

# ANI Pharmaceuticals Reports Record Third Quarter Results and Year-To-Date 2016 Highlights and Narrows Full-year Guidance

For the third quarter 2016:

- Record net revenues of \$38.5 million, an increase of 93% as compared to the same period in 2015
- GAAP net income of \$2.5 million and diluted GAAP earnings per share of \$0.22
- Adjusted non-GAAP EBITDA of \$16.4 million
- Adjusted non-GAAP net income per diluted share of \$1.09

Baudette, Minnesota (November 3, 2016) – ANI Pharmaceuticals, Inc. (“ANI”) (NASDAQ: ANIP) today reported record financial results for the three and nine months ended September 30, 2016, and reaffirmed and narrowed its 2016 financial guidance. The Company will host its earnings conference call this morning, November 3, 2016, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 93840986.

## Financial Summary

<i>(in thousands, except per share data)</i>	<u>Q3 2016</u>	<u>Q3 2015</u>	<u>YTD 2016</u>	<u>YTD 2015</u>
<b>Net revenues</b>	\$ 38,525	\$19,972	\$90,417	\$58,287
<b>Net income</b>	\$ 2,543	\$ 4,559	\$ 5,014	\$ 12,499
<b>GAAP earnings per diluted share</b>	\$ 0.22	\$ 0.39	\$ 0.43	\$ 1.07
<b>Adjusted non-GAAP EBITDA<sup>(a)</sup></b>	\$ 16,354	\$11,618	\$43,178	\$33,938
<b>Adjusted non-GAAP net income per diluted share<sup>(b)</sup></b>	\$ 1.09	\$ 0.80	\$ 2.93	\$ 2.20

<sup>(a)</sup> See Table 2 for US GAAP reconciliation.

<sup>(b)</sup> See Table 3 for US GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

“ANI had another record quarter, with revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP net income per diluted share increasing 93%, 41%, and 36%, respectively, as compared to the prior year quarter. These increases are the direct result of our nine product launches in the first three quarters of 2016. We expect to launch at least one additional product before year end, for a total of eleven.”

## ANI Reaffirms and Narrows Guidance for the Full Year 2016

ANI’s estimates are based on projected results for the twelve months ending December 31, 2016 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 2016 to be between \$128 million and \$134 million.
- Reported (US GAAP) diluted EPS to be between \$0.60 and \$0.75, assuming 11,625 thousand weighted average shares outstanding.
- Adjusted non-GAAP EBITDA to be between \$59 million and \$63 million.
- Adjusted non-GAAP net income per diluted share to be between \$4.00 and \$4.25.

ANI will provide guidance for 2017 when the Company announces its fourth quarter 2016 results.

## Corticotropin Re-commercialization Update

ANI has assembled a Corticotropin re-commercialization team of scientists and subject matter experts who have extensive experience with the development and manufacturing of animal-derived pharmaceutical products. ANI has also established a laboratory exclusively for Corticotropin analytical method development. The team has already achieved several key milestones, including identifying and initiating the development of analytical methods that will be required to re-commercialize Corticotropin, a critical portion of the sNDA filing. At the same time, ANI has also secured the supply of porcine pituitaries necessary for both small and commercial-scale active pharmaceutical ingredient manufacturing, which is also pivotal for the re-launch of Corticotropin. Finally, ANI has contracted with an accomplished contract manufacturer and initiated manufacturing of Corticotropin active pharmaceutical ingredient. Due to these efforts, the project is tracking ahead of ANI's internal timeline. ANI remains dedicated to the re-commercialization of Corticotropin and will provide updates regarding further progress as appropriate.

## Third Quarter Results

Net Revenues (in thousands)	Three Months Ended September 30,		Change	% Change
	2016	2015		
Generic pharmaceutical products	\$ 30,191	\$ 15,102	\$ 15,089	100%
Branded pharmaceutical products	6,834	2,253	4,581	203%
Contract manufacturing	1,427	1,280	147	12%
Contract services and other income	73	1,337	(1,264)	(95)%
Total net revenues	<u>\$ 38,525</u>	<u>\$ 19,972</u>	<u>\$ 18,553</u>	93%

For the three months ended September 30, 2016, ANI reported net revenues of \$38.5 million, an increase of 93% from \$20.0 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 100%, to \$30.2 million from \$15.1 million in the prior period, primarily due to sales of the ten products launched over the previous twelve months.
- Revenues from sales of branded pharmaceuticals increased 203%, to \$6.8 million from \$2.3 million in the prior period, primarily due to sales of Inderal® LA, which was launched in Q2 2016.
- Contract manufacturing revenue increased by 12% to \$1.4 million from \$1.3 million in the prior year period, primarily as a result of the timing of customer orders.
- Contract services and other income decreased by 95%, to \$0.1 million from \$1.3 million, primarily because sales of Vancomycin in the ANI label have replaced the royalties previously received on the product.

