ANI Pharmaceuticals Reports Second Quarter and Year-To-Date 2018 Results and Updates Guidance

Acquires WellSpring Pharma Services for $18 Million in Cash to Expand Contract Manufacturing Business and Accelerate ANDA Pipeline Re-commercialization Efforts

Targets sNDA Filing for Cortrophin Gel by Q1 2020

Records Initial Royalties on Commercial Sales of Yescarta®

For the second quarter 2018:

- **Net revenues of $47.3 million, an increase of 6% as compared to the same period in 2017**
- **GAAP net income of $2.8 million and diluted GAAP earnings per share of $0.23**
- **Adjusted non-GAAP EBITDA of $19.0 million**
- **Adjusted non-GAAP diluted earnings per share of $1.13**

Baudette, Minnesota (August 7, 2018) – ANI Pharmaceuticals, Inc. ("ANI") (NASDAQ: ANIP) today reported its financial results for the three and six months ended June 30, 2018 and updated its 2018 financial guidance. The Company will host its earnings conference call this morning, August 7, 2018, at 10:30 AM ET. Investors and other interested parties can join the call by dialing (866) 776-8875. The conference ID is 9878939.

Financial Summary

(in thousands, except per share data)	Q2 2018	Q2 2017	YTD 2018	YTD 2017
Net revenues	$ 47,268	$ 44,764	$ 93,751	$ 81,392
Net income	$ 2,777	$ 2,681	$ 5,027	$ 3,833
GAAP earnings per diluted share	$ 0.23	$ 0.23	$ 0.42	$ 0.33
Adjusted non-GAAP EBITDA[(a)]	$ 19,034	$ 19,112	$ 40,788	$ 33,841
Adjusted non-GAAP diluted earnings per share[(b)]	$ 1.13	$ 0.98	$ 2.45	$ 1.72

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

Arthur S. Przybyl, President and CEO, stated,

> "In the second quarter of 2018 ANI continued to successfully execute on its strategy to grow the brand and generic business platforms and to advance our key pipeline assets. In addition, today, we announced that we acquired WellSpring, a contract development and manufacturing business located near Toronto, Canada in order to expand our third business platform, contract manufacturing, and to increase our capacity to re-commercialize our pipeline of acquired ANDAs that require a tech transfer.
>
> During the second quarter we acquired a basket of 23 generic products from IDT and we acquired a portfolio of six generic products, a license, supply, and distribution agreement for a seventh generic product, and related equipment from the Impax/Amneal business combination.

We believe these acquisitions provide compelling short and long-term opportunities for continued revenue and EBITDA growth for ANI. These opportunities are discussed in further detail below.

In June we launched Cholestyramine, our tenth product launch from our pipeline of acquired ANDAs, and our fourth generic product launch in the second quarter, after successfully completing a manufacturing site transfer to our Baudette facilities. We also entered into an agreement with ClarusOne, a large buying consortium, that we believe will provide us with an opportunity to increase our generic product revenues.

In July we launched our internally-developed morphine sulfate oral solution product, as well as two of the branded products we acquired in December 2017, Arimidex and Casodex, and we expect to launch the two Atacand branded products in the ANI label in October of 2018. Finally, we have advanced our Cortrophin product, and have announced a target FDA supplemental NDA filing date, which is discussed in further detail below."

ANI Updates Guidance for the Full Year 2018

ANI's estimates are based upon actual results for the six months ending June 30, 2018 and projected results for the remaining six 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 EPS figures)

	2018 Guidance Range					2017	2018 Guidance
	First Half	Second Half		Full Year		Full Year	Growth
	Actual	Low	High	Low	High	Actual	Low	High
Net Revenues	$ 93.8	$ 101.2	$ 111.2	$ 195.0	$ 205.0	$ 176.8	10%	16%
Adjusted non-GAAP EBITDA	40.8[(c)]	41.2	47.2	82.0	88.0	74.2[(e)]	11%	19%
Adjusted non-GAAP diluted earnings per share	$ 2.45[(d)]	$ 2.35	$ 2.92	$ 4.80	$ 5.27	$ 3.91[(f)]	23%	35%

(c) See Table 3 for US GAAP reconciliation.
(d) See Table 4 for US GAAP reconciliation.
(e) See Table 6 for US GAAP reconciliation.
(f) See Table 7 for US GAAP reconciliation.

