ANI Pharmaceuticals Reports Third Quarter and Year-To-Date 2015 Results and Highlights

For the third quarter 2015:

- **Net revenues of $20.0 million, an increase of 15% versus third quarter 2014**
- **Adjusted non-GAAP EBITDA of $11.6 million and operating income of $8.5 million, increases of 15% and 3%, respectively, versus third quarter 2014**
- **Adjusted non-GAAP net income per diluted share of $0.80 and diluted earnings per share of $0.39**

Baudette, Minnesota (November 3, 2015) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported financial results for the three and nine months ended September 30, 2015 and updated its financial guidance for 2015. The Company will host its earnings conference call this morning, November 3, 2015, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (844) 295-8236. The conference ID is 59208657.

Arthur S. Przybyl, President and CEO, stated,

> "We are pleased to report a strong third quarter, with increases over the prior year in revenue, EBITDA, and operating income. We have a compelling product pipeline of 85 drugs that represent over $4.6 billion in IMS sales. Recently, we launched two new generic drugs, Oxycodone and Vancomycin, which will help to expand our growing generic business segment and increased our total currently-marketed products to 14. Our near-term focus is on launching ten additional drugs over the next five quarters. Two of these drugs represent the potential for significant upside to our revenues and EBITDA. Business development activities included a new agreement with IDT Australia to commercialize 18 previously approved drugs and our announcement to acquire two Corticotropin NDAs from Merck. These NDAs have the future potential to be the largest selling drugs in ANI's portfolio."

Net revenues and Adjusted Non-GAAP EBITDA

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2015	**2014**	**2015**	**2014**
Net revenues	$ 19,972	$ 17,387	$ 58,287	$ 34,933
Adjusted Non-GAAP EBITDA[(a)]	$ 11,618	$ 10,078	$ 33,938	$ 14,549

[(a)] See Table 2 for US GAAP reconciliation.

Year-to-Date Highlights Include:

- Year-to-date net revenues of $58.3 million, an increase of 67% as compared to $34.9 million for the same period in 2014.
- Year-to-date adjusted non-GAAP EBITDA of $33.9 million, an increase of 133% as compared to $14.5 million for the same period in 2014.
- Year-to-date operating income of $26.4 million, an increase of 186% as compared to $9.2 million for the same period in 2014.
- Year-to-date adjusted non-GAAP net income per diluted share of $2.20.

- Year-to-date diluted earnings per share of $1.07.
- Awarded two new contracts for EEMT, which were effective in the 2nd and 3rd quarters.
- Launched Oxycodone Hydrochloride oral solution.
- Launched Vancomycin capsules.
- Launched Etodolac capsules and Propafenone tablets.
- Received ANDA approval for Nimodipine capsules (via Sofgen partnership).
- Entered into an agreement to acquire 2 NDAs for purified Corticotropin gel and Corticotropin-zinc Hydroxide for $75 million.
- Entered into a collaborative arrangement with IDT Australia to commercialize up to 18 drugs related to previously-approved ANDAs.
- Acquired 22 generic products for $25.0 million.
- Acquired Flecainide ANDA for $4.5 million.
- Acquired 1% Testosterone Gel NDA.

Third Quarter Results

Net Revenues (in thousands)	**Three Months Ended September 30,**			
	2015	**2014**	**Change**	**% Change**
Generic pharmaceutical products	$ 15,102	$ 10,188	$ 4,914	48 %
Branded pharmaceutical products	2,253	4,806	(2,553)	(53)%
Contract manufacturing	1,280	1,350	(70)	(5)%
Contract services and other income	1,337	1,043	294	28 %
Total net revenues	$ 19,972	$ 17,387	$ 2,585	15 %

For the three months ended September 30, 2015, ANI reported net revenues of $20.0 million, an increase of 15% from $17.4 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 48%, to $15.1 million from $10.2 million in the prior period, primarily due to increased sales of EEMT, as well as sales from Methazolamide, which was launched in the fourth quarter of 2014, and Etodolac and Propafenone, which were launched in the first quarter of 2015.
- Revenues from sales of branded pharmaceuticals decreased 53%, to $2.3 million from $4.8 million in the prior period, primarily as a result of lower unit sales of Reglan, decreases in unit sales of Lithobid and Vancocin, and increased Medicaid utilization and Medicaid rebates for both Lithobid and Vancocin.
- Contract manufacturing revenue decreased by 5% to $1.3 million from $1.4 million in the prior year period, primarily as a result of timing of customer orders.
- Contract services and other revenues increased by 28%, to $1.3 million from $1.0 million, primarily due to royalties received on sales of the authorized generic of Vancocin. In November, the Company launched an authorized generic for Vancocin under its own label, which replaced the authorized generic product previously on the market.

