# ANI Pharmaceuticals Reports Fourth Quarter and Full Year 2015 Results and Provides 2016 Guidance

**For the full year ended December 31, 2015:**

- **Net revenues of $76.3 million, adjusted non-GAAP EBITDA of $43.5 million, and operating income of $32.7 million, increases of 36%, 59%, and 63% versus the prior year**
- **Adjusted non-GAAP net income per diluted share of $2.72 and diluted earnings per share of $1.32**

**For the fourth quarter 2015:**

- **Net revenues of $18.0 million, adjusted non-GAAP EBITDA of $9.5 million, and operating income of $6.3 million**
- **Adjusted non-GAAP net income per diluted share of $0.52 and diluted earnings per share of $0.25**

Baudette, Minnesota (February 23, 2016) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported financial results for the three and twelve months ended December 31, 2015, and provided its financial guidance for the 2016 year. The Company will host its earnings conference call this morning, February 23, 2016, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (844) 295-8236. The conference ID is 48813555.

Arthur S. Przybyl, President and CEO, stated,

> "We are pleased with our progress during the past year and look forward to realizing the benefits of our 2015 business and product development activities in 2016. In 2015, we introduced six new products, significantly expanding our marketed product line, which now totals 17. We also acquired an additional 23 products and entered into an agreement to commercialize 18 more. To date in 2016, we have entered into two additional acquisitions for six products, bringing our total number of products under development to 85. Three of the acquired products are accretive to 2016 revenues and adjusted non-GAAP EBITDA, and are included in our financial guidance.
>
> On January 4, 2016, we completed our acquisition of the two NDAs for Corticotropin and Corticotropin-Zinc, products which provide us with an opportunity to compete in a well-established and growing market that exceeds $1 billion and offer a less expensive alternative to both patients and payors. 2016 is an important year for this project as we begin the work we believe is necessary to recommercialize the products, including working closely with the FDA, building out our dedicated team, and re-establishing the supply chain.
>
> The recommercialization of Corticotropin and Corticotropin-Zinc represents a compelling, strategic opportunity for ANI and our shareholders which, at the same time, will provide patients and their physicians with a valuable therapeutic option for a variety of critical, acute, and chronic diseases that afflict millions of Americans."

**2016 Financial Guidance**

ANI's estimates are based on projected results for the twelve months ended 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 $105 million and $120 million.
- Adjusted non-GAAP EBITDA[(a)], to be between $45 million and $53 million.
- Adjusted non-GAAP net income per diluted share[(b)], to be between $2.94 and $3.31, assuming 11,552 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:

- Net 2016 revenues for current marketed products (17 products) to be between $92 million and $98 million.
- Net 2016 revenues for new product introductions (see table below) to be between $13 million and $22 million.
- EEMT market share is anticipated to remain stable at approximately 50%.
- Cost of sales[(c)] of approximately 34%.
- Operating expenses[(d)], inclusive of research and development costs, of between $24 and $25.5 million.
- Depreciation and amortization expense of approximately $18.7 million.
- Interest expense of approximately $11.2 million.
- Current tax provision of between $7.0 and $11.0 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.

**2016 New Product Introductions**

| Product | Total Annual Market Size[(e)] | Estimated Launch | FDA Approvals Required |
|---|---|---|---|
| Hydrocortisone rectal cream, 1% and 2.5% | $73M | Q2 2016 | Approved |
| Anti-cancer drug, (TAD[(f)] 2/26/2016) | Undisclosed | Q2 2016 | ANDA |
| Dexcel product | $44M | Q3 2016 | ANDA |
| Anti-Infective | $69M | Q3 2016 | CBE-30 |
| Three IDT products | $97M | Q3 2016 | CBE-30s |
| Four C-II products | $46M | Q4 2016 | ANDAs |

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

If the market conditions for these products remain as anticipated, the annualized effect of these products would be as follows:

- Annualized net revenues estimated to be between $52 million and $65 million.
- Annualized adjusted non-GAAP EBITDA[(a)], estimated to be between $34 million and $40 million.

**2015 Highlights Include:**

- Net revenues of $76.3 million, an increase of 36% as compared to $56.0 million for the same period in 2014.
- Adjusted non-GAAP EBITDA of $43.5 million, an increase of 59% as compared to $27.3 million for the same period in 2014.
- Operating income of $32.7 million, an increase of 63% as compared to $20.0 million for the same period in 2014.
- Adjusted non-GAAP net income per diluted share of $2.72.
- Diluted earnings per share of $1.32.
- Launched six products: Etodolac, Propafenone, Oxycodone oral solution, Vancomycin, Nimodipine, and Flecainide.
- Acquired ANDAs for 23 generic products and an NDA for 1% Testosterone Gel.
- Entered into a distribution agreement with IDT Australia Limited to market 18 generic products in the U.S.
- Entered into an agreement to acquire two NDAs for Corticotropin and Corticotropin-Zinc. The transaction closed in January 2016.
- Established a common stock repurchase plan. In January 2016, we repurchased $2.5 million of our common stock under the plan.

