

ANI Pharmaceuticals Reports First Quarter 2018 Results and Reaffirms Guidance

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

Baudette, Minnesota (May 8, 2018) – 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>	Q1 2018	Q1 2017
Net revenues	\$ 46,483	\$ 36,628
Net income	\$ 2,250	\$ 1,152
GAAP earnings per diluted share	\$ 0.19	\$ 0.10
Adjusted non-GAAP EBITDA^(a)	\$ 21,754	\$ 14,729
Adjusted non-GAAP diluted earnings per share^(b)	\$ 1.32	\$ 0.74

^(a) See Table 3 for U.S. GAAP reconciliation.

^(b) 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>2018 Guidance</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			% Change
	March 31,			
	2018	2017	Change	
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 ⁽¹⁾
Contract manufacturing	945	1,793	(848)	(47)%
Total net revenues	<u>\$ 46,483</u>	<u>\$ 36,628</u>	<u>\$ 9,855</u>	27%

⁽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)

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
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.

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