ANI Pharmaceuticals Reports Record Full Year Results, Reports Fourth Quarter 2017 Results, and Provides 2018 Guidance

For the full year ended December 31, 2017:

- **Record net revenues of $176.8 million, an increase of 37% versus 2016**
- **GAAP net loss of $1.1 million, including a $13.4 million charge due to the Tax Cuts and Jobs Act**
- **Diluted GAAP loss per share of $0.09, including $1.16 impact of charge due to the Tax Cuts and Jobs Act**
- **Adjusted non-GAAP EBITDA of $74.2 million**
- **Adjusted non-GAAP diluted earnings per share of $3.91**

For the fourth quarter 2017:

- **Net revenues of $47.3 million, an increase of 24% as compared to the same period in 2016**
- **GAAP net loss of $9.6 million, including impact of $13.4 million charge due to the Tax Cuts and Jobs Act**
- **Diluted GAAP loss per share of $0.83, including $1.16 impact of charge due to the Tax Cuts and Jobs Act**
- **Adjusted non-GAAP EBITDA of $19.7 million**
- **Adjusted non-GAAP diluted earnings per share of $1.08**

Guidance for 2018:

- **Net revenues of $212 million to $228 million**
- **Adjusted non-GAAP EBITDA of $90 million to $100 million**
- **Adjusted non-GAAP diluted earnings per share of $5.43 to $6.08**

Baudette, Minnesota (February 27, 2018) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three and twelve months ended December 31, 2017, and provided its 2018 financial guidance. The Company will host its earnings conference call this morning, February 27, 2018, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 9773589.

Financial Summary

(in thousands, except per share data)	Q4 2017	Q4 2016	2017	2016
Net revenues	$ 47,286	$ 38,205	$ 176,842	$ 128,622
Net (loss)/income	$ (9,629)	$ (1,080)	$ (1,076)	$ 3,934
GAAP (loss)/earnings per diluted share	$ (0.83)	$ (0.09)	$ (0.09)	$ 0.34
Adjusted non-GAAP EBITDA[(a)]	$ 19,672	$ 17,933	$ 74,175	$ 61,112
Adjusted non-GAAP diluted earnings per share[(b)]	$ 1.08	$ 0.90	$ 3.91	$ 2.96

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

Arthur S. Przybyl, President and CEO, stated,

"2017 was a record year for ANI, with revenues, adjusted non-GAAP EBITDA, and adjusted non-GAAP diluted earnings per share increasing 37%, 21%, and 32%, respectively, as compared to 2016. These increases are the result of the continued strength of our base business and six product launches in 2017, including four generic products and two brands, InnoPran XL® and Inderal® XL.

In December 2017, we continued to execute the strategic plan to grow our commercial portfolio by acquiring the NDAs and U.S. product rights for Atacand®, Atacand HCT®, Arimidex® and Casodex® – all products that can be manufactured at our containment facility in Baudette Minnesota. Since becoming a public company in 2013, ANI has deployed nearly $300M in product acquisitions to help build our current portfolio of commercial and pipeline products. We will continue to evaluate opportunities to expand the business throughout 2018.

Notably, we continue to work toward the development and subsequent commercialization of two branded pipeline products, Vancocin® oral solution and Cortrophin® gel.

Our Cortrophin® gel re-commercialization project continues to advance in line with internal timelines. Our team achieved important milestones in 2017, including the establishment of commercial relationships for our supply chain including raw material, API manufacture and finished dose manufacture. Successes in API manufacturing, analytical method development and process characterization allow ANI to advance manufacturing of commercial scale API and the registration batch in 2018.

Since going public in June 2013, we have focused on increasing our revenue and adjusted non-GAAP EBITDA through new product introductions, as evidenced in the table below showing our revenue and adjusted non-GAAP EBITDA growth from 2013 to our 2018 guidance, as well as the number of ANI's commercial products at the end of each year. The compound annual growth rates from 2013 to 2017 for net revenue and adjusted non-GAAP EBITDA are 56% and 77%, respectively."

(in millions, except product data)	**Net Revenue**	**Adjusted non-GAAP EBITDA[(c)]**	**Number of Products**
Actual Results:			
2013	$ 30	$ 8	7
2014	$ 56	$ 27	10
2015	$ 76	$ 43	16
2016	$ 129	$ 61	25
2017	$ 177	$ 74	31
Mid-point of 2018 Guidance:			
2018	$ 220	$ 95	

[(c)] See Tables 3 and 6 for U.S. GAAP reconciliation.