**Fourth Quarter Results**

| **Net Revenues** (in thousands) | **Three Months Ended December 31,** | | | |
|---|---|---|---|---|
| | **2015** | **2014** | **Change** | **% Change** |
| Generic pharmaceutical products | $ 14,047 | $ 12,774 | $ 1,273 | 10 % |
| Branded pharmaceutical products | 2,341 | 4,861 | (2,520) | (52)% |
| Contract manufacturing | 1,307 | 1,810 | (503) | (28)% |
| Contract services and other income | 340 | 1,592 | (1,252) | (79)% |
| Total net revenues | $ 18,035 | $ 21,037 | $ (3,002) | (14)% |

For the three months ended December 31, 2015, ANI reported net revenues of $18.0 million, a decrease of 14% from $21.0 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 10%, to $14.0 million from $12.8 million in the prior period, primarily due to increased unit sales and pricing for EEMT, as well as a full quarter of sales from Methazolamide, Etodolac, and Propafenone, and a partial quarter of sales from Oxycodone oral solution and Vancomycin, both of which launched in the fourth quarter of 2015.
- Revenues from sales of branded pharmaceuticals decreased 52%, to $2.3 million from $4.9 million in the prior period, primarily as a result of lower unit sales of Reglan and Lithobid and increased Medicaid utilization for Lithobid and Vancocin.
- Contract manufacturing revenue decreased by 28% to $1.3 million from $1.8 million in the prior year period, primarily as a result of the timing and volume of customer orders.
- Contract services and other income decreased by 79%, to $0.3 million from $1.6 million, primarily due to recognition of only one month of royalties on sales of the authorized generic of Vancocin in 2015. In the fourth quarter of 2015, ANI's authorized generic partner for Vancocin adjusted its estimates for chargebacks, rebates, and other deductions from gross sales, which resulted in a

$0.2 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.

Cost of sales increased as a percentage of net revenues to 20% from 17%, primarily due to decreased revenue from our higher-margin branded pharmaceutical products, partially offset by margin increases for the Company's generic products.

Research and development costs increased to $0.7 million for the three months ended December 31, 2015, from $0.6 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, and collaborations with partners.

Selling, general, and administrative expenses increased to $5.5 million for the three months ended December 31, 2015, from $4.7 million in the prior year period. The increase was primarily due to increased business development activities and increased personnel and compensation costs.

Other expense increased to $2.8 million in the three months ended December 31, 2015, from $0.7 million in the prior year period, due to a full quarter of interest expense related to the convertible debt issued in December 2014.

Net income was $2.9 million for the three months ended December 31, 2015, as compared to net income of $21.0 million in the prior year period. Fourth quarter 2014 net income included a $16.7 million tax benefit from the reversal of the majority of the valuation allowance previously recorded against the Company's deferred tax assets. Fourth quarter 2014 net income would have been $4.3 million without the impact of the $16.7 million tax benefit. Diluted earnings per share for the three months ended December 31, 2015 was $0.25, based on 11,552 thousand diluted shares outstanding, as compared to diluted earnings per share of $1.82 in the prior year period. The impact of the $16.7 million tax benefit on Q4 2014 diluted earnings per share was $1.45. Without the impact of the tax benefit, the Company's Q4 2014 diluted earnings per share would have been $0.37.

Adjusted non-GAAP net income per diluted share was $0.52. For a reconciliation of adjusted non-GAAP net income per diluted share to GAAP net income, please see Table 3.

