ANI Pharmaceuticals Reports Record Third Quarter and Year-To-Date 2017 Results and Narrows Full Year Guidance

For the third quarter 2017:

- **Net revenues of $48.2 million, an increase of 25% as compared to the same period in 2016**
- **GAAP net income of $4.7 million and diluted GAAP earnings per share of $0.40**
- **Adjusted non-GAAP EBITDA of $20.7 million**
- **Adjusted non-GAAP diluted earnings per share of $1.11**

Baudette, Minnesota (November 2, 2017) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three and nine months ended September 30, 2017, and reaffirmed its 2017 financial guidance. The Company will host its earnings conference call this morning, November 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 95990267.

Financial Summary

(in thousands, except per share data)	Q3 2017	Q3 2016	YTD 2017	YTD 2016
Net revenues	$ 48,164	$ 38,525	$ 129,556	$ 90,417
Net income	$ 4,720	$ 2,543	$ 8,553	$ 5,014
GAAP earnings per diluted share	$ 0.40	$ 0.22	$ 0.73	$ 0.43
Adjusted non-GAAP EBITDA[(a)]	$ 20,662	$ 16,354	$ 54,503	$ 43,178
Adjusted non-GAAP diluted earnings per share[(b)]	$ 1.11	$ 0.77	$ 2.83	$ 2.05

[(a)] See Table 3 for US GAAP reconciliation.
[(b)] See Table 4 for US GAAP reconciliation.

Arthur S. Przybyl, President and CEO, stated,

> "This was a record quarter for ANI, with revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted earnings per share increasing 25%, 26%, and 44%, respectively, as compared to the prior year. These increases are the direct result of the launches of InnoPran XL® and Inderal® XL in February 2017 and the continued impact of generic products launched in 2016 and 2017.
>
> ANI continues to grow its branded product revenue base, an important strategic objective for the Company. To that end, we continue to advance the development and subsequent commercialization of two branded products, Vancocin® oral solution and Cortrophin® gel. Both of these drugs are FDA approved products, but will require ANI to file a prior approval supplement with the FDA prior to commercialization."

ANI Narrows Guidance for the Full Year 2017

ANI estimates are based on projected results for the twelve months ending December 31, 2017 and reflect management's current beliefs about product pricing, prescription trends, inventory levels, cost of sales, operating costs, timing of research and development spend, taxes, and the anticipated timing of future product launches and events. ANI is updating its full year 2017 guidance range to narrow its previously published guidance for net revenues and adjusted non-GAAP EBITDA. In conjunction with this change, ANI is narrowing and making a modest upward revision in its projected full year adjusted non-GAAP diluted earnings per share and improvement in its cost of sales as a percentage of revenues

(excluding the impact of inventory step-up). The changes to guidance reflect better than previously-forecast product mix and gross profit pull through on net revenues.

(in millions, except per share data and percentages)	**Previous Guidance**	**Revised Guidance**
Net revenues	$181 to $190	$181 to $183
Cost of sales as a percent of revenues (excluding impact of inventory step-up)	42% to 44%	39% to 41%
Adjusted non-GAAP EBITDA	$73.1 to $77.2	$74.0 to $76.3
Adjusted non-GAAP diluted earnings per share	$3.58 to $3.94	$3.83 to $4.00

Cortrophin® Gel Re-commercialization Update

In the third quarter of 2017, ANI executed a long-term commercial supply agreement with its Cortrophin® gel fill/finish contract manufacturer ("CMO"), specializing in aseptic parenteral manufacturing using mobile isolator technology. ANI plans to initiate manufacturing Cortrophin® gel development batches in the fourth quarter of 2017, using the active pharmaceutical ingredient ("API") from its recently manufactured intermediate scale batches. Combined with its current relationships with raw material suppliers for porcine pituitary glands and purified corticotropin powder (the API), ANI has now reached a very important milestone by securing its Cortrophin® gel supply chain.

ANI has continued to advance the manufacture of corticotropin API, successfully manufacturing its first intermediate scale batch of API. This intermediate scale batch of corticotropin API was five times larger than its initial successful small-scale API batch and resulted in proportional increases in both yield and potency. ANI initiated manufacturing a second intermediate scale batch in the third quarter and expects to complete manufacturing of intermediate scale API batches two and three by the end of this year. ANI expects to be able to demonstrate lot-to-lot consistency as it continues to build its comprehensive characterization package. ANI plans to initiate commercial scale API manufacturing in early 2018.

