AEOLUS PHARMACEUTICALS, INC.
Form 424B3
February 08, 2005

Prospectus Supplement filed pursuant to Rule 424(b)(3)

in connection with Registration Statement No. 333-115523

Aeolus Pharmaceuticals, Inc.

(f/k/a Incara Pharmaceuticals Corporation)

Prospectus Supplement No. 11 dated February 8, 2005

(To Prospectus dated May 27, 2004)

6,156,000 shares of common stock

This Prospectus Supplement supplements information contained in that certain Prospectus, dated May 27, 2004, as amended or supplemented, relating to the offer and sale by the selling stockholders listed in the Prospectus of up to 6,156,000 shares of common stock of Aeolus Pharmaceuticals, Inc. (f/k/a Incara Pharmaceuticals Corporation). This Prospectus Supplement is not complete without, and may not be delivered or used except in connection with, the original Prospectus. We will not receive any proceeds from the sale of the shares of common stock by selling stockholders.

As a result of the name change, which was effective on July 16, 2004, our common stock is traded on the OTC Bulletin Board under the symbol AOLS.

Filing of Current Report on Form 8-K

On February 8, 2005, we filed a Current Report on Form 8-K, the contents of which are to be included after the paragraph in the discussion under the heading Our Business Indications for Catalytic Antioxidants outside Neurological Diseases Radiation-Induced Mucositis on page 15 of the Prospectus and are set forth below:

Aeolus Pharmaceuticals, Inc. anticipates filing, before the end of the first quarter of this year, the required regulatory documents with the United States Food and Drug Administration to be in a position to initiate a placebo-controlled, Phase 1, multiple dose study to evaluate the safety, tolerability and pharmacokinetics of AEOL 10150 administered by subcutaneous injection in patients with mucositis caused by radiation treatment for cancer. Subcutaneous injection is the route of administration being utilized in Aeolus current Phase 1 single dose study in patients with amyotrophic lateral sclerosis, or ALS.

Mucositis, also known as mucous membrane inflammation, is commonly defined as the swelling, irritation, and ulceration of the mucosal cells that line the digestive tract that can occur anywhere along the digestive tract from the mouth to the anus. Mucositis is a painful side effect of radiation treatment of certain cancers.

In Aeolus opinion, data developed using AEOL 10150 in accepted animal models of mucositis indicate that AEOL 10150 might eventually prove to be useful as a potential treatment option for patients suffering from mucositis caused by radiation treatment for cancer.

Aeolus believes that the proposed clinical design of the Phase 1 multiple dose study in patients with mucositis caused by radiation treatment for cancer will be adequate to assess the safety, tolerability and pharmacokinetics of multiple doses of AEOL 10150 with respect to determining the ability to proceed to a Phase 2 efficacy study of the compound in patients with mucositis caused by radiation treatment for cancer. Aeolus also believes that data developed from this proposed Phase 1 multiple dose study will help Aeolus design a Phase 2/3 registration study of AEOL 10150 in patients with ALS.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 3 of the original Prospectus.

NEITHER THE SEC NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OUR SECURITIES OR DETERMINED THAT THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. IT IS ILLEGAL FOR ANYONE TO TELL YOU OTHERWISE.

The date of this Prospectus Supplement No. 11 is February 8, 2005.