ANI Pharmaceuticals Reports First Quarter Results and Year-To-Date 2016 Highlights and Reaffirms Updated Guidance

For the first quarter 2016:

- **Net revenues of $20.6 million, adjusted non-GAAP EBITDA of $11.4 million, and operating income of $5.7 million**
- **Adjusted non-GAAP net income per diluted share of $0.76 and diluted earnings per share of $0.12**

Baudette, Minnesota (May 5, 2016) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported financial results for the three months ended March 31, 2016, and reaffirmed its financial guidance for 2016 as updated on April 4, 2016. The Company will host its earnings conference call this morning, May 5, 2016, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (844) 295-8236. The conference ID is 93601942.

Arthur S. Przybyl, President and CEO, stated,

> "ANI had a strong first quarter. Thus far in 2016, we have closed three acquisitions and received two FDA approvals. We anticipate launching a total of seven products in the second quarter of 2016, three of which were launched in April.
>
> We began the year with the completion of our acquisition of the Corticotropin NDAs on January 4th, followed closely by the January 28th acquisition of the exclusive rights to distribute the authorized generic of Lipofen®, as well as 1% and 2.5% hydrocortisone rectal cream. We launched the hydrocortisone rectal cream products in April and are currently launching the authorized generic of Lipofen® in our own label. On April 1st, we completed our acquisition of the Inderal® NDA, which will be accretive to revenue and adjusted non-GAAP EBITDA starting in the second quarter and is included in our guidance."

ANI's Updated 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, and the anticipated timing of future product launches and events.

- Net revenues for 2016 to be between $119 million and $134 million.
- Adjusted non-GAAP EBITDA[(a)], to be between $55 million and $63 million.
- Adjusted non-GAAP net income per diluted share[(b)], to be between $3.54 and $3.91, assuming 11,489 thousand weighted average shares outstanding.
- Reported (US GAAP) diluted EPS to be between $0.30 and $0.65.

ANI's 2016 guidance is based on certain assumptions including:

- EEMT market share is anticipated to remain stable at approximately 50%.
- Cost of sales[(c)] of approximately 35%.
- Operating expenses[(d)], inclusive of research and development costs, of between $24 and $24.5 million.

- Depreciation and amortization expense of approximately $22.6 million.
- Interest expense of approximately $11.4 million.
- Current tax provision of between $11.5 and $16.5 million.

[a] See Table 2 for US GAAP reconciliation.
[b] See Table 3 for US GAAP reconciliation.
[c] Exclusive of depreciation and amortization.
[d] Excludes non-cash stock compensation expense.

New Product Introductions

Product	Total Annual Market Size[e]	Estimated Launch	FDA Approvals Required
Inderal® LA	$23M	Launched April 2016	Approved
Propranolol ER	$165M	Launched April 2016	Approved
Hydrocortisone rectal cream, 1% and 2.5%	$84M	Launched April 2016	Approved
Fenofibrate 50mg and 150mg	$24M	May 2016	Approved
Authorized generic product	$21M	May 2016	Approved
Oxycodone capsules	$7.5M	June 2016	Approved
Anti-cancer drug	Undisclosed	June 2016	ANDA
Donepezil	$41M	Q3 2016	Approved
Anti-Infective	$75M	Q3 2016	CBE-30
Three IDT products	$86M	Q3 2016/Q4 2016	CBE-30s
Three additional C-II products (TADs[f] 1/2/2017 and 2/15/2017)	$39M	Q1 2017	ANDAs

[e] Per IMS Health
[f] FDA's Target Action Date, per FDA communications

Year-to-Date Highlights Include:

- First quarter net revenues of $20.6 million, an increase of 9% as compared to $18.8 million for the same period in 2015.
- First quarter adjusted non-GAAP EBITDA of $11.4 million, a slight decrease of 1% as compared to $11.5 million for the same period in 2015.
- First quarter operating income of $5.7 million, a decrease of 41% as compared to $9.6 million for the same period in 2015.
- First quarter adjusted non-GAAP diluted earnings per share of $0.76.
- First quarter diluted earnings per share of $0.12.
- Appointment of Stephen P. Carey as Vice President and Chief Financial Officer.
- Acquired NDAs for Corticotropin and Corticotropin-Zinc.
- Acquired exclusive rights to distribute an authorized generic of Lipofen® and 1% and 2.5% hydrocortisone rectal cream.
- Acquired the product rights for Inderal® LA.
- Received ANDA approval for Donepezil tablets (via Dexcel partnership).
- Received ANDA approval for Oxycodone capsules.
- Launched 1% and 2.5% hydrocortisone rectal cream.
- Launched Inderal® LA and Propranolol ER.
- Repurchased 65 thousand shares of ANIP common stock for $2.5 million.

