

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

For the second quarter 2015:

- Net revenues of \$19.5 million, an increase of 194% versus second quarter 2014
- Adjusted non-GAAP EBITDA of \$10.9 million and operating income of \$8.4 million, increases of over 4,700% and 442%, respectively, versus second quarter 2014
- Adjusted non-GAAP diluted earnings per share of \$0.55 and diluted earnings per share of \$0.31

Baudette, Minnesota (August 4, 2015) – ANI Pharmaceuticals, Inc. (“ANI”) (NASDAQ: ANIP) today reported financial results for the three and six months ended June 30, 2015 and updated its financial guidance for 2015. The Company will host its earnings conference call this morning, August 4, 2015, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (855) 582-8078. The conference ID is 90889796.

Year-to-Date Highlights Include:

- Year-to-date net revenues of \$38.3 million, an increase of 118% as compared to \$17.5 million for the same period in 2014.
- Year-to-date adjusted non-GAAP EBITDA of \$22.3 million, an increase of 399% as compared to \$4.5 million for the same period in 2014.
- Year-to-date operating income of \$18.0 million, an increase of over 1,600% as compared to \$1.0 million for the same period in 2014.
- Year-to-date adjusted non-GAAP diluted earnings per share of \$1.12.
- Year-to-date diluted earnings per share of \$0.68.
- Awarded two new contracts for EEMT, effective in the 2nd and 3rd quarters.
- Launched Etodolac capsules and Propafenone tablets.
- Received ANDA approval for Oxycodone Hydrochloride Oral Solution.
- Received ANDA approval for Nimodipine capsules (via Sofgen partnership).
- Acquired 22 generic products for \$25.0 million.
- Acquired Flecainide ANDA for \$4.5 million.
- Acquired 1% Testosterone Gel NDA.

Net revenues and Adjusted Non-GAAP EBITDA (in thousands)

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Net revenues	\$ 19,516	\$ 6,647	\$ 38,315	\$ 17,546
Adjusted Non-GAAP EBITDA ^(a)	\$ 10,858	\$ 226	\$ 22,320	\$ 4,470

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

Arthur S. Przybyl, President and CEO, stated,

“ANI’s first half 2015 results yielded material increases in revenue, EBITDA, operating income, and earnings per share over the prior year period, due primarily to our acquisitions of Lithobid and Vancocin as well as the launch of Methazolamide tablets, Etodolac capsules and Propafenone tablets, three of the generic products we acquired in 2014. The revenue and EBITDA contributions from these products demonstrate the importance of our business development activities to our continued growth.

Consistent with that strategy, year to date we have acquired 24 products representing \$1.0 billion in IMS sales, including our most recent acquisition in July, when we acquired 22 generic products from Teva, bringing our total pipeline to 67 products, a substantial product pipeline for a pharmaceutical company our size. Equally important, 48 of our pipeline products can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

We are similarly focusing on organic growth as a revenue and EBITDA driver, by expanding our internally-developed product pipeline and growing our market share on our existing products. As previously announced, we received FDA approval for our Oxycodone Hydrochloride Oral Solution and our partnered Nimodipine Capsules, both of which we expect to launch in the fourth quarter of 2015, and closed several new sales agreements for EEMT in the first half of 2015. EEMT revenues increased from \$8.9 million in the first quarter to \$9.8 million in the second quarter and we expect additional increases in our EEMT revenues beginning in the third quarter.”

Second Quarter Results

Net Revenues (in thousands)	Three Months Ended June 30,		Change	% Change
	2015	2014		
Generic pharmaceutical products	\$ 13,764	\$ 4,836	\$ 8,928	185%
Branded pharmaceutical products	2,136	569	1,567	275%
Contract manufacturing	1,091	1,152	(61)	(5)%
Contract services and other income	2,525	90	2,435	2,706%
Total net revenues	<u>\$ 19,516</u>	<u>\$ 6,647</u>	<u>\$ 12,869</u>	194%

For the three months ended June 30, 2015, ANI reported net revenues of \$19.5 million, an increase of 194% from \$6.6 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 185%, to \$13.8 million from \$4.8 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. EEMT revenues are expected to increase in the third quarter due to sales agreements established in the first half of 2015.