Adjusted non-GAAP EBITDA was $11.6 million for the three months ended September 30, 2015, compared to $10.1 million in the prior year period, an increase of 15%. For a reconciliation of adjusted non-GAAP EBITDA to GAAP operating income, please see Table 2.

Cost of sales decreased as a percentage of net revenues to 16% from 18%, primarily due to a favorable shift in product mix toward the Company's higher-margin products and margin increases for the Company's generic products.

Research and development costs decreased to $0.8 million for the three months ended September 30, 2015, from $0.9 million in the prior year period. The decrease was due to timing of work on development projects. Major development projects include the ANDAs acquired in 2014 and 2015, Flecainide, and collaborations with partners.

Selling, general and administrative expenses increased to $5.4 million for the three months ended September 30, 2015, from $4.1 million in the prior year period. The increase was primarily due to increased business development activities and increased personnel and compensation costs.

Operating income was $8.5 million for the three months ended September 30, 2015, as compared to $8.2 million in the prior year period.

Other income/expense changed to $2.8 million of expense in the three months ended September 30, 2015, from $0.1 million of income in the prior year period, due to interest expense related to the convertible debt issued in December 2014.

Net income was $4.6 million for the three months ended September 30, 2015, as compared to net income of $6.7 million in the prior year period. Diluted earnings per share for the three months ended September 30, 2015 was $0.39, based on 11,563 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.59 in the prior year period.

Adjusted non-GAAP net income per diluted share was $0.80. For a reconciliation of adjusted non-GAAP net income per diluted share to GAAP net income, please see Table 3.

Results for Nine Months Ended September 30, 2015

Net Revenues (in thousands)	**Nine Months Ended September 30,**			
	2015	**2014**	**Change**	**% Change**
Generic pharmaceutical products	$ 41,122	$ 23,077	$ 18,045	78%
Branded pharmaceutical products	8,662	6,149	2,513	41%
Contract manufacturing	3,576	4,121	(545)	(13)%
Contract services and other income	4,927	1,586	3,341	211%
Total net revenues	$ 58,287	$ 34,933	$ 23,354	67%

For the nine months ended September 30, 2015, ANI reported net revenues of $58.3 million, an increase of 67% from $34.9 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 78%, to $41.1 million from $23.1 million in the prior period, primarily due to increased sales of EEMT, as well as sales from Methazolamide, which was launched in the fourth quarter of 2014, and Etodolac and Propafenone, which were launched in the first quarter of 2015.
- Revenues from sales of branded pharmaceuticals increased 41%, to $8.7 million from $6.1 million in the prior period, primarily as a result of sales of Lithobid and Vancocin, which were

acquired in the third quarter of 2014, partially offset by lower unit sales of Reglan and increased Medicaid utilization and Medicaid rebates for Lithobid and Vancocin.

- Contract manufacturing revenue decreased by 13% to $3.6 million from $4.1 million in the prior year period, primarily as a result of timing of customer orders.
- Contract services and other revenues increased by 211%, to $4.9 million from $1.6 million, primarily due to royalties received on sales of the authorized generic of Vancocin. In the second quarter, ANI's authorized generic partner for Vancocin adjusted its estimates for chargebacks, rebates, and other deductions from gross sales for the last five months of 2014, which resulted in a non-recurring $1.4 million increase in royalty revenue. In November, the Company launched an authorized generic for Vancocin under its own label, which replaced the authorized generic product previously on the market.

Adjusted non-GAAP EBITDA was $33.9 million for the nine months ended September 30, 2015, compared to $14.5 million in the prior year period, an increase of 133%. For a reconciliation of adjusted non-GAAP EBITDA to GAAP operating income, please see Table 2.

Cost of sales decreased as a percentage of net revenues to 16% from 22%, primarily due to higher margin sales of the Lithobid and Vancocin branded products and margin increases for the Company's generic products.

Research and development costs increased to $2.2 million for the nine months ended September 30, 2015, from $2.1 million in the prior year period. The increase was due to work on development projects, including the ANDAs acquired in 2014 and 2015, Flecainide, and collaborations with partners.

Selling, general and administrative expenses increased to $15.7 million for the nine months ended September 30, 2015, from $13.2 million in the prior year period. The increase was primarily due to increased expenses associated with the Company's business development activities and increased personnel and compensation. These increases were partially offset by a non-recurring prior period $1.3 million catch-up adjustment for non-cash stock-based compensation expense recognized upon shareholder approval of an increase in shares available for issuance under ANI's stock compensation plan.

Operating income was $26.4 million for the nine months ended September 30, 2015, as compared to $9.2 million in the prior year period.