Generic Pharmaceutical Products

Second Quarter Revenue Results and Update

Revenues from sales of generic pharmaceuticals decreased 4%, to $30.2 million from $31.5 million in the prior period, primarily due to volume decreases for Fenofibrate and sales decreases for Propranolol ER driven by price, tempered by the impact of a full quarter of sales of Diphenoxylate Hydrochloride and

Atropine Sulfate and the second quarter 2018 launch of Ezetimibe-Simvastatin. So far in 2018, ANI has launched five generic products: Morphine Sulfate Oral Solution, Cholestyramine for Oral Suspension, Ezetimibe-Simvastatin, Desipramine, and Felbamate, increasing its generic commercialized product portfolio to a total of 29 products. In June, ANI entered into an Agreement with ClarusOne, one of the three largest buying consortia, that will allow ANI to compete for additional generic business. Finally, we are excited to announce that we have been granted priority review status for an ANDA filing submitted through one of our development partners. The assigned GDUFA date for this product is in April 2019.

Key Generic Pipeline Products

Product	Reference Drug	Required Filing	Timing	Total Annual Market[(g)]
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	$ 47M

(g) Based on data from IQVIA

Branded Pharmaceutical Products

Second Quarter Revenue Results and Update

Revenues from sales of branded pharmaceuticals decreased 10%, to $10.5 million from $11.7 million in the prior period, primarily due to lower revenue from Inderal LA due to decreased unit sales, partially offset by increased sales of Inderal XL and InnoPran XL. In July, ANI launched two branded products, Arimidex and Casodex, in the ANI label, increasing the number of branded products sold under the ANI's label to nine. ANI expects to launch two additional branded products in the ANI label, Atacand and Atacand HCT in October 2018.

Key Brand Pipeline Products

Product	Required Filing	Filing Date	Total Annual Market[(h)]
Vancocin® Oral Solution	PAS	September 2018	$ 450M
Cortrophin® Gel	sNDA	By Q1 2020	$1,200M

(h) Based on data from IQVIA

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 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 second quarter of 2018, ANI continued to advance the manufacture of Corticotropin active pharmaceutical ingredient ("API"), completing the manufacture of four successful pilot-scale API batches and initiating the manufacture of commercial scale batches of Corticotropin API. ANI is on track to initiate API process validation and registration batch manufacturing in the first quarter of 2019.

ANI continued to manufacture Cortrophin® Gel drug product, which has been placed on stability. The work has been valuable in identifying critical process parameters and manufacturing and quality attributes of the drug product. ANI intends to initiate commercial scale drug product manufacturing activities this year.

Following ANI's request for a Type C meeting with the FDA in the fourth quarter of 2017, the FDA granted the meeting and provided an initial response in March 2018. Further oral and written communications with the FDA occurred in the second quarter of 2018. Based on these communications, the FDA's expectations for our supplemental NDA filing have been further defined and incorporated into ANI's regulatory plan. The FDA feedback has not fundamentally changed ANI's regulatory strategy and has not altered the timeline for the project. As a result, ANI expects 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

Second Quarter Revenue Results and Update

Contract manufacturing revenue increased by 10% to $1.7 million from $1.5 million in the prior year period, primarily as a result of the timing and volume of customer orders.