Operating expenses increased to \$30.6 million for the three months ended September 30, 2016, from \$11.5 million in the prior year period. The increase was primarily due to a \$13.4 million increase in cost of sales as compared with the prior period, as a result of a higher mix of sales of products with profit-sharing arrangements, increased volume, and \$1.1 million of cost of sales related to the inventory step-up on Inderal® LA and Propranolol ER inventory. In addition, depreciation and amortization increased by \$3.9 million as compared with the prior period, driven by amortization of a higher intangible asset base.

Excluding the \$1.1 million of costs related to the Inderal® LA inventory step-up, cost of sales increased as a percentage of net revenues to 40% from 16%, primarily as a result of increased sales of products with profit-sharing arrangements.

Net income was \$2.5 million for the three months ended September 30, 2016, as compared to net income of \$4.6 million in the prior year period. The effective tax rate for the three months ended September 30, 2016 was 50%, including a 57% rate for current taxes partially offset by a 7% rate benefit for deferred taxes.

Diluted earnings per share for the three months ended September 30, 2016 was \$0.22, based on 11,625 thousand diluted shares outstanding, as compared to diluted earnings per share of \$0.39 in the prior year period. Adjusted non-GAAP net income per diluted share was \$1.09, as compared to adjusted non-GAAP net income per diluted share of \$0.80 in the prior year period. For a reconciliation of adjusted non-GAAP net income per diluted share to the most directly comparable GAAP financial measure, please see Table 3.

### Results for Nine Months Ended September 30, 2016

Net Revenues (in thousands)	Nine Months Ended September 30,		Change	% Change
	2016	2015		
Generic pharmaceutical products	\$ 65,905	\$ 41,122	\$ 24,783	60%
Branded pharmaceutical products	19,919	8,662	11,257	130%
Contract manufacturing	3,977	3,576	401	11%
Contract services and other income	616	4,927	(4,311)	(87)%
Total net revenues	\$ 90,417	\$ 58,287	\$ 32,130	55%

For the nine months ended September 30, 2016, ANI reported net revenues of \$90.4 million, an increase of 55% from \$58.3 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 60%, to \$65.9 million from \$41.1 million in the prior period, primarily due to sales of the ten products launched over the previous twelve months.
- Revenues from sales of branded pharmaceuticals increased 130%, to \$19.9 million from \$8.7 million in the prior period, primarily due to sales of Inderal® LA, which was launched in Q2 2016.
- Contract manufacturing revenue increased by 11% to \$4.0 million from \$3.6 million in the prior year period, primarily as a result of the timing of customer orders.
- Contract services and other income decreased by 87%, to \$0.6 million from \$4.9 million, primarily because sales of Vancomycin in the ANI label have replaced the royalties previously received on the product, partially offset by royalty income on sales of Fenofibrate, the authorized generic of Lipofen®. ANI received royalties on sales of Fenofibrate during a brief transition period prior to launching the product under the ANI label.

Operating expenses increased to \$71.6 million for the nine months ended September 30, 2016, from \$31.9 million in the prior year period. The increase was primarily due to a \$22.7 million increase in cost of sales as compared with the prior period, as a result of a higher mix of sales of products with profit-sharing arrangements, increased volumes, and \$3.2 million of cost of sales related to the inventory step-up on Inderal® LA and Propranolol ER inventory. In addition, depreciation and amortization increased by \$11.7 million as compared with the prior period, driven by amortization of a higher intangible asset base. Selling, general, and administrative expenses for the period includes \$1.3 million of principally non-cash expense, representing the entire cost of ANI's CFO transition.

Excluding the \$3.2 million of costs related to the Inderal® LA inventory step-up, cost of sales increased as a percentage of net revenues to 32% from 16%, primarily as a result of increased sales of products with profit-sharing arrangements.