2018 Financial Guidance

For the twelve months ending December 31, 2018, ANI is providing guidance on net revenue, adjusted non-GAAP EBITDA and adjusted non-GAAP diluted earnings per share. The following table summarizes 2018 guidance as compared to 2017 actual results:

(in millions, except per share data and percentages)	**2017 Actual**	**2018 Guidance**	**% Increase from Prior Year**
Net revenues	$176.8	$212 to $228	20% to 29%
Adjusted non-GAAP EBITDA	$74.2	$90 to $100	21% to 35%
Adjusted non-GAAP diluted earnings per share	$3.91	$5.43 to $6.08	39% to 55%

ANI's 2018 financial guidance reflects management's current assumptions regarding customer relationships, product pricing, prescription trends, competition, inventory levels, cost of sales, operating costs, timing of research and development spend, taxes, and the anticipated timing of future product launches and other key events. 2018 guidance includes:

- revenues and expenses related to our December 29, 2017 acquisition of the NDAs and U.S. product rights for Atacand®, Atacand HCT®, Arimidex® and Casodex®;
- continued growth in Research and Development spending driven by increased investment in our Cortrophin® Gel Re-Commercialization program. The above guidance ranges include approximately $14.0 million to $16.0 million of total ANI Research and Development expense as compared to $9.1 million incurred in 2017;
- continued select investment in Selling, General, and Administrative expenses to support the continued growth of our business and brands;
- a combined federal and state effective income tax rate of 23%; and
- approximately 11.7 million shares of fully diluted common stock outstanding.

Effect of Tax Reform and Capital Allocation

The recently enacted Tax Cuts and Jobs Act will significantly enhance ANI's ability to invest in value generating opportunities and continue to leverage its wholly U.S. based manufacturing and research and development footprint.

- **Lower marginal tax rate**: combined federal and state marginal tax rate will decrease from approximately 37% to 23%.
- **Improved cash flow**: favorable impact of reduced cash tax burden in 2018 will approximate $10 to $13 million.
- **Strong capital position**: ANI believes that this benefit, coupled with its existing cash balance of $31.1 million as of December 31, 2017, forecast cash flow from operating activities, and access to $50 million under its revolving credit facility will place it in a strong position to pursue business development activities in the coming year.
- **Continued internal investment:** ANI plans to invest approximately $7 million in capital projects during 2018 in support of its operations and employees in Baudette, Minnesota. This is in addition to the $10.4 million invested during the course of 2017.

Cortrophin® Gel Re-commercialization Update

In the fourth quarter of 2017, ANI has continued to advance the manufacture of Corticotropin active pharmaceutical ingredient ("API"), now successfully manufacturing three intermediate scale batches of API. All three intermediate scale batches of API exhibit lot-to-lot consistency across many different

chemical and biological test methods that we continue to employ in building our comprehensive characterization package. These methods are also being utilized to successfully demonstrate comparability to historically manufactured commercial lots of API. ANI has ordered the capital equipment necessary for commercial scale API manufacturing and soon plans to qualify this equipment for cGMP commercial scale manufacturing. We plan to initiate commercial scale API manufacturing in early 2018 and hope to initiate process validation and registration batch manufacturing by the end of 2018.

ANI executed a long-term commercial supply agreement with its existing Corticotropin API manufacturer and has now secured the long-term supply for both Corticotropin API and for the finished goods – Cortrophin® gel drug product. We have begun to manufacture development scale batches of Cortrophin® gel in the fourth quarter of 2017, whereby the Cortrophin® gel batches are using the API from our recently manufactured intermediate scale batches.

ANI requested a Type C meeting with the FDA in the fourth quarter of 2017 to provide the regulatory plan for re-commercialization of Cortrophin® gel. The FDA granted the Type C meeting with an FDA response scheduled to occur by the end of the first quarter of 2018.

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.

Fourth Quarter Results

Net Revenues (in thousands)	**Three Months Ended December 31,**			
	2017	**2016**	**Change**	**% Change**
Generic pharmaceutical products	$ 29,829	$ 29,296	$ 533	2%
Branded pharmaceutical products	15,521	6,524	8,997	138%
Contract manufacturing	1,895	1,560	335	21%
Contract services and other income	41	825	(784)	(95)%
Total net revenues	$ 47,286	$ 38,205	$ 9,081	24%

For the three months ended December 31, 2017, ANI reported net revenues of $47.3 million, an increase of 24% from $38.2 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased slightly to $29.8 million from $29.3 million in the prior period, primarily due to increased unit sales of Flecainide and Methazolamide, as well as 2017 product launches, partially offset by decreased sales of EEMT due to market contraction and decreased sales of Propranolol ER due to lower prices.
- Revenues from sales of branded pharmaceuticals increased 138%, to $15.5 million from $6.5 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 21% to $1.9 million from $1.6 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 95%, to $41 thousand from $0.8 million, primarily due to lack of the $0.6 million royalty payment related to a license for patent rights received in 2016.

Operating expenses increased to $39.9 million for the three months ended December 31, 2017, from $36.9 million in the prior year period. The increase was primarily due to a $3.5 million increase in cost of sales as compared with the prior period, as a result of $2.9 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 $2.5 million as compared with the prior period, primarily due to work on the Cortrophin® gel re-commercialization and Vancocin® oral solution projects.

Excluding the $2.9 million of net inventory step-up costs related to sales of Inderal® XL and InnoPran XL® in the fourth quarter of 2017 and the $2.8 million of net inventory step-up costs related to sales of Inderal® LA and Propranolol ER in the fourth quarter of 2016, cost of sales remained relatively consistent at 37% of net revenues.

