ANI Pharmaceuticals Reports Third Quarter and Year-To-Date 2018 Results and Reaffirms Guidance

For the third quarter 2018:

- **Record net revenues of $50.7 million, an increase of 5% as compared to the same period in 2017**
- **GAAP net income of $5.0 million and diluted GAAP earnings per share of $0.42**
- **Adjusted non-GAAP EBITDA of $21.4 million**
- **Adjusted non-GAAP diluted earnings per share of $1.29**

Baudette, Minnesota (November 6, 2018) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three and nine months ended September 30, 2018 and reaffirmed its 2018 financial guidance. The Company will host its earnings conference call this morning, November 6, 2018, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 3193426.

Financial Summary

(in thousands, except per share data)	Q3 2018	Q3 2017	YTD 2018	YTD 2017
Net revenues	$ 50,703	$ 48,164	$ 144,454	$ 129,556
Net income	$ 5,037	$ 4,720	$ 10,064	$ 8,553
GAAP earnings per diluted share	$ 0.42	$ 0.40	$ 0.85	$ 0.73
Adjusted non-GAAP EBITDA[(a)]	$ 21,429	$ 20,662	$ 62,217	$ 54,503
Adjusted non-GAAP diluted earnings per share[(b)]	$ 1.29	$ 1.11	$ 3.74	$ 2.83

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

Arthur S. Przybyl, President and CEO, stated,

> "ANI had a strong third quarter, generating record net revenues. Our year-to-date results include record net revenues, an increase of 11% over the prior year period, record adjusted non-GAAP EBITDA, an increase of 14% over the prior year period, and record adjusted non-GAAP diluted earnings per share, an increase of 32% over the prior year period. Our balance sheet and cash flows remain robust and we continue to seek acquisitive opportunities to augment our internal growth.
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> "Since our last earnings release we have launched three new generic products: Cholestyramine, and authorized generics of Brethine® and Atacand HCT®. This year we have launched seven generic products, increasing our total generic drug portfolio to 31 products.
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> "Recently, we launched two brand products and now have a portfolio of 11 brand products sold under the ANI label. In September, we filed our prior approval supplement with the FDA for Vancocin® Oral Solution and our work continues to progress on re-commercializing Cortrophin® and filing the supplemental NDA in the first quarter of 2020.
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> "Finally, in August, ANI acquired Wellspring Pharma Services to expand our contract manufacturing and development business. We are currently integrating that business and look forward to making further use of the manufacturing facility to advance work on our pipeline products."

ANI Reaffirms Guidance for the Full Year 2018

ANI's estimates are based upon actual results for the nine months ending September 30, 2018 and projected results for the remaining three months of the year. ANI's full year 2018 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, integration and contribution of recent acquisitions and other key events. 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:

($ in millions except per share data)

	2018 Guidance
Net Revenues	$195 to $205
Adjusted non-GAAP EBITDA	$82 to $88
Adjusted non-GAAP diluted earnings per share	$4.80 to $5.27

Generic Pharmaceutical Products

Third Quarter Revenue Results and Update

Revenues from sales of generic pharmaceuticals decreased 1%, to $30.3 million from $30.5 million in the prior period, primarily due to volume decreases for Fenofibrate, EEMT, and Nilutamide, tempered by the second quarter 2018 launch of Ezetimibe-Simvastatin. To date in 2018, ANI has launched seven generic products: Candesartan Hydrochlorothiazide (the authorized generic of Atacand HCT®), Terbutaline Sulfate (the authorized generic of Brethine®), Morphine Sulfate Oral Solution, Cholestyramine for Oral Suspension, Ezetimibe-Simvastatin, Desipramine, and Felbamate, increasing its generic commercialized product portfolio to a total of 31 products.

Key Generic Pipeline Products

Product	**Reference Drug**	**Required Filing**	**Timing**	**Total Annual Market[(c)]**
Methylphenidate ER Tablets	Concerta®	None (approved)	Launch Q1 2019	$1,300M
Aspirin/Dipyridamole ER Capsules	Aggrenox®	None (approved)	Launch no later than October 1, 2019	$ 176M
Undisclosed	Undisclosed	ANDA filed – priority review granted	GDUFA date: April 2019	$ 46M

[(c)] Based on data from IQVIA

Branded Pharmaceutical Products

Third Quarter Revenue Results and Update

Revenues from sales of branded pharmaceuticals decreased 7%, to $14.6 million from $15.7 million in the prior period, primarily due to lower unit sales and price of Inderal® LA and lower unit sales of Vancocin®, tempered by sales of Casodex® and Arimidex®, which were launched in July 2018, as well as sales of Inderal® XL and InnoPran XL®, both of which were acquired in the first quarter of 2017 and which were re-launched under the ANI label in the first quarter of 2018. In October, ANI launched two additional branded products in the ANI label, Atacand® and Atacand HCT®, increasing the number of branded products sold under the ANI label to eleven.

