

ANI Pharmaceuticals Reports Full Year 2016 Results and Fourth Quarter Results and Provides 2017 Guidance

For the full year ended December 31, 2016:

- Record net revenues of \$128.6 million, an increase of 69% versus the prior year
- GAAP net income of \$3.9 million, including \$6.7 million non-cash impairment charge for a non-core asset
- Diluted GAAP earnings per share of \$0.34, including impact of non-cash impairment charge of \$0.36, net of tax
- Adjusted non-GAAP EBITDA of \$61.1 million
- Adjusted non-GAAP net income per diluted share of \$3.78 (previous methodology)

For the fourth quarter 2016:

- Net revenues of \$38.2 million, an increase of 112% as compared to the same period in 2015
- GAAP net loss of \$1.1 million, including \$6.7 million non-cash impairment charge for a non-core asset
- Diluted GAAP loss per share of \$0.09, including impact of non-cash impairment charge of \$0.36, net of tax
- Adjusted non-GAAP EBITDA of \$17.9 million
- Adjusted non-GAAP net income per diluted share of \$0.84 (previous methodology)

Guidance for 2017:

- Net revenues of \$181 million to \$190 million
- Adjusted non-GAAP EBITDA of \$73.1 million to \$77.2 million
- New adjusted non-GAAP diluted earnings per share methodology yielding \$3.58 to \$3.94 per share, as compared to \$2.96 per share for 2016 as calculated under the new methodology

Baudette, Minnesota (March 2, 2017) – ANI Pharmaceuticals, Inc. (“ANI”) (NASDAQ: ANIP) today reported its financial results for the three and twelve months ended December 31, 2016, and provided its financial guidance for the 2017 year. The Company will host its earnings conference call this morning, March 2, 2017, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 51451144.

Financial Summary

| <i>(in thousands, except per share data)</i> | <u>Q4 2016</u> | <u>Q4 2015</u> | <u>2016</u> | <u>2015</u> |
|---|----------------|----------------|-------------|-------------|
| Net revenues | \$ 38,205 | \$18,035 | \$128,622 | \$ 76,322 |
| Net (loss)/income | \$(1,080) | \$ 2,876 | \$ 3,934 | \$ 15,375 |
| GAAP (loss)/earnings per diluted share | \$ (0.09) | \$ 0.25 | \$ 0.34 | \$ 1.32 |
| Adjusted non-GAAP EBITDA^(a) | \$ 17,933 | \$ 9,518 | \$ 61,112 | \$ 43,456 |
| Adjusted non-GAAP net income per diluted share^(b) | \$ 0.84 | \$ 0.52 | \$ 3.78 | \$ 2.72 |

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

^(b) Previous methodology; see Table 4 for US GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

“ANI had a record year in 2016. Our annual revenues increased 69% to \$128.6 million and our annual adjusted non-GAAP EBITDA increased 41% to \$61.1 million. In the fourth quarter, revenue increased 112% to \$38.2 million and adjusted non-GAAP EBITDA increased 88% to \$17.9 million. We continue to regard revenue and adjusted non-GAAP EBITDA as important valuation metrics for ANI. In fact, our reported revenues, adjusted non-GAAP EBITDA, and operating cash flows all established new records for ANI in 2016. ANI generated \$27.5 million in operating cash flows and we invested \$4.6 million in capital expenditures in 2016.

“Our revenue and adjusted non-GAAP EBITDA growth in 2016 was fueled by several important factors: we launched several products, acquired the NDA for Inderal® LA, and acquired licenses to distribute HC rectal cream and the authorized generic of Lipofen®. We exited 2016 with 25 commercial products, up from 16 at the beginning of the year. To support this growth, and our future growth plans, we hired 45 full time employees in 2016, increasing our overall headcount by 32% primarily to support our manufacturing facilities in Minnesota. All but one of our finished dosage form products are manufactured in the United States. Importantly, we acquired the NDAs for Corticotropin and Corticotropin-Zinc in early 2016 and have advanced the re-commercialization project by hiring our project team, establishing our analytical labs, sourcing porcine pituitaries, and selecting our raw material manufacturer. As a result, work has already begun on the manufacturing of development lots of raw material and advancing chemistry and analytical development, as we reference in our Corticotropin Re-commercialization Update.