ANI has continued to modernize the corticotropin characterization package by developing and implementing new and current analytical technologies that were not part of the original Cortrophin® gel NDA. These molecular biology techniques have been successfully developed to analyze both corticotropin as well as other related peptides. ANI has also developed a variety of methods to characterize in-process samples after completion of critical stages of corticotropin API manufacturing. These methods are being used to better control the API manufacturing process and identify its critical process parameters. These methods are being utilized throughout the API manufacturing process as a means of establishing lot-to-lot consistency and process control and demonstrating comparability to historically manufactured commercial lots of API.

ANI intends to request a meeting with the FDA in the fourth quarter of 2017 to present its Regulatory Filing Plan.

For further details, please see ANI's Cortrophin® Gel Re-commercialization Milestone Update in Table 5.

Vancocin® Oral Solution Update

ANI is currently advancing a commercialization effort for Vancocin® oral solution. Following completion of ongoing formulation and manufacturing optimization, ANI intends to file a prior approval supplement ("PAS") in the second half of 2018. This product will be manufactured at ANI's site in Baudette, MN. The launch of this product will fulfill a currently unmet patient need for an FDA approved liquid oral dosage form of the vancomycin molecule. This product will compete in a market that currently exceeds $450 million annually. When launched, ANI estimates that Vancocin® oral solution could achieve peak sales potential of $50 million.

Third Quarter Results

Net Revenues (in thousands)	**Three Months Ended September 30,**			
	2017	**2016**	**Change**	**% Change**
Generic pharmaceutical products	$ 30,546	$ 30,191	$ 355	1%
Branded pharmaceutical products	15,688	6,834	8,854	130%
Contract manufacturing	1,829	1,427	402	28%
Contract services and other income	101	73	28	38%
Total net revenues	$ 48,164	$ 38,525	$ 9,639	25%

For the three months ended September 30, 2017, ANI reported net revenues of $48.2 million, an increase of 25% from $38.5 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased slightly to $30.5 million from $30.2 million in the prior period.
- Revenues from sales of branded pharmaceuticals increased 130%, to $15.7 million from $6.8 million in the prior period, primarily due to sales of Inderal® XL and InnoPran XL®, both of which were launched in Q1 2017, as well as increased sales of Inderal® LA and other branded products.
- Contract manufacturing revenue increased by 28% to $1.8 million from $1.4 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 38%, to $0.1 million from $73 thousand.

Operating expenses increased to $38.8 million for the three months ended September 30, 2017, from $30.6 million in the prior year period. The increase was primarily due to a $4.4 million increase in cost of sales as compared with the prior period, as a result of $2.8 million of cost of sales related to the net inventory step-up on Inderal® XL and InnoPran XL® inventory, higher sales of products sold with profit-sharing arrangements, and increased volume. In addition, research and development increased by $1.6 million as compared with the prior period, primarily due to work on the Cortrophin® gel re-commercialization project and depreciation and amortization increased by $1.1 million as compared with the prior period, driven by amortization of a higher intangible asset base.

Excluding the $2.8 million of net inventory step-up costs related to sales of Inderal® XL and InnoPran XL® in the third quarter of 2017 and the $1.1 million of net inventory step-up costs related to sales of Inderal® LA and Propranolol ER in the third quarter of 2016, cost of sales decreased as a percentage of net revenues to 38% from 40%, primarily as a result of a change in product mix toward increased sales of branded products with higher margins.

Net income was $4.7 million for the three months ended September 30, 2017, as compared to net income of $2.5 million in the prior year period. The effective tax rate for the three months ended September 30, 2017 was 26%.

Diluted earnings per share for the three months ended September 30, 2017 was $0.40, based on 11,677 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.22 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.11, as compared to adjusted non-GAAP diluted earnings per share of $0.77 in the prior year period. For a reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure, please see Table 4.