Key Brand Pipeline Products

Product	Required Filing	Filing Date	Total Annual Market[(d)]
Vancocin® Oral Solution	PAS	Filed September 2018	$ 450M
Cortrophin® Gel	sNDA	By Q1 2020	$1,140M

[(d)] Based on data from IQVIA

Vancocin® Oral Solution Update

ANI is currently advancing a commercialization effort for Vancocin® oral solution. ANI filed a prior approval supplement ("PAS") in September 2018. This product will be manufactured at ANI's site in Baudette, Minnesota and will compete in a market that currently exceeds $450 million annually.

Cortrophin® Gel Re-commercialization Update

In the third quarter of 2018, ANI continued commercial scale manufacturing of Corticotropin API. Thus far, commercial scale Corticotropin API appears to be consistent with the pilot scale batches previously manufactured, and moreover, consistent with legacy API batches that had been manufactured previously. The Company is on track to initiate API process validation, viral clearance validation, and API registration batch manufacturing in the first quarter of 2019.

ANI has finalized development of all API and drug product analytical methods to be used to support the API characterization package. Analytical methods to be used for batch release and stability have also been developed and will be validated prior to initiation of process validation and registration batch manufacturing, specifically by the first quarter of 2019 for API and the second quarter of 2019 for drug product.

The Company continued to manufacture Cortrophin® Gel finished dose drug product, which has been placed on stability. Commercial scale drug product manufacturing activities are scheduled to begin in the fourth quarter of 2018, utilizing API that was also manufactured at commercial scale. ANI is on track to initiate media fill simulations in the first quarter of 2019 and drug product process validation and registration batch manufacturing in the second quarter of 2019.

ANI is on track to file a supplemental NDA by the first quarter of 2020.

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

Contract Manufacturing

Third Quarter Revenue Results and Update

Contract manufacturing revenue increased by 55% to $2.8 million from $1.8 million in the prior year period, primarily due to the impact of contract manufacturing revenue from our Canadian subsidiary, ANI Pharmaceuticals Canada Inc. ("ANI Canada"). Through our ANI Canada subsidiary, we acquired WellSpring Pharma Services Inc. ("WellSpring"), a Canadian company located in Oakville, Ontario that performs contract development and manufacturing of pharmaceutical products, in August 2018. With an employee base of about 100, ANI Pharmaceuticals Canada Inc. (formerly WellSpring) is a well-established contract development and manufacturing facility with capabilities in solid oral, semi-solids, and liquids that operates out of a 100,000 square foot site that ANI acquired as part of the transaction. ANI Canada has a diverse customer base, focused on both brand and generic drug products. The site manufactures drug product for both the U.S. and Canadian prescription drug markets and has substantial capacity.

Royalty and Other Income

Third Quarter Revenue Result and Update

Royalty and other income increased to $3.0 million from $0.1 million, primarily due to the royalties received on sales of Atacand® and Atacand HCT®. These product royalties will decrease as a direct result of ANI transferring these products into the ANI label branded product. In addition, during the three months ended September 30, 2018, we recognized $0.5 million of royalties from sales and milestones related to Gilead's Yescarta® product, as further described below. In addition, the three months ended September 30, 2018 include the impact of product development services and laboratory services revenue from our ANI Canada subsidiary.

Key Royalty Product: Yescarta®

ANI is entitled to a percentage of global Yescarta® net sales as well as a portion of certain product milestones, such as the recent positive opinion issued by the European Medicines Agency ("EMA") Committee for Medicinal Products for Human Use ("CHMP").