- Revenues from sales of branded pharmaceuticals increased 275%, to \$2.1 million from \$0.6 million in the prior period, primarily as a result of sales of Lithobid and Vancocin, which were acquired in the third quarter of 2014.
- Contract manufacturing revenue decreased by 5% to \$1.1 million from \$1.2 million in the prior year period, primarily as a result of timing of customer orders.
- Contract services and other revenues increased by 2,706%, to \$2.5 million from \$0.1 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 the fourth quarter of 2015, the Company expects to launch an authorized generic for Vancocin under its own label, which will replace the authorized generic product currently on the market.

Adjusted non-GAAP EBITDA was \$10.9 million for the three months ended June 30, 2015, compared to \$0.2 million in the prior year period, an increase of over 4,700%. 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 32%, 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 \$1.0 million for the three months ended June 30, 2015, from \$0.9 million in the prior year period. The increase was due to work on development projects, including the ANDAs acquired in 2014, Flecainide, and new collaborations.

Selling, general and administrative expenses increased to \$5.6 million for the three months ended June 30, 2015, from \$5.4 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 \$8.4 million for the three months ended June 30, 2015, as compared to a \$2.5 million operating loss in the prior year period.

Other expense increased to \$2.7 million in the three months ended June 30, 2015 from \$36 thousand in the prior year period, due to interest expense related to the convertible debt issued in December 2014.

Net income was \$3.6 million for the three months ended June 30, 2015, reflecting an effective tax rate of 37.0%, as compared to a \$2.4 million net loss in the prior year period. Diluted earnings per share for the three months ended June 30, 2015 was \$0.31, based on 11,548,831 diluted shares outstanding, as compared to diluted loss per share of \$0.21 in the prior year period.

Adjusted non-GAAP diluted earnings per share was \$0.55. For a reconciliation of adjusted non-GAAP diluted earnings per share to GAAP net income, please see Table 3.

Results for Six Months Ended June 30, 2015

Net Revenues

(in thousands)

	Six Months Ended June 30,		Change	% Change
	2015	2014		
Generic pharmaceutical products	\$ 26,021	\$ 12,880	\$ 13,141	102%
Branded pharmaceutical products	6,408	1,353	5,055	374%
Contract manufacturing	2,295	2,771	(476)	(17)%
Contract services and other income	3,591	542	3,049	563%
Total net revenues	<u>\$ 38,315</u>	<u>\$ 17,546</u>	<u>\$ 20,769</u>	118%

For the six months ended June 30, 2015, ANI reported net revenues of \$38.3 million, an increase of 118% from \$17.5 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 102%, to \$26.0 million from \$12.9 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. EEMT revenues are expected to increase in the third quarter due to sales agreements established in the first half of 2015.
- Revenues from sales of branded pharmaceuticals increased 374%, to \$6.4 million from \$1.4 million in the prior period, primarily as a result of sales of Lithobid and Vancocin, which were acquired in the third quarter of 2014.
- Contract manufacturing revenue decreased by 17% to \$2.3 million from \$2.8 million in the prior year period, primarily as a result of timing of customer orders.
- Contract services and other revenues increased by 563%, to \$3.6 million from \$0.5 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 the fourth quarter of 2015, the Company expects to launch an authorized generic for Vancocin under its own label, which will replace the authorized generic product currently on the market.

Adjusted non-GAAP EBITDA was \$22.3 million for the six months ended June 30, 2015, compared to \$4.5 million in the prior year period, an increase of 399%. 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 15% from 27%, 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 \$1.4 million for the six months ended June 30, 2015, from \$1.2 million in the prior year period. The increase was due to work on development projects, including the ANDAs acquired in 2014 and new collaborations.

Selling, general and administrative expenses increased to \$10.3 million for the six months ended June 30, 2015, from \$9.1 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 \$18.0 million for the six months ended June 30, 2015, as compared to \$1.0 million in the prior year period.

Other expense increased to \$5.4 million in the six months ended June 30, 2015 from \$7 thousand in the prior year period, due to interest expense related to the convertible debt issued in December 2014.

Net income was \$7.9 million for the six months ended June 30, 2015, reflecting an effective tax rate of 36.9%, as compared to \$1.0 million in the prior year period. Diluted earnings per share for the six months ended June 30, 2015 was \$0.68, based on 11,555,522 diluted shares outstanding, as compared to diluted earnings per share of \$0.09 in the prior year period.