Other income/expense changed to $8.2 million of expense in the nine months ended September 30, 2015, from $0.1 million of income in the prior year period, due to interest expense related to the convertible debt issued in December 2014.

Net income was $12.5 million for the nine months ended September 30, 2015, as compared to $7.7 million in the prior year period. Diluted earnings per share for the nine months ended September 30, 2015 was $1.07, based on 11,559 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.70 in the prior year period.

Adjusted non-GAAP net income per diluted share was $2.20. For a reconciliation of adjusted non-GAAP net income per diluted share to GAAP net income, please see Table 3.

ANI's Updated Guidance

ANI's updated guidance is based on management's current estimates of the Company's market share for its products, product pricing, cost of sales, and operating costs. The following tables provide summaries of ANI's updated 2015 fourth quarter and full year guidance ranges:

(in millions, except EPS)	**4Q 2015 Guidance**
Net revenues	$17.2 - $20.0
Adjusted non-GAAP EBITDA[(a)]	$9.4 - $11.5
Adjusted non-GAAP net income per diluted share[(b)]	$0.63 - $0.76

(in millions, except EPS and %s)	**Full Year 2015 Current**
Net revenues	$75.5 - $78.3
Cost of sales[(c)]	16.0%
Operating expenses[(d)]	$17.3
Research and development costs	$2.8 - $3.1
Adjusted non-GAAP EBITDA[(a)]	$43.3 - $45.4
Depreciation and amortization	$6.9
Total interest expense, net	$11.1
Cash interest expense, net	$4.2
Non-cash interest expense	$6.9
Estimated effective tax rate	31.5%
Adjusted non-GAAP net income per diluted share[(b)]	$2.83 - $2.96

[(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.

Selected Balance Sheet Data

(in thousands)

	September 30, 2015	**December 31, 2014**
Cash	$ 150,913	$ 169,037
Accounts Receivable, net	$ 21,645	$ 17,297
Inventory, net	$ 13,741	$ 7,518
Current Assets	$ 197,522	$ 203,478
Current Liabilities	$ 12,190	$ 13,233

ANI generated $12.6 million of positive cash flows from operations in the nine months ended September 30, 2015. Also during the first nine months of 2015, ANI acquired a basket of ANDAs for 22 products for $25 million and a generic product, Flecainide tablets, for $4.5 million. As a result of the net effect of these sources and uses of cash, ANI had $150.9 million of cash at September 30, 2015. As previously

announced, the Company entered into an asset purchase agreement to acquire purified Corticotropin gel and Corticotropin-zinc Hydroxide from Merck (known as MSD outside of the United States and Canada) for $75 million in cash and a percentage of future net sales. The asset acquisition is expected to close in January 2016.

Net accounts receivable increased from $17.3 million to $21.6 million. ANI's net inventory increased from $7.5 million to $13.7 million, as a direct result of raw materials acquired for key products. ANI's total current assets decreased to $197.5 million at September 30, 2015, from $203.5 million at December 31, 2014.

ANI Product Development Pipeline

Overview

ANI's pipeline consists of 85 products, 54 of which were acquired. Of these acquired products, ANI expects that 47 can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

Product Launches

Having launched Oxycodone Hydrochloride oral solution in October and Vancomycin capsules in November, ANI anticipates launching ten additional products by the end of 2016:

Product	Total Annual Market Size[(a)]	Estimated Launch	FDA Approvals Required
Nimodipine capsules (partnered with Sofgen)	$24M	Q4 2015	Approved
Flecainide tablets	$79M	Q4 2015	CBE-30
Dexcel product	$47M	Q2 2016	ANDA
Anti-cancer drug, (TAD[(b)] 2/26/2016)	Undisclosed	Q1 2016	ANDA
Five ANDAs acquired in July	$264M	Q4 2016	CBE-30
Testosterone 1% gel	$370M	Q4 2016	CBE-30

[(a)] Per IMS Health
[(b)] FDA's Target Action Date, per FDA communications

Product Development

ANI expects to file three prior approval supplements, seven CBE-30s, the Company's first Paragraph IV filing, and one internally-developed ANDA in the next 15 months. A table summarizing ANI's pipeline of products is below:

Products	ANI	Partnered	Total
At FDA	5	2	7
Development	3	21	24
Acquired Products	54	0	54

ANI's product development pipeline includes extended-release products, narcotics, anti-cancers, oral solutions, suspensions and solid dosage forms. These 85 generic products address a total annual market size of approximately $4.6 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, 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, 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 narcotics, 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; 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.

For more information about ANI, please contact:
Investor Relations
IR@anipharmaceuticals.com