Net income was \$5.0 million for the nine months ended September 30, 2016, as compared to net income of \$12.5 million in the prior year period. The effective tax rate for the nine months ended September 30, 2016 was 51%, including a 59% rate for current taxes partially offset by an 8% rate benefit for deferred taxes.

Diluted earnings per share for the nine months ended September 30, 2016 was \$0.43, based on 11,552 thousand diluted shares outstanding, as compared to diluted earnings per share of \$1.07 in the prior year period. Adjusted non-GAAP net income per diluted share was \$2.93, as compared to adjusted non-GAAP net income per diluted share of \$2.20 in the prior year period. For a reconciliation of adjusted non-GAAP net income per diluted share to the most directly comparable GAAP financial measure, please see Table 3.

#### **Year-to-Date Highlights Include:**

- Record year-to-date net revenues of \$90.4 million, an increase of 55% as compared to the same period in 2015.
- Year-to-date net income of \$5.0 million and year-to-date diluted earnings per share of \$0.43, each a decrease of 60% as compared to the same period in 2015.
- Year-to-date adjusted non-GAAP EBITDA of \$43.2 million, an increase of 27% as compared to the same period in 2015.
- Year-to-date adjusted non-GAAP diluted earnings per share of \$2.93, an increase of 33% as compared to the same period in 2015.
- Acquired NDAs for Corticotropin and Corticotropin-Zinc.
- Launched 10 products, including one mature brand and nine generics.

#### **Selected Balance Sheet Data**

*(in thousands)*

	<b><u>September 30, 2016</u></b>	<b><u>December 31, 2015</u></b>
Cash	\$ 16,155	\$ 154,684
Accounts receivable, net	\$ 47,477	\$ 21,932
Inventory, net	\$ 28,261	\$ 13,387
Current assets	\$ 95,475	\$ 192,583
Current liabilities	\$ 30,491	\$ 11,756

ANI generated \$15.4 million of positive cash flows from operations in the nine months ended September 30, 2016. In January 2016, ANI purchased from Merck the NDAs for Corticotropin and Corticotropin-Zinc for \$75.0 million and a percentage of future net sales on products sold under the NDAs. Also in January 2016, ANI purchased from H2-Pharma, LLC the exclusive U.S. distribution rights for two products, as well as an early stage development project for a generic injectable drug product, for \$8.8 million in cash and the assumption of an accrued royalty of \$1.2 million. In April 2016, ANI purchased from Cranford Pharmaceuticals, LLC the rights, title, and interest in the NDA for Inderal® LA, as well as certain documentation, trademark rights, and finished goods for \$60.0 million in cash and milestone payments based on future gross profits from sales of products under the NDA. ANI also transferred \$5.0 million to an escrow account to secure the future milestone payments. As a result of the net effect of these sources and uses of cash, ANI had \$16.2 million of cash at September 30, 2016.

## **ANI Product Development Pipeline**

ANI's pipeline consists of 78 products, addressing a total annual market size of \$3.7 billion, based on data from IMS Health. Of these 78 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 2016 guidance for adjusted non-GAAP EBITDA and adjusted non-GAAP net income per diluted 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, 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 non-cash stock-based compensation, non-cash interest expense, depreciation amortization, and deferred tax expenses and benefits. Management uses adjusted non-GAAP net income when analyzing Company performance.

Adjusted non-GAAP net income is defined as net income/(loss), plus tax expense, the excess of fair value over cost of acquired inventory, stock-based compensation expense, non-cash interest expense, depreciation and amortization expense, less the current portion of the tax provision. 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 Net Income per Diluted Share***

ANI's management considers adjusted non-GAAP net income per diluted 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 non-cash stock-based compensation, non-cash interest expense, depreciation, amortization, and deferred tax expenses and benefits. Management uses adjusted non-GAAP net income per diluted share when analyzing Company performance.

Adjusted non-GAAP net income per diluted share is defined as adjusted non-GAAP net income, as defined above, divided by the diluted weighted average shares outstanding during the period. Adjusted non-GAAP net income per diluted share should be considered in addition to, but not in lieu of, earnings or

loss per share reported under GAAP. A reconciliation of adjusted non-GAAP net income per diluted 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 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; 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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