AEOLUS PHARMACEUTICALS, INC.
Form 424B3
March 29, 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. 12 dated March 29, 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 March 29, 2005, we filed a Current Report on Form 8-K to report the issuance of a press release, the contents of which are to be included after the paragraph in the discussion under the heading Our Business Oxygen Stress and Disease Submission of IND on page 14 of the Prospectus and are set forth below:

Aeolus Pharmaceuticals, Inc. (OTC Bulletin Board: AOLS.OB), a developer of a potential new class of disease-modifying compounds that have evidenced efficacy in pre-clinical models of central nervous system diseases and disorders and oncology, announced today interim results for its multi-center, double-blind, randomized, placebo-controlled, Phase 1, escalating single dose study to evaluate the safety, tolerability and pharmacokinetics of AEOL 10150 administered by subcutaneous injection in patients with amyotrophic lateral sclerosis (ALS or Lou Gehrig s disease). ALS, the most common motor neuron disease, results from progressive degeneration of both upper and lower motor neurons and is usually fatal within 5 years of symptom onset.

The study is designed to evaluate single doses of up to six levels of AEOL 10150: 3, 12, 30, 45, 60, and 75 mg in 4-5 patients diagnosed with ALS (per dose group, 3 or 4 receiving AEOL 10150 and 1 receiving placebo). The interim report summarizes the findings from the first three groups of patients (3, 12 and 30 mg). Each dose group was conducted at a separate clinical center.

Based upon the interim analysis, it was concluded that single doses of AEOL 10150 ranging from 3 mg to 30 mg were tolerated as well as placebo. In addition, no serious adverse events were reported. Based upon pre-clinical data, the presumed efficacious dose of AEOL 10150 in humans for the possible treatment of ALS is 3-10 mg.

In accordance with the study design, patients with Clinically Definite ALS, Clinically Probable ALS, Clinically Probably-Laboratory-Supported ALS, or Definite Familial-Laboratory Supported ALS (i.e., Clinically Possible ALS with an identified SOD gene mutation) were recruited. On Day 1, patients received a single subcutaneous dose of AEOL 10150 or placebo (3-4:1) in accordance with the randomization schedule. Patients remained in-house for 72 hours post-dose for assessments, and were then discharged on Day 3 after all 48-hour procedures were performed. Patients returned to the clinical research

unit on Day 7 or 8 for follow-up assessments. Serial blood and urine samples were collected over the 48-hour post-dosing period. Safety was assessed via physical examinations, neurological examinations, vital signs, ECGs, safety laboratory tests, Unified Parkinson s Disease Rating Scale (UPDRS), ALS assessments, spirometry, injection site evaluations, and adverse event monitoring.

Following administration of single doses of AEOL 10150, plasma AUC values ranged from 354.2 ng hr/mL in the 3 mg group to 4579.9 ng hr/mL in the 30 mg group. Correspondingly, Cmax ranged from 114.8 ng/mL to 733.4 ng/mL, and mean Tmax ranged from 0.5 to 1.3 hours in these same groups. The half-life of AEOL 10150 ranged from 2.61 to 5.25 hours. Results per dose group are summarized at the end of this release.

The most frequently reported adverse events were injection site reactions, followed by dizziness and headache. Adverse events were primarily mild in severity, and approximately one-half of the events were considered to have a possible relationship to the study medication. In addition, no clinically meaningful findings were noted in the safety laboratory, vital sign, UPDRS, functional ALS, or ECG data.

We are very optimistic that the Phase 1 single dose study of AEOL 10150 is progressing