

ANI Pharmaceuticals Reports First Quarter Results and Year-To-Date 2017 Highlights and Reaffirms Guidance

For the first quarter 2017:

- Net revenues of \$36.6 million, an increase of 78% as compared to the same period in 2016
- GAAP net income of \$1.2 million and diluted GAAP earnings per share of \$0.10
- Adjusted non-GAAP EBITDA of \$14.7 million
- Adjusted non-GAAP diluted earnings per share of \$0.74

Baudette, Minnesota (May 4, 2017) – ANI Pharmaceuticals, Inc. (“ANI”) (NASDAQ: ANIP) today reported its financial results for the three months ended March 31, 2017, and reaffirmed its 2017 financial guidance. The Company will host its earnings conference call this morning, May 4, 2017, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 93296077.

Financial Summary

<i>(in thousands, except per share data)</i>	<u>Q1 2017</u>	<u>Q1 2016</u>
Net revenues	\$ 36,628	\$20,555
Net income	\$ 1,152	\$ 1,346
GAAP earnings per diluted share	\$ 0.10	\$ 0.12
Adjusted non-GAAP EBITDA^(a)	\$ 14,729	\$11,380
Adjusted non-GAAP diluted earnings per share^(b)	\$ 0.74	\$ 0.53

^(a) See Table 2 for US GAAP reconciliation.

^(b) See Table 3 for US GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

“ANI had a strong quarter, with revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted earnings per share increasing 78%, 29%, and 40%, respectively, as compared to the prior year. In the first quarter, we achieved our internal projections and, as a result, we are reaffirming our guidance for 2017. Results for 2017 will include the impact of recent contract wins that have increased our market share of EEMT to approximately 65%, the full effect of which will begin in the second quarter. Results for 2017 will also include the impacts of the launch of the InnoPran XL® and Inderal® XL products, the launch of Inderal® LA in the ANI label, and additional targeted product launches. These factors will have a positive effect on our revenues and adjusted non-GAAP EBITDA for the remainder of the year.”

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%.
- Sales, general, and administrative costs to be between \$30.2 million and \$30.9 million.
- Research and development costs to be between \$6.5 million and \$6.8 million.
- 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 first quarter 2017, ANI's active pharmaceutical ingredient ("API") manufacturer successfully manufactured a development lot of Corticotropin API, replicating the yield and process from when the API was last manufactured. In the second quarter, ANI has initiated the scale-up of the API manufacturing process and process characterization, which is the next step prior to commercial scale API manufacturing. ANI has identified potential finished dosage form contract manufacturers and plans to select one and initiate Corticotropin finished dosage form manufacturing in the second half of 2017. ANI has continued to make progress developing analytical methods to analyze the components of the purified Corticotropin API powder. These analytical methods are being used to generate results that are, in turn, compared to results from historical batches of API. ANI has developed a comprehensive regulatory filing plan for the Corticotropin Gel product and intends to meet and present the plan to the FDA in the second half of 2017.

First Quarter Results

Net Revenues (in thousands)	Three Months Ended March 31,		Change	% Change
	2017	2016		
Generic pharmaceutical products	\$ 26,572	\$ 13,252	\$ 13,320	101%
Branded pharmaceutical products	8,039	5,596	2,443	44%
Contract manufacturing	1,793	1,384	409	30%
Contract services and other income	224	323	(99)	(31)%
Total net revenues	<u>\$ 36,628</u>	<u>\$ 20,555</u>	<u>\$ 16,073</u>	78%

For the three months ended March 31, 2017, ANI reported net revenues of \$36.6 million, an increase of 78% from \$20.6 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 101%, to \$26.6 million from \$13.3 million in the prior period, primarily due to sales of the generic products launched during 2016.
- Revenues from sales of branded pharmaceuticals increased 44%, to \$8.0 million from \$5.6 million in the prior period, primarily due to sales of Inderal® LA, which was launched in Q2 2016, and sales of Inderal® XL and InnoPran XL®, which were launched in late February 2017.
- Contract manufacturing revenue increased by 30% to \$1.8 million from \$1.4 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 31%, to \$0.2 million from \$0.3 million, primarily because sales of Fenofibrate in the ANI label have replaced the royalties previously received on the product.

Operating expenses increased to \$32.0 million for the three months ended March 31, 2017, from \$14.9 million in the prior year period. The increase was primarily due to a \$13.0 million increase in cost of sales as compared with the prior period, as a result of a higher sales of products sold with profit-sharing arrangements, increased volume, and \$1.5 million of cost of sales related to the net inventory step-up on Inderal® LA, Inderal® XL, and InnoPran XL® inventory. In addition, depreciation and amortization increased by \$2.1 million as compared with the prior period, driven by amortization of a higher intangible asset base.

Excluding the \$1.5 million of net inventory step-up costs related to sales of Inderal® LA, Inderal® XL, and InnoPran XL®, cost of sales increased as a percentage of net revenues to 41% from 17%, primarily as a result of increased sales of products with profit-sharing arrangements.

Net income was \$1.2 million for the three months ended March 31, 2017, as compared to net income of \$1.3 million in the prior year period. The effective tax rate for the three months ended March 31, 2017 was 31%.

Diluted earnings per share for the three months ended March 31, 2017 was \$0.10, based on 11,653 thousand diluted shares outstanding, as compared to diluted earnings per share of \$0.12 in the prior year period. Adjusted non-GAAP diluted earnings per share was \$0.74, as compared to adjusted non-GAAP diluted earnings per share of \$0.53 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 3.

Selected Balance Sheet Data

(in thousands)

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
Cash	\$ 10,826	\$ 27,365
Accounts receivable, net	\$ 46,697	\$ 45,895
Inventory, net	\$ 45,893	\$ 26,183
Current assets	\$ 106,981	\$ 103,007
Current liabilities	\$ 32,425	\$ 31,948

ANI generated \$6.5 million of positive cash flows from operations in the three months ended March 31, 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, 53 were acquired and of these acquired products, ANI expects that 46 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 2.

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 3.

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 3.

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.

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