WellSpring Acquisition

Today, ANI acquired WellSpring Pharma Services Inc., a contract development and manufacturing organization ("CDMO"), located near Toronto in Oakville, Canada. With an employee base of about 100, WellSpring is a well-established CDMO 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. WellSpring has a diverse customer base, focused on both brand and generic drug products. The company currently manufactures 17 commercial products for 11 different customers and is assisting customers on 13 additional products that are in development or awaiting FDA approval. The site manufactures drug product for both the U.S. and Canadian prescription drug markets and has substantial capacity.

ANI anticipates substantial synergy in the WellSpring acquisition. Through this acquisition ANI intends to not only broaden its existing CMO platform but also to utilize the acquired facility and capabilities to expand and accelerate the re-commercialization effort associated with ANI's pipeline of acquired ANDAs that require a tech transfer. WellSpring currently generates $15 to $20 million dollars in annual revenues and ANI expects the acquisition will be accretive to Adjusted EBITDA beginning in 2019.

We are excited to welcome the WellSpring customers and the WellSpring employees to ANI.

Royalty and Other Income

Second Quarter Revenue Result and Update

Royalty and other income increased to $4.9 million from $0.1 million, primarily due to the royalties received on sales of Atacand®, Atacand HCT®, Arimidex®, and Casodex®. These product royalties will decrease as a direct result of ANI transferring these products into the ANI label branded product. In addition, ANI recognized royalties related to Yescarta®, which is discussed in further detail below.

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"). These revenue streams originate from assets acquired in the BioSante transaction and subsequent licensing arrangements between ANI and various parties including Kite Pharma, Inc. ANI recognized $0.9 million of royalties related to the product in Q2 2018.

Second Quarter Results

Net Revenues (in thousands)	**Three Months Ended June 30,**			
	2018	**2017**	**Change**	**% Change**
Generic pharmaceutical products	$ 30,202	$ 31,490	$ (1,288)	(4)%
Branded pharmaceutical products	10,530	11,671	(1,141)	(10)%
Contract manufacturing	1,679	1,529	150	10%
Royalty and other income	4,857	74	4,783	NM[(1)]
Total net revenues	$ 47,268	$ 44,764	$ 2,504	6%

[(1)] Not Meaningful

For the three months ended June 30, 2018, ANI reported net revenues of $47.3 million, an increase of 6% from $44.8 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals decreased 4%, to $30.2 million from $31.5 million in the prior period, primarily due to volume decreases for Fenofibrate and sales decreases for Propranolol ER driven by price, tempered by the impact of a full quarter of sales of Diphenoxylate Hydrochloride and Atropine Sulfate, as well as the second quarter 2018 launch of Ezetimibe-Simvastatin.
- Revenues from sales of branded pharmaceuticals decreased 10%, to $10.5 million from $11.7 million in the prior period, primarily due to lower revenue from Inderal LA due to decreased unit sales, partially offset by increased 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.
- Contract manufacturing revenue increased by 10% to $1.7 million from $1.5 million in the prior year period, primarily as a result of the timing and volume of customer orders.
- Royalty and other income increased to $4.9 million from $0.1 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 $40.0 million for the three months ended June 30, 2018, from $37.8 million in the prior year period. The increase was primarily due to a $3.0 million increase in research and development as compared with the prior period, 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 the timing of work on development projects, primarily the Cortrophin® gel re-commercialization project and work on the ANDAs purchased in 2014 and 2015. In addition, selling, general, and administrative expense increased by $2.6 million due to increased personnel and related costs and depreciation and amortization increased by $1.2 million due primarily 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 $4.5 million decrease in cost of sales, due to decreased sales of products subject to profit-sharing arrangements.

Cost of sales as a percentage of net revenues decreased to 35% during the three months ended June 30, 2018, from 40% during same period in 2017, excluding the $3.2 million of net inventory step-up costs related to sales of Inderal® XL, InnoPran XL®, and Inderal® LA in the second quarter of 2017. The decrease was primarily due to increased royalty income, change in product mix toward higher-margin brand products, and lower sales of products subject to profit-sharing arrangements.