**Results for the Year Ended December 31, 2015**

**Net Revenues**
(in thousands)

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | **2015** | **2014** | **Change** | **% Change** |
| Generic pharmaceutical products | $ 55,169 | $ 35,852 | $ 19,317 | 54% |
| Branded pharmaceutical products | 11,003 | 11,010 | (7) | 0% |
| Contract manufacturing | 4,883 | 5,931 | (1,048) | (18)% |
| Contract services and other income | 5,267 | 3,177 | 2,090 | 66% |
| Total net revenues | $ 76,322 | $ 55,970 | $ 20,352 | 36% |

For the year ended December 31, 2015, ANI reported net revenues of $76.3 million, an increase of 36% from $56.0 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 54%, to $55.2 million from $35.9 million in the prior period, primarily due to increased pricing for EEMT, as well as a full year of sales from Methazolamide, which was launched in the fourth quarter of 2014, and a partial year of sales from Etodolac, Propafenone, Oxycodone oral solution, and Vancomycin, all of which were launched in 2015.
- Net revenues for branded pharmaceutical products were $11.0 million for both the years ended December 31, 2015 and 2014. This was the result of an increase due to a full year of revenue from our Lithobid and Vancocin products, both acquired in the third quarter of 2014, which was offset by both lower unit sales of Reglan and increased Medicaid utilization for Lithobid and Vancocin.
- Contract manufacturing revenue decreased by 18% to $4.9 million from $5.9 million in the prior year period, primarily as a result of the timing and volume of customer orders.
- Contract services and other income increased by 66%, to $5.3 million from $3.2 million, primarily due to royalties received on sales of the authorized generic of Vancocin. In the second and fourth quarters, ANI's authorized generic partner for Vancocin adjusted its estimates for chargebacks, rebates, and other deductions from gross sales, which resulted in $1.4 million and $0.2 million increases in royalty revenue in the respective quarters. In November, the Company launched an authorized generic for Vancocin under its own label, which replaced the authorized generic product previously on the market.

Cost of sales decreased as a percentage of net revenues to 17% from 20%, 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 $2.9 million for the year ended December 31, 2015, from $2.7 million in the prior year period. The increase was due to work on development projects, including the ANDAs acquired in 2014 and 2015, and collaborations with partners.

Selling, general, and administrative expenses increased to $21.2 million for the year ended December 31, 2015, from $17.9 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 costs. These increases were partially offset by a non-recurring $1.3 million catch-up adjustment for non-cash stock-based compensation expense, recognized in 2014, upon shareholder approval of an increase in shares available for issuance under ANI's stock compensation plan.

Other expense increased to $11.0 million in the year ended December 31, 2015, from $0.6 million in the prior year period, due to a full year of interest expense related to the convertible debt issued in December 2014.

Net income was $15.4 million for the year ended December 31, 2015, as compared to $28.7 million in the prior year period. Net income in 2014 included a $16.7 million tax benefit from the reversal of the majority of the valuation allowance previously recorded against the Company's deferred tax assets. 2014 net income would have been $12.0 million without the impact of the $16.7 million tax benefit. Diluted earnings per share for the year ended December 31, 2015 was $1.32, based on 11,557 thousand diluted shares outstanding, as compared to diluted earnings per share of $2.59 in the prior year period. The impact of the $16.7 million tax benefit on 2014 diluted earnings per share was $1.51. Without the impact of the tax benefit, the Company's 2014 diluted earnings per share would have been $1.08.

Adjusted non-GAAP net income per diluted share was $2.72. 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)*

| | December 31, 2015 | December 31, 2014 |
|---|---|---|
| Cash | $ 154,684 | $ 169,037 |
| Accounts Receivable, net | $ 21,932 | $ 17,297 |
| Inventory, net | $ 13,387 | $ 7,518 |
| Current Assets | $ 192,583 | $ 194,991 |
| Current Liabilities | $ 11,756 | $ 13,233 |

ANI generated $17.3 million of positive cash flows from operations in the year ended December 31, 2015. Also in 2015, ANI acquired ANDAs for 23 products for $29.5 million and U.S. distribution rights for 18 products for $1.0 million. As a result of the net effect of these sources and uses of cash, ANI had $154.7 million of cash at December 31, 2015. On January 4, 2016, ANI purchased from Merck the NDAs for Corticotropin and Corticotropin-Zinc for a $75 million upfront payment and a percentage of future net sales on products sold under the NDAs. On January 28, 2016, ANI 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 $10.0 million in consideration.

Net accounts receivable increased from $17.3 million to $21.9 million. ANI's net inventory increased from $7.5 million to $13.4 million, as a direct result of raw materials acquired for key products. ANI's total current assets decreased to $192.6 million at December 31, 2015, from $195.0 million at December 31, 2014.

**ANI Product Development Pipeline**

**Overview**

ANI's pipeline consists of 85 products, 57 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 | 4 | 2 | 6 |
| Development | 3 | 19 | 22 |
| Acquired Products | 57 | 0 | 57 |

ANI's product development pipeline includes extended-release products, controlled substances, anti-cancers, oral solutions, suspensions and solid dosage forms. These 85 generic products address a total annual market size of nearly $4.5 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; 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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