Third Quarter Results

Net Revenues (in thousands)	**Three Months Ended September 30,**			
	2018	**2017**	**Change**	**% Change**
Generic pharmaceutical products	$ 30,287	$ 30,546	$ (259)	(1)%
Branded pharmaceutical products	14,589	15,688	(1,099)	(7)%
Contract manufacturing	2,826	1,829	997	55%
Royalty and other income	3,001	101	2,900	NM[(1)]
Total net revenues	$ 50,703	$ 48,164	$ 2,539	5%

[(1)] Not Meaningful

For the three months ended September 30, 2018, ANI reported net revenues of $50.7 million, an increase of 5% from $48.2 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals decreased 1%, to $30.3 million from $30.5 million in the prior period, primarily due to volume decreases for Fenofibrate, EEMT, and Nilutamide, tempered by the second quarter 2018 launch of Ezetimibe-Simvastatin.
- Revenues from sales of branded pharmaceuticals decreased 7%, to $14.6 million from $15.7 million in the prior period, primarily due to lower unit sales and price of Inderal® LA and lower unit sales of Vancocin®, tempered by sales of Casodex® and Arimidex®, which were launched in July 2018, as well as sales of Inderal® XL and InnoPran XL®, both of which were acquired in the first quarter of 2017 and re-launched under the ANI label in the first quarter of 2018.
- Contract manufacturing revenue increased by 55% to $2.8 million from $1.8 million in the prior year period, primarily due to the results of our ANI Canada subsidiary.
- Royalty and other income increased to $3.0 million from $0.1 million, due to the royalties received on sales of Atacand®, Atacand HCT®, royalties from Yescarta® sales and milestones, and the impact of product development services and laboratory services revenue from our ANI Canada subsidiary.

Operating expenses increased to $40.6 million for the three months ended September 30, 2018, from $38.8 million in the prior year period. The increase was primarily due to a $3.7 million increase in selling, general, and administrative as compared with the prior period, as a result of increases in personnel and related costs and $0.9 million of costs associated with the WellSpring acquisition and integration. Research and development expense increased by $2.0 million as compared with the prior period, primarily as a result of increased work on development projects, primarily the Cortrophin® Gel re-commercialization project and work on the ANDAs acquired in the asset purchase agreement with Impax/Amneal. In addition, depreciation and amortization increased by $1.4 million due to the amortization of the product rights for Atacand®, Atacand HCT®, Arimidex®, and Casodex®, which were acquired in December 2017. These increases were partially offset by the $5.5 million decrease in cost of sales, due to decreased sales of products subject to profit-sharing arrangements, as well as the $2.8 million impact in 2017 of costs of sales related to the excess of fair value over cost on Inderal® XL and InnoPran XL® inventory, the impact of which did not continue in the third quarter of 2018.

Cost of sales as a percentage of net revenues decreased to 31% during the three months ended September 30, 2018, from 38% during same period in 2017, excluding the $44 thousand of net inventory step-up costs relating to contract manufacturing sales in our ANI Canada entity in the third quarter of 2018 and $2.8 million of net inventory step-up costs related to sales of Inderal® XL, InnoPran XL®, and Inderal® LA in the third quarter of 2017. The decrease was primarily due to increased royalty income and lower sales of products subject to profit-sharing arrangements.

Net income was $5.0 million for the three months ended September 30, 2018, as compared to net income of $4.7 million in the prior year period. The effective tax rate for the three months ended September 30, 2018 was 21%.

Diluted earnings per share for the three months ended September 30, 2018 was $0.42, based on 11,804 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.40 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.29, as compared to adjusted non-GAAP diluted earnings per share of $1.11 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, 2018

Net Revenues (in thousands)	**Nine Months Ended September 30,**			
	2018	**2017**	**Change**	**% Change**
Generic pharmaceutical products	$ 83,716	$ 88,608	$ (4,892)	(6)%
Branded pharmaceutical products	41,714	35,398	6,316	18%
Contract manufacturing	5,450	5,151	299	6%
Royalty and other income	13,574	399	13,175	NM[(1)]
Total net revenues	$ 144,454	$ 129,556	$ 14,898	11%

