dilutive effect of Notes	-	-	(96)	-
Adjusted Diluted Weighted-Average Shares Outstanding	11,980	11,785	11,944	11,772
Adjusted non-GAAP Diluted Earnings per Share	$ 1.08	$ 1.32	$ 5.06	$ 5.07

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

Objective	Duration	Steps / Details	Status
Manufacture Commercial Scale Batches of Corticotropin API	2-3 months per batch	• Scale-up manufacturing process 5x to projected commercial scale • Finalize API manufacturing process & initiate PV / registration batches • Method development for API characterization methods • Method validation for API release / stability methods • Perform viral clearance studies and validation	Complete Complete Complete Complete Complete
Manufacture Commercial Scale Batches of Cortrophin® Gel Drug Product	1 month per batch	• Finalize drug product manufacturing process • Initiate process validation • Method validation for API release / stability methods • Manufacture three API and three drug product registration batches	Complete Complete Complete Complete
Registration Stability for sNDA	6 months	• Initiate registration stability studies • Demonstrate 6 months accelerated and real-time stability prior to sNDA submission	Complete On Track
sNDA Submission	4 months	• Target date: March 2020 • sNDA filing four month PDUFA date: July 2020	On Track