

Amphastar Receives FDA Approval for Albuterol Sulfate Inhalation Aerosol

May 22, 2024

RANCHO CUCAMONGA, CA / ACCESSWIRE / May 22, 2024 / Amphastar Pharmaceuticals, Inc. (NASDAQ:AMPH) today announced that the U.S. Food and Drug Administration ("FDA") has granted approval for the Company's Abbreviated New Drug Application ("ANDA") for Albuterol Sulfate Inhalation Aerosol, previously known as AMP-008. This product is for the treatment or prevention of bronchospasm in patients four years of age and older with reversible obstructive airway disease and the prevention of exercise-induced bronchospasm in patients four years of age and older. The FDA determined that Amphastar's albuterol is bioequivalent and therapeutically equivalent to Teva Respiratory LLC's ProAir[®] HFA (albuterol sulfate) Inhalation Aerosol.

Amphastar's CEO and President, Dr. Jack Zhang, commented: "Our first generic inhalation product's approval reflects both our technological and manufacturing ability. While patients can benefit from increased access to this combination drug product, we are proud to manufacture the finished product in the United States, as our commitment to quality remains our top priority. This approval sets a solid foundation for future growth in developing our other generic inhalation products, highlighting our expertise in developing complex products."

According to IQVIA, the U.S. sales for the branded and generic albuterol sulfate Inhalation Aerosol products were approximately \$1.7 billion for the 12 months that ended March 31, 2024.

Amphastar plans to launch its Albuterol Sulfate Inhalation Aerosol in the third quarter of 2024.

Pipeline Information

The Company currently has three abbreviated new drug applications ("ANDAs") on file with the U.S. Food and Drug Administration (the "FDA") targeting products with a market size of over \$1.4 billion, three biosimilar products in development targeting products with a market size of over \$7 billion, and four generic products in development targeting products with a market size of over \$3 billion. This market information is based on IQVIA data for the 12 months ended March 31, 2024. The Company is developing multiple proprietary products with injectable and intranasal dosage forms.

Amphastar's Chinese subsidiary, Amphastar Nanjing Pharmaceuticals, Co., Ltd. ("ANP"), currently has multiple Drug Master Files ("DMFs"), on file with the FDA and is developing several additional DMFs.

Company Information

Amphastar is a bio-pharmaceutical company that focuses primarily on developing, manufacturing, marketing, and selling technically-challenging generic and proprietary injectable, inhalation, and intranasal products. Additionally, the Company sells insulin API products. Most of the Company's finished products are used in hospital or urgent care clinical settings and are primarily contracted and distributed through group purchasing organizations and drug wholesalers. More information and resources are available at www.amphastar.com.

Amphastar's logo and other trademarks or service marks of Amphastar, including, but not limited to Amphastar[®], BAQSIMI[®], Primatene MIST[®], REXTOVY[™], Amphadase[®], and Cortrosyn[®], are the property of Amphastar.

Forward-Looking Statements

All statements in this press release that are not historical are forward-looking statements, including, among other things, statements relating to our expectations regarding future financial performance and business trends, our future growth, sales and marketing of our products, market size and expansion, product portfolio, product development, the timing of FDA filings or approvals, including the DMFs of ANP, the timing of product launches, acquisitions and other matters related to our pipeline of product candidates, the timing and results of clinical trials, the prospective benefits of the acquisition of BAQSIMI[®], including its potential for continued revenue growth, the success of our integration of BAQSIMI[®], and other future events. These statements are not facts but rather are based on Amphastar's historical performance and our current expectations, estimates, and projections regarding our business, operations, and other similar or related factors. Words such as "may," "might," "will," "could," "would," "should," "anticipate," "predict," "potential," "continue," "expect," "intend," "plan," "project," "believe," "estimate," and other similar or related expressions are used to identify these forward-looking statements, although not all forward-looking statements contain these words. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and assumptions that are difficult or impossible to predict and, in some cases, beyond Amphastar's control. Actual results may differ materially from those in the forward-looking statements as a result of a number of factors, including those described in Amphastar's filings with the Securities and Exchange Commission, including in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 29, 2024 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 filed with the SEC on May 10, 2024. In particular, there can be no guarantee that the acquisition of BAQSIMI[®] will be beneficial to our business, that any event, change or other circumstance could cause the results of the acquisition and integration of BAQSIMI[®] into our product portfolio to differ from Amphastar's expectation, that all or any of the contingent consideration will be payable on the terms described herein or at all, or that Amphastar can reliably predict the impact of BAQSIMI[®] on its financial results or financial guidance. You can locate these reports through our website at <http://ir.amphastar.com> and on the SEC's website at www.sec.gov. The forward-looking statements in this release speak only as of the date of the release. Amphastar undertakes no obligation to revise or update information or any forward-looking statements in this press release to reflect events or circumstances in the future, even if new information becomes available or if subsequent events cause our expectations to change.

Contact Information:

Amphastar Pharmaceuticals, Inc.
Bill Peters
Chief Financial Officer
(909) 476-3416

SOURCE: Amphastar Pharmaceuticals, Inc.

View the original [press release](http://accesswire.com) on accesswire.com