“Forecasting 2017, we are providing annual guidance that indicates continued revenue and adjusted non-GAAP EBITDA growth. The midpoint of our 2017 guidance assumes revenue growth of 44% to \$185.5 million and adjusted non-GAAP EBITDA growth of 23% to \$75.1 million. We have a robust pipeline of product opportunities and anticipate launching several new products in 2017. We remain strategically committed to advancing our growth through selective acquisitions, and to this end, we recently acquired the Inderal® XL and InnoPran XL® products. We are forecasting approximately \$40 to \$45 million in operating cash flow and expect to invest upwards of \$11 million in capital expenditures in 2017. Our investment in R&D is increasing primarily due to Corticotropin project activities. The balance sheet remains strong; we are levered approximately two times and have access to additional liquidity for potential future transactions.

“Management's 2017 commitment to our shareholders remains the same as 2016: to continue to grow revenues and adjusted non-GAAP EBITDA and to advance Corticotropin to an eventual sNDA filing.”

2017 Financial Guidance

ANI's estimates are based on projected results for the twelve months ending December 31, 2017 and reflect management's current beliefs about product pricing, market size, market share, inventory levels, cost of sales, operating costs, taxes, and the anticipated timing of future product launches and events. Beginning in 2017, management is changing the method under which it calculates adjusted non-GAAP net income per diluted share to reflect the estimated tax impact of adjustments utilizing an estimated federal and state statutory rate, which is currently projected to be approximately 37%. Management believes that the new methodology will more appropriately reflect adjusted non-GAAP net income per diluted share as a performance measure. In addition, we will refer to this measure as adjusted non-GAAP diluted earnings per share on a go-forward basis. Table 3 provides a reconciliation of 2016 adjusted non-GAAP diluted earnings per share, calculated in accordance with the new methodology, to the most directly comparable US GAAP measure.

The following table shows 2017 guidance as compared with 2016 actual results.

| <i>(in millions, except per share data and percentages)</i> | <u>2016</u> | <u>2017 Guidance</u> | <u>% Increase</u> |
|--|-------------|----------------------|-------------------|
| Net revenues | \$128.6 | \$181 to \$190 | 41% to 48% |
| Cost of sales as a percent of revenues (excluding impact of inventory step-up) | 33% | 42% to 44% | n/a |
| Sales, general, and administrative | \$ 27.8 | \$30.2 to \$30.9 | 8% to 11% |
| Research and development | \$ 2.9 | \$6.5 to \$6.8 | 125% to 134% |
| Adjusted non-GAAP EBITDA ^(c) | \$ 61.1 | \$73.1 to \$77.2 | 20% to 26% |
| Adjusted non-GAAP diluted earnings per share ^(d) | \$ 2.96 | \$3.58 to \$3.94 | 21% to 33% |

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

^(d) New methodology; see Table 3 for US GAAP reconciliation.

Corticotropin Re-commercialization Update

Corticotropin API Manufacturing Update

In the 4th quarter of 2016, ANI's contract active pharmaceutical ingredient ("API") manufacturer has initiated the manufacturing of R&D development batches of Corticotropin API. Work has begun to re-establish each of the individual process steps necessary for the API manufacturing process. Immediately following the completion of these R&D development batches, work will then begin to scale up the API manufacturing process towards commercial scale manufacturing. ANI has initiated a search to identify a finished dosage form contract manufacturer for the Corticotropin drug product. Once identified, ANI will begin work to initiate Corticotropin finished dosage form product manufacturing.

Corticotropin Analytics Update

The ANI Corticotropin team has continued to make substantial progress towards developing approximately 20 different analytical methods. Some of these methods are being re-established from previously existing methods that were part of the monograph from the original API manufacturer, Diosynth. ANI recognizes that analytical technologies have improved over time, so included in the method development is a range of new, state of the art analytical methods that include molecular biological methods, such as SDS-PAGE electrophoresis, Western Blot, and ELISA, and instrumental methods, such as HPLC/UV and LC/MS/MS. Several of these methods will be used to prepare a comprehensive characterization package for ANI's newly manufactured Corticotropin API and other methods will be used to test and release new batches of API as they are manufactured.