Net loss was $9.6 million for the three months ended December 31, 2017, as compared to net loss of $1.1 million in the prior year period. The net loss was primarily due to a $13.4 million charge recorded as a result of the re-measurement of our net deferred tax assets in relation to the tax rate decrease established in the Tax Cuts and Jobs Act, which was enacted on December 22, 2017. Changes in tax rates and tax laws are accounted for in the period of enactment, therefore the charge was recorded in the three months ended December 31, 2017. The effective tax rate for the three months ended December 31, 2017 was 321%, 308% of which related to the charge from the Tax Cuts and Jobs Act.

Diluted loss per share for the three months ended December 31, 2017 was $0.83, based on 11,560 thousand diluted shares outstanding and including a $1.16 of impact from the charge related to the Tax Cuts and Jobs Act, as compared to diluted loss per share of $0.09 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.08, as compared to adjusted non-GAAP diluted earnings per share of $0.90 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 Year Ended December 31, 2017

Net Revenues (in thousands)	**Year Ended December 31,**			
	2017	**2016**	**Change**	**% Change**
Generic pharmaceutical products	$ 118,437	$ 95,201	$ 23,236	24%
Branded pharmaceutical products	50,919	26,443	24,476	93%
Contract manufacturing	7,046	5,537	1,509	27%
Contract services and other income	440	1,441	(1,001)	(70)%
Total net revenues	$ 176,842	$ 128,622	$ 48,220	37%

For the year ended December 31, 2017, ANI reported net revenues of $176.8 million, an increase of 37% from $128.6 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals increased 24%, to $118.4 million from $95.2 million in the prior period, primarily due to annualization of sales of the generic products launched during 2016, as well as 2017 product launches.
- Revenues from sales of branded pharmaceuticals increased 93%, to $50.9 million from $26.4 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, which launched in Q2 2016.
- Contract manufacturing revenue increased by 27% to $7.0 million from $5.5 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 70%, to $0.4 million from $1.4 million, primarily due to lack of the $0.6 million royalty payment related to a license for patent rights received in 2016, and also because sales of Fenofibrate in the ANI label have replaced the royalties previously received on the product.

Operating expenses increased to $148.5 million for the year ended December 31, 2017, from $108.5 million in the prior year period. The increase was primarily due to a $30.3 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 $10.4 million of cost of sales related to the inventory step-up on Inderal® XL, InnoPran XL®, and Inderal® LA inventory. In addition, research and development increased by $6.2 million as compared with the prior period, primarily due to work on the Cortrophin® gel re-commercialization and Vancocin® oral solution projects.

Excluding the $10.4 million of net inventory step-up costs related to sales of Inderal® XL, InnoPran XL®, and Inderal® LA in the year ended December 31, 2017 and $5.9 million of net inventory step-up costs related to sales of Inderal® LA and Propranolol ER in the year ended December 31, 2016, cost of sales increased as a percentage of net revenues to 39% from 33%, primarily as a result of increased sales of products with profit-sharing arrangements.

Net loss was $1.1 million for the year ended December 31, 2017, as compared to net income of $3.9 million in the prior year period. The net loss was primarily due to a $13.4 million charge recorded as a result of the re-measurement of our net deferred tax assets in relation to the tax rate decrease established in the Tax Cuts and Jobs Act, which was enacted on December 22, 2017. Changes in tax rates and tax laws are accounted for in the period of enactment, therefore the charge was recorded in the year ended December 31, 2017. The effective tax rate for the year ended December 31, 2017 was 107%, 82% of which related to the charge from the Tax Cuts and Jobs Act.

Diluted loss per share for the year ended December 31, 2017 was $0.09, based on 11,547 thousand diluted shares outstanding and including a $1.16 of impact from the charge related to the Tax Cuts and Jobs Act, as compared to diluted earnings per share of $0.34 in the prior year period. Adjusted non-GAAP diluted earnings per share was $3.91, as compared to adjusted non-GAAP diluted earnings per share of $2.96 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)

	December 31, 2017	December 31, 2016
Cash	$ 31,144	$ 27,365
Accounts receivable, net	$ 58,788	$ 45,895
Inventory, net	$ 37,727	$ 26,183
Current assets	$ 131,605	$ 103,007
Current liabilities	$ 39,228	$ 31,948
Non-current debt	$ 198,154	$ 120,643

ANI generated $39.4 million of cash flow from operations in the year ended December 31, 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. In December 2017, ANI purchased from AstraZeneca AB and AstraZeneca UK Limited the right, title, and interest in the NDAs and the U.S. rights to market Atacand®, Atacand HCT®, Arimidex®, and Casodex®, for $46.5 million in cash. ANI made the $46.5 million cash payment with funds from a $75.0 million five-year term loan entered into with Citizens Bank N.A. in December 2017. The funds from the term loan were also used to pay down the $25.0 million remaining balance on the line of credit.

ANI Product Development Pipeline

ANI's pipeline consists of 74 products, addressing a total annual market size of $3.1 billion, based on data from IMS Health. Of these 74 products, 51 were acquired and of these acquired products, ANI expects that 44 can be commercialized based on either CBE-30s or prior approval supplements filed with the FDA.

Non-GAAP Financial Measures

The Company's fiscal 2018 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.

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