ANI Pharmaceuticals Completes Acquisition of Generic Products and Assets from Amneal/Impax

May 7, 2018

BAUDETTE, Minnesota (May 7, 2018) - ANI Pharmaceuticals, Inc. (“ANI”) (Nasdaq: ANIP) today announced that it has completed the acquisition of a portfolio of six generic products, related manufacturing and supply agreements, and equipment and technical know-how from Amneal Pharmaceuticals, LLC and Impax Laboratories, Inc. (NASDAQ: IPXL) for cash consideration of $2.3 million. The portfolio of generic products has a combined current annual U.S. market of $1.7 billion according to Iqvia/IMS Health.

This transaction provides ANI with:

- Immediate revenue and profit from twelve SKUs of three currently commercialized products: Ezetimibe-Simvastatin tablets, Felbamate tablets and Desipramine tablets. Starting today ANI will commence shipping to customers.
- Approved ANDAs for Aspirin/Dipyridamole ER capsules and Methylphenidate ER tablets; these products require successful validation prior to launch. ANI will immediately begin validation efforts for these two products.
- An option with a date certain launch for Aspirin/Dipyridamole ER capsules of no later than October 1, 2019. The option allows ANI to source the product from Amneal through March 1, 2021 or until ANI launches its own product, whichever date is earlier. If ANI elects to exercise the option to launch product supplied by Amneal it will owe a milestone payment of between $0 and $10 million depending on the number of generic products in the market at the time of launch. Currently this is a $120 million annual U.S. market with only one generic competitor, according to Iqvia/IMS Health.
- Two pipeline products: Erythromycin IR tablets and Diclofenac-Misoprostol DR tablets. ANI acquired a development package for Erythromycin IR tablets and will assume the development work for this product with the goal of filing an ANDA in the near future. Currently there is only one generic competitor for Erythromycin IR tablets. In addition, ANI has assumed a multi-year license, supply and distribution agreement for Diclofenac-Misoprostol DR tablets.

Arthur S. Przybyl, ANI’s President and CEO stated, “We are excited to add these products and the revenue and profit generated by today’s three product launches to our generic platform. Importantly, we look forward to launching Aspirin/Dipyridamole ER capsules no later than October 1, 2019. At the same time, we will begin validation efforts for Methylphenidate ER tablets, which represents a compelling opportunity for ANI.”

About ANI

ANI Pharmaceuticals, Inc. (the “Company” or “ANI”) is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. The Company's targeted areas of product development currently include narcotics, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. For more information, please visit our 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 approval from the U.S. Food and Drug Administration; general business and economic conditions; market trends; products development; regulatory and other approvals and marketing.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as its proxy statement. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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