First Quarter Results

Net Revenues (in thousands)	**Three Months Ended March 31,**			
	2016	**2015**	**Change**	**% Change**
Generic pharmaceutical products	$ 13,252	$ 12,256	$ 996	8%
Branded pharmaceutical products	5,596	4,272	1,324	31%
Contract manufacturing	1,384	1,205	179	15%
Contract services and other income	323	1,066	(743)	(70)%
Total net revenues	$ 20,555	$ 18,799	$ 1,756	9%

For the three months ended March 31, 2016, ANI reported net revenues of $20.6 million, an increase of 9% from $18.8 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 8%, to $13.3 million from $12.3 million in the prior period, primarily due to, sales of Oxycodone oral solution, Vancomycin, Nimodipine, and Flecainide, all of which were launched in Q4 2015, as well as full quarter sales of Etodolac, and Propafenone, which launched in Q1 2015.
- Revenues from sales of branded pharmaceuticals increased 31%, to $5.6 million from $4.3 million in the prior period, primarily as a result of higher sales of Lithobid and Vancocin, partially offset by lower unit sales of Reglan and increased Medicaid utilization for Lithobid and Vancocin.
- Contract manufacturing revenue increased by 15% to $1.4 million from $1.2 million in the prior year period, primarily as a result of the timing of customer orders.
- Contract services and other income decreased by 70%, to $0.3 million from $1.1 million, primarily because the Company launched an authorized generic for Vancocin under its own label, which replaced the authorized generic product previously on the market, partially offset by royalty income on sales of the authorized generic of Lipofen®, which is anticipated to launch under the ANI label in the second quarter.

Cost of sales increased as a percentage of net revenues to 17% from 15%, primarily as a result of increased sales of products with profit-sharing arrangements.

Research and development costs increased to $1.0 million for the three months ended March 31, 2016, from $0.4 million in the prior year period. The increase was due to timing of work on development projects. Major development projects include the ANDAs acquired in 2014 and 2015, as well as collaborations with partners.

Selling, general, and administrative expenses increased to $5.9 million for the three months ended March 31, 2016, from $4.8 million in the prior year period. The increase was primarily due to increased personnel and compensation costs to support growth of the business.

Net income was $1.3 million for the three months ended March 31, 2016, as compared to net income of $4.4 million in the prior year period, primarily due to a $3.3 million increase in depreciation and amortization in the current period. Diluted earnings per share for the three months ended March 31, 2016 was $0.12, based on 11,489 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.38 in the prior year period.

Adjusted non-GAAP net income per diluted share was $0.76, as compared to adjusted non-GAAP net income per diluted share of $0.71 in the prior year period. For a reconciliation of adjusted non-GAAP net income per diluted share to GAAP net income, please see Table 3.

Selected Balance Sheet Data

(in thousands)

	March 31, 2016	December 31, 2015
Cash	$ 77,747	$ 154,684
Accounts receivable, net	$ 22,481	$ 21,932
Inventory, net	$ 13,922	$ 13,387
Current assets	$ 116,552	$ 192,583
Current liabilities	$ 16,211	$ 11,756

ANI generated $11.0 million of positive cash flows from operations in the three months ended March 31, 2016. Also in the first quarter, 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. ANI also purchased from H2-Pharma, LLC the exclusive U.S. distribution rights for three 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. As a result of the net effect of these sources and uses of cash, ANI had $77.7 million of cash at March 31, 2016. On April 1, 2016, ANI purchased from Cranford Pharmaceuticals 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 upon closing and milestone payments based on future gross profits from sales of products under the NDA. The $60.0 million was paid from cash on hand. At closing, ANI also transferred $5.0 million to an escrow account to secure future milestone payments.

Net accounts receivable increased from $21.9 million to $22.5 million. ANI's net inventory increased from $13.4 million to $13.9 million, as a direct result of raw materials acquired for key products. ANI's total current assets decreased to $116.6 million at March 31, 2016, from $192.6 million at December 31, 2015.

ANI Product Development Pipeline

Overview

ANI's pipeline consists of 81 products, 55 of which were acquired. Of these acquired products, ANI expects that 48 can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

Product Development

ANI expects to file two prior approval supplements and two CBE-30s in 2016. A table summarizing ANI's pipeline of products is below:

Products	ANI	Partnered	Total
At FDA	3	1	4
Development	3	19	22
Acquired Products	55	0	55

ANI's product development pipeline includes extended-release products, controlled substances, anti-cancers, oral solutions, suspensions, and solid dosage forms. These 81 generic products address a total annual market size of $4.1 billion, based on data from IMS Health.

Non-GAAP Financial Measures

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 operating income/(loss), excluding depreciation, amortization, the excess of fair value over cost of acquired inventory, and stock-based compensation 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.

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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