Results for Nine Months Ended September 30, 2017

Net Revenues (in thousands)	**Nine Months Ended September 30,**			
	2017	**2016**	**Change**	**% Change**
Generic pharmaceutical products	$ 88,608	$ 65,905	$ 22,703	34%
Branded pharmaceutical products	35,398	19,919	15,479	78%
Contract manufacturing	5,151	3,977	1,174	30%
Contract services and other income	399	616	(217)	(35)%
Total net revenues	$ 129,556	$ 90,417	$ 39,139	43%

For the nine months ended September 30, 2017, ANI reported net revenues of $129.6 million, an increase of 43% from $90.4 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 34%, to $88.6 million from $65.9 million in the prior period, primarily due to sales of the generic products launched during 2016.
- Revenues from sales of branded pharmaceuticals increased 78%, to $35.4 million from $19.9 million in the prior period, primarily due to sales of Inderal® XL and InnoPran XL®, both of which were launched in Q1 2017, as well as sales of Inderal® LA, which launched in Q2 2016.
- Contract manufacturing revenue increased by 30% to $5.2 million from $4.0 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 35%, to $0.4 million from $0.6 million, primarily because sales of Fenofibrate in the ANI label have replaced the royalties previously received on the product.

Operating expenses increased to $108.6 million for the nine months ended September 30, 2017, from $71.6 million in the prior year period. The increase was primarily due to a $26.7 million increase in cost of sales as compared with the prior period, as a result of higher sales of products sold with profit-sharing arrangements, increased volume, and $7.5 million of cost of sales related to the inventory step-up on Inderal® XL, InnoPran XL®, and Inderal® LA inventory. In addition, depreciation and amortization increased by $4.4 million as compared with the prior period, driven by amortization of a higher intangible asset base.

Excluding the $7.5 million of net inventory step-up costs related to sales of Inderal® XL, InnoPran XL®, and Inderal® LA in the nine months ended September 30, 2017 and $3.2 million of net inventory step-up costs related to sales of Inderal® LA and Propranolol ER in the nine months ended September 30, 2016, cost of sales increased as a percentage of net revenues to 39% from 32%, primarily as a result of increased sales of products with profit-sharing arrangements.

Net income was $8.6 million for the nine months ended September 30, 2017, as compared to net income of $5.0 million in the prior year period. The effective tax rate for the nine months ended September 30, 2017 was 29%.

Diluted earnings per share for the nine months ended September 30, 2017 was $0.73, based on 11,666 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.43 in the prior year period. Adjusted non-GAAP diluted earnings per share was $2.83, as compared to adjusted non-GAAP diluted earnings per share of $2.05 in the prior year period. For a reconciliation of adjusted non-GAAP diluted earnings per share to the most directly comparable GAAP financial measure, please see Table 4.

Selected Balance Sheet Data

(in thousands)

	September 30, 2017	December 31, 2016
Cash	$ 18,031	$ 27,365
Accounts receivable, net	$ 62,174	$ 45,895
Inventory, net	$ 38,478	$ 26,183
Current assets	$ 125,582	$ 103,007
Current liabilities	$ 36,384	$ 31,948
Non-current debt	$ 151,284	$ 120,643

ANI generated $23.6 million of positive cash flows from operations in the nine months ended September 30, 2017. In February 2017, ANI purchased from Cranford Pharmaceuticals, LLC a distribution license, trademark, and certain finished goods inventory for Inderal® XL for $20.2 million in cash, using cash on hand. In February 2017, ANI purchased from Holmdel Pharmaceuticals, LP the NDA, trademark, and certain finished goods inventory for InnoPran XL®, including a license to an Orange Book listed patent, for $30.6 million in cash. ANI made the $30.6 million cash payment using $30.0 million of funds from its Line of Credit and $0.6 million of cash on hand. ANI paid down $5.0 million on the Line of Credit in the third quarter of 2017.

ANI Product Development Pipeline

ANI's pipeline consists of 75 products, addressing a total annual market size of $3.5 billion, based on data from IMS Health. Of these 75 products, 52 were acquired and of these acquired products, ANI expects that 45 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, costs related to major transactions not consummated, and other income / 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 3.

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 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, costs related to major transactions not consummated, 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 4.

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 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 4.

About ANI

ANI Pharmaceuticals, Inc. (the "Company" or "ANI") is an integrated specialty pharmaceutical company 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; regulatory environment; 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