[(1)] Not Meaningful

For the nine months ended September 30, 2018, ANI reported net revenues of $144.5 million, an increase of 11% from $129.6 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals decreased 6%, to $83.7 million from $88.6 million in the prior period, primarily due to volume decreases for Fenofibrate, EEMT, and Nilutamide, as well as sales decreases for Propranolol ER driven by price, tempered by the second quarter 2018 launch of Ezetimibe-Simvastatin and the second quarter 2017 launch of Diphenoxylate Hydrochloride and Atropine Sulfate.
- Revenues from sales of branded pharmaceuticals increased 18%, to $41.7 million from $35.4 million in the prior period, primarily due to sales of Inderal® XL and InnoPran XL®, both of which were acquired in the first quarter of 2017, and which were re-launched under our label in the first quarter of 2018, as well as sales of Casodex® and Arimidex®, which were launched in July 2018, tempered by to lower unit sales of Inderal® LA and Vancocin®.
- Contract manufacturing revenue increased by 6% to $5.5 million from $5.2 million in the prior year period, primarily due to the impact of contract manufacturing sales from our ANI Canada subsidiary, partially offset by the timing of orders.
- Royalty and other income increased to $13.6 million from $0.4 million, primarily due to the royalties received on sales of Atacand®, Atacand HCT®, Arimidex®, and Casodex®, as well as royalties from Yescarta® sales and milestones.

Operating expenses increased to $120.5 million for the nine months ended September 30, 2018, from $108.6 million in the prior year period. The increase was primarily due to a $8.0 million increase in selling, general, and administrative as compared with the prior period, as a result of increases in personnel and related costs and $1.3 million of costs associated with the WellSpring acquisition and integration. Research and development expense increased by $5.5 million as compared with the prior period, primarily as a result of $1.3 million of in-process research and development, which was recognized as research and development expense in relation to the asset acquisition from Impax/Amneal, as well as increased work on development projects, primarily the Cortrophin® Gel re-commercialization project and work on the ANDAs acquired in the asset purchase agreement with Impax/Amneal. In addition, depreciation and amortization increased by $4.2 million due primarily to the amortization of the product rights for Atacand®, Atacand HCT®, Arimidex®, and Casodex®, which were acquired in December 2017.

Excluding the $5.7 million of net inventory step-up, primarily related to the sales and write off Inderal® XL and InnoPran XL® in the nine months ended September 30, 2018 and $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, cost of sales as a percentage of net revenues decreased to 33% during the nine months ended September 30, 2018, from 39% during same period in 2017, primarily due to increased

royalty revenues, change in product mix towards higher-margin brand products, and lower sales of products subject to profit-sharing arrangements.

Net income was $10.1 million for the nine months ended September 30, 2018, as compared to net income of $8.6 million in the prior year period. The effective tax rate for the nine months ended September 30, 2018 was 21%.

Diluted earnings per share for the nine months ended September 30, 2018 was $0.85, based on 11,767 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.73 in the prior year period. Adjusted non-GAAP diluted earnings per share was $3.74, as compared to adjusted non-GAAP diluted earnings per share of $2.83 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, 2018	December 31, 2017
Cash	$ 44,136	$ 31,444
Accounts receivable, net	$ 67,647	$ 58,788
Inventory, net	$ 40,006	$ 37,727
Current assets	$ 156,793	$ 131,605
Current liabilities	$ 46,902	$ 39,228
Non-current debt	$ 200,076	$ 198,154

ANI generated $39.8 million of positive cash flows from operations in the nine months ended September 30, 2018. In December 2017, ANI entered into a credit agreement with Citizens Bank, N.A. that included a $75 million term loan and a $50 million line of credit. The $75 million term loan was used to pay down ANI's former $25.0 million line of credit and to purchase 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. The $50 million line of credit currently remains undrawn. In April 2018, ANI purchased from IDT Australia, Limited the ANDAs for 23 previously-marketed generic drug products and API for four of the acquired products for $2.7 million in cash and a single-digit royalty on net profits from sales of one of the products. In May 2018, ANI purchased from Impax/Amneal the approved ANDAs for three previously-commercialized generic drug products, the approved ANDAs for two generic drug products that have not yet been commercialized, the development package for one generic drug product, a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval, and certain manufacturing equipment required to manufacture one of the products, for $2.3 million in cash. In August 2018, ANI acquired WellSpring. As a result of the transaction, ANI acquired WellSpring's pharmaceutical manufacturing facility, laboratory, and offices, current book of commercial business, as well as an organized workforce for a purchase price of $18 million, subject to customary adjustments. Subject to further adjustments, estimated consideration was $17.3 million, paid with cash on hand.

ANI Product Development Pipeline

ANI's pipeline consists of 75 products, addressing a total annual market size of $4.5 billion, based on data from IQVIA. Of these 75 products, 70 were acquired and of these acquired products, ANI expects that 54 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, expense from acquired in-process research and development, transaction and integration expenses, 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, transaction and integration expenses, non-cash interest expense, depreciation and amortization expense, expense from acquired in-process research and development, 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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