Net income was $2.8 million for the three months ended June 30, 2018, as compared to net income of $2.7 million in the prior year period. The effective tax rate for the three months ended June 30, 2018 was 21%.

Diluted earnings per share for the three months ended June 30, 2018 was $0.23, based on 11,789 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.23 in the prior year period. Adjusted non-GAAP diluted earnings per share was $1.13, as compared to adjusted non-GAAP diluted earnings per share of $0.98 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 Six Months Ended June 30, 2018

Net Revenues (in thousands)	**Six Months Ended June 30,**			
	2018	**2017**	**Change**	**% Change**
Generic pharmaceutical products	$ 53,429	$ 58,061	$ (4,632)	(8)%
Branded pharmaceutical products	27,125	19,711	7,414	38%
Contract manufacturing	2,624	3,322	(698)	(21)%
Royalty and other income	10,573	298	10,275	NM[(1)]
Total net revenues	$ 93,751	$ 81,392	$ 12,359	15%

[(1)] Not Meaningful

For the six months ended June 30, 2018, ANI reported net revenues of $93.8 million, an increase of 15% from $81.4 million in the prior year period, due to the following factors:

- Revenues from sales of generic pharmaceuticals decreased 8%, to $53.4 million from $58.1 million in the prior period, primarily due to volume decreases for Fenofibrate and sales decreases for Propranolol ER driven by price, tempered by the impact of the second quarter 2017 launch of Diphenoxylate Hydrochloride and Atropine Sulfate and the second quarter 2018 launch of Ezetimibe-Simvastatin.
- Revenues from sales of branded pharmaceuticals increased 38%, to $27.1 million from $19.7 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.

- Contract manufacturing revenue decreased by 21% to $2.6 million from $3.3 million in the prior year period, primarily as a result of the timing and volume of customer orders.
- Royalty and other income increased to $10.6 million from $0.3 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 $80.0 million for the six months ended June 30, 2018, from $69.8 million in the prior year period. The increase was primarily due to a $4.2 million increase in selling, general, and administrative as compared with the prior period, as a result of increases in personnel and related costs. Research and development expense increased by $3.5 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 the timing of work on development projects, primarily the Cortrophin® gel re-commercialization project and work on the ANDAs purchased in 2014 and 2015. In addition, depreciation and amortization increased by $2.7 million due to the amortization of the product rights for Atacand®, Atacand HCT®, Arimidex®, and Casodex®, which were acquired in December 2017.

Excluding the $5.6 million of net inventory step-up related to the sales and write off Inderal® XL and InnoPran XL® in the six months ended June 30, 2018 and $4.7 million of net inventory step-up costs related to sales of Inderal® XL, InnoPran XL®, and Inderal® LA in the six months ended June 30, 2017, cost of sales as a percentage of net revenues decreased to 34% during the six months ended June 30, 2018, from 41% during same period in 2017, primarily as a change in product mix towards higher-margin brand products and lower sales of products subject to profit-sharing arrangements.

Net income was $5.0 million for the six months ended June 30, 2018, as compared to net income of $3.8 million in the prior year period. The effective tax rate for the six months ended June 30, 2018 was 21%.

Diluted earnings per share for the six months ended June 30, 2018 was $0.42, based on 11,748 thousand diluted shares outstanding, as compared to diluted earnings per share of $0.33 in the prior year period. Adjusted non-GAAP diluted earnings per share was $2.45, as compared to adjusted non-GAAP diluted earnings per share of $1.72 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)

	June 30, 2018	December 31, 2017
Cash	$ 54,994	$ 31,444
Accounts receivable, net	$ 56,115	$ 58,788
Inventory, net	$ 37,756	$ 37,727
Current assets	$ 152,367	$ 131,605
Current liabilities	$ 39,678	$ 39,228
Non-current debt	$ 199,389	$ 198,154

ANI generated $31.5 million of positive cash flows from operations in the six months ended June 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.

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 55 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 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 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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