Adjusted non-GAAP diluted earnings per share was \$1.12. For a reconciliation of adjusted non-GAAP diluted earnings per 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 second half and full year guidance ranges:

<i>(in millions, except EPS)</i>	<u>2H 2015 Guidance</u>
Net revenues	\$44 - \$46
Adjusted non-GAAP EBITDA ^(a)	\$26 - \$28
Adjusted non-GAAP diluted EPS ^(b)	\$1.32 - \$1.38

<i>(in millions, except EPS and %s)</i>	<u>Full Year 2015 Current</u>	<u>Full Year 2015 Prior^(c)</u>
Net revenues	\$82 - \$84	\$80 - 88
Cost of sales ^(d)	15.5% - 16.5%	15% - 17.5%
Operating expenses ^(e)	\$17 - \$17.5	\$16.2 - \$16.5
Research and development costs	\$3.5 - \$4	\$3
Adjusted non-GAAP EBITDA ^(a)	\$48 - \$50	\$48.8 - \$53.1
Depreciation and amortization	\$5.75	\$5.5
Total interest expense	\$11.2	\$11.2
Cash interest expense	\$4.3	\$4.3
Non-cash interest expense	\$6.9	\$6.9
Estimated effective tax rate	37%	36.8%
Adjusted non-GAAP EPS ^(b)	\$2.44 - \$2.50	\$2.44 - \$2.67

^(a) Excludes non-cash stock compensation expense. See Table 2 for US GAAP reconciliation.

^(b) Excludes non-cash stock compensation and non-cash interest expense. See Table 3 for US GAAP reconciliation.

^(c) Per ANI's Q1 2015 earnings press release dated May 5, 2015.

^(d) Exclusive of depreciation and amortization.

^(e) Excludes non-cash stock compensation expense.

Selected Balance Sheet Data

(in thousands)

	<u>June 30, 2015</u>	<u>December 31, 2014</u>
Cash	\$ 166,731	\$ 169,037
Accounts Receivable, net	\$ 18,880	\$ 17,297
Inventory, net	\$ 12,701	\$ 7,518
Current Assets	\$ 208,948	\$ 203,478
Current Liabilities	\$ 6,949	\$ 13,233

ANI generated \$2.3 million of positive cash flows from operations in the six months ended June 30, 2015. Also during the first half of 2015, ANI acquired 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 \$166.7 million of cash at June 30, 2015.

Net accounts receivable increased from \$17.3 million to \$18.9 million. ANI's net inventory increased from \$7.5 million to \$12.7 million, as a direct result of raw materials acquired for key products, and inventories related to EEMT, Lithobid and Vancocin. ANI's total current assets increased to \$208.9 million at June 30, 2015, from \$203.5 million at December 31, 2014.

ANI Product Development Pipeline

Overview

ANI's July 2015 acquisition of the ANDAs for 22 generic products brings the Company's pipeline to 67 products, 54 of which were acquired. Of these products, ANI expects that 48 can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

Product Launches

ANI anticipates launching eleven products by the end of 2016:

<u>Product</u>	<u>Total Annual Market Size</u> ^(a)	<u>Estimated Launch</u>	<u>FDA Approvals Required</u>
Oxycodone HCl oral solution	\$30M	Q4 2015	Approved
Nimodipine capsules (partnered with Sofgen)	\$25M	Q4 2015	Approved
Flecainide tablets	\$67M	Q1 2016	CBE-30
Dexcel product	\$53M	Q1 2016	ANDA
Anti-cancer drug, (TAD ^(b) 2/26/2016)	Undisclosed	Q1 2016	ANDA
Five ANDAs acquired in July	\$253M	Q4 2016	CBE-30
Testosterone 1% gel	\$300M	Q4 2016	PAS

^(a) Per IMS Health

^(b) FDA's Target Action Date, per FDA communications

Product Development

Research and development costs of \$1.0 million during the second quarter of 2015 represent a 147% increase over the first quarter, due primarily to several upcoming product filings. ANI expects to file three prior approval supplements, six CBE-30s, the Company's first Paragraph IV filing, and one internally-developed ANDA in the next 18 months. A table summarizing ANI's pipeline of products is below:

<u>Products</u>	<u>ANI</u>	<u>Partnered</u>	<u>Total</u>
At FDA	5	2	7
Development	3	3	6
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 67 generic products address a total annual market size of approximately \$4.0 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 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 non-cash stock-based compensation and non-cash interest expense. Management uses adjusted non-GAAP diluted earnings per share when analyzing Company performance.

Adjusted non-GAAP diluted earnings per share is defined as net income/(loss), excluding stock-based compensation and non-cash interest expense, divided by the diluted weighted average shares outstanding during the period. Adjusted non-GAAP diluted earnings per 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 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 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.anipharma.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 approval 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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