Corticotropin Project Team Update

ANI has continued to advance its Corticotropin project team, which now includes analytical expertise, API and drug product manufacturing expertise, and extensive experience with the development and manufacturing of animal-derived pharmaceutical products. The Corticotropin project team also includes resources with previous hands-on experience in manufacturing Corticotropin API at Diosynth, where it was previously manufactured in the Netherlands. ANI has recently hired Karen Quinn, Ph.D. to lead its Corticotropin Regulatory Affairs group, whose primary responsibility will be to lead ANI's regulatory strategy for Corticotropin with the FDA and subsequently file an sNDA to re-commercialize Corticotropin in the U.S. market.

Fourth Quarter Results

| Net Revenues (in thousands) | Three Months Ended December 31, | | Change | % Change |
|---------------------------------------|--|------------------|------------------|-----------------|
| | 2016 | 2015 | | |
| Generic pharmaceutical products | \$ 29,296 | \$ 14,047 | \$ 15,249 | 109% |
| Branded pharmaceutical products | 6,524 | 2,341 | 4,183 | 179% |
| Contract manufacturing | 1,560 | 1,307 | 253 | 19% |
| Contract services and other income | 825 | 340 | 485 | 143% |
| Total net revenues | <u>\$ 38,205</u> | <u>\$ 18,035</u> | <u>\$ 20,170</u> | 112% |

For the three months ended December 31, 2016, ANI reported net revenues of \$38.2 million, an increase of 112% from \$18.0 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 109%, to \$29.3 million from \$14.0 million in the prior period, primarily due to sales of the ten generic products launched during the 2016 year.
- Revenues from sales of branded pharmaceuticals increased 179%, to \$6.5 million from \$2.3 million in the prior period, primarily due to sales of Inderal® LA, which was launched in Q2 2016.
- Contract manufacturing revenue increased by 19% to \$1.6 million from \$1.3 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 143%, to \$0.8 million from \$0.3 million, primarily due to a \$0.6 million royalty payment related to a license for patent rights.

Operating expenses increased to \$36.9 million for the three months ended December 31, 2016, from \$11.8 million in the prior year period. The increase was primarily due to a \$13.4 million increase in cost of sales as compared with the prior period, as a result of a higher mix of sales of products with profit-sharing arrangements, increased volume, and \$2.8 million of cost of sales related to the inventory step-up on Inderal® LA and Propranolol ER inventory. In the fourth quarter of 2016, an impairment charge of \$6.7 million was recognized in relation to ANI's testosterone gel NDA intangible asset, which was initially recognized as part of the accounting for the merger with BioSante. In addition, depreciation and amortization increased by \$3.7 million as compared with the prior period, driven by amortization of a higher intangible asset base.

Excluding the \$2.8 million of costs related to the Inderal® LA inventory step-up, cost of sales increased as a percentage of net revenues to 37% from 20%, primarily as a result of increased sales of products with profit-sharing arrangements.

Net loss was \$1.1 million for the three months ended December 31, 2016, as compared to net income of \$2.9 million in the prior year period. The effective tax rate for the three months ended December 31, 2016 was 33%.

Diluted loss per share for the three months ended December 31, 2016 was \$0.09, based on 11,516 thousand diluted shares outstanding, as compared to diluted earnings per share of \$0.25 in the prior year period. Adjusted non-GAAP net income per diluted share was \$0.84 (previous methodology), as compared to adjusted non-GAAP net income per diluted share of \$0.52 in the prior year period. For a reconciliation of adjusted non-GAAP net income per diluted share to the most directly comparable GAAP financial measure, please see Table 4.

Results for the Year Ended December 31, 2016

Net Revenues

(in thousands)

| | Year Ended December 31, | | Change | % Change |
|------------------------------------|-------------------------|------------------|------------------|----------|
| | 2016 | 2015 | | |
| Generic pharmaceutical products | \$ 95,201 | \$ 55,169 | \$ 40,032 | 73% |
| Branded pharmaceutical products | 26,443 | 11,003 | 15,440 | 140% |
| Contract manufacturing | 5,537 | 4,883 | 654 | 13% |
| Contract services and other income | 1,441 | 5,267 | (3,826) | (73)% |
| Total net revenues | <u>\$ 128,622</u> | <u>\$ 76,322</u> | <u>\$ 52,300</u> | 69% |

For the year ended December 31, 2016, ANI reported net revenues of \$128.6 million, an increase of 69% from \$76.3 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 73%, to \$95.2 million from \$55.2 million in the prior period, primarily due to sales of the ten generic products launched during 2016.
- Revenues from sales of branded pharmaceuticals increased 140%, to \$26.4 million from \$11.0 million in the prior period, primarily due to sales of Inderal® LA, which was launched in Q2 2016.
- Contract manufacturing revenue increased by 13% to \$5.5 million from \$4.9 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 73%, to \$1.4 million from \$5.3 million, primarily because sales of Vancomycin in the ANI label have replaced the royalties previously received on the product. This decrease was partially offset by a \$0.6 million royalty payment related to a license for patent rights.

Operating expenses increased to \$108.5 million for the year ended December 31, 2016, from \$43.6 million in the prior year period. The increase was primarily due to a \$36.1 million increase in cost of sales as compared with the prior period, as a result of a higher mix of sales of products with profit-sharing arrangements, increased volumes, and \$5.9 million of cost of sales related to the inventory step-up on Inderal® LA and Propranolol ER inventory. In the fourth quarter of 2016, an impairment charge of \$6.7 million was recognized in relation to ANI's testosterone gel NDA intangible asset, which was initially recognized as part of the accounting for the merger with BioSante. In addition, depreciation and amortization increased by \$15.4 million as compared with the prior period, driven by amortization of a higher intangible asset base. Selling, general, and administrative expenses for the period includes \$1.3 million of principally non-cash expense, representing the entire cost of ANI's second quarter CFO transition.

Excluding the \$5.9 million of costs related to the Inderal® LA inventory step-up, cost of sales increased as a percentage of net revenues to 33% from 17%, primarily as a result of increased sales of products with profit-sharing arrangements.

Net income was \$3.9 million for the year ended December 31, 2016, as compared to net income of \$15.4 million in the prior year period. The effective tax rate for the year ended December 31, 2016 was 55%.

Diluted earnings per share for the year ended December 31, 2016 was \$0.34, based on 11,573 thousand diluted shares outstanding, as compared to diluted earnings per share of \$1.32 in the prior year period. Adjusted non-GAAP net income per diluted share was \$3.78 (previous methodology), as compared to adjusted non-GAAP net income per diluted share of \$2.72 in the prior year period. For a reconciliation of adjusted non-GAAP net income per diluted share to the most directly comparable GAAP financial measure, please see Table 4.

Selected Balance Sheet Data

(in thousands)

| | <u>December 31, 2016</u> | <u>December 31, 2015</u> |
|--------------------------|--------------------------|--------------------------|
| Cash | \$ 27,365 | \$ 154,684 |
| Accounts receivable, net | \$ 45,895 | \$ 21,932 |
| Inventory, net | \$ 26,183 | \$ 13,387 |
| Current assets | \$ 103,007 | \$ 192,583 |
| Current liabilities | \$ 31,948 | \$ 11,756 |

ANI generated \$27.5 million of positive cash flows from operations in the year ended December 31, 2016. In January 2016, 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. Also in January 2016, ANI purchased from H2-Pharma, LLC the exclusive U.S. distribution rights for two 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. In April 2016, ANI purchased from Cranford Pharmaceuticals, LLC 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 in cash and milestone payments based on future gross profits from sales of products under the NDA. ANI also transferred \$5.0 million to an escrow account to secure the future milestone payments. As a result of the net effect of these sources and uses of cash, ANI had \$27.4 million of cash at December 31, 2016.

ANI Product Development Pipeline

ANI's pipeline consists of 78 products, addressing a total annual market size of \$3.7 billion, based on data from IMS Health. Of these 78 products, 54 were acquired and of these acquired products ANI expects that 47 can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

Non-GAAP Financial Measures

The Company's fiscal 2017 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, other income/expense, non-cash impairment charges, and other significant non-cash or unusual charges as determined and disclosed by management. 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 (new methodology, 2017 onward)

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, 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 3.

Adjusted non-GAAP Diluted Earnings per Share (new methodology, 2017 onward)

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 3.

Adjusted non-GAAP Net Income (2016 and prior methodology)

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, non-cash impairment charges, 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, and non-cash impairment charges, 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 4.

Adjusted non-GAAP Net Income per Diluted Share (2016 and prior methodology)

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 and amortization, non-cash impairment charges, 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 4.

About ANI

ANI Pharmaceuticals, Inc. (the "Company" or "ANI") is an integrated specialty pharmaceutical company focused on delivering value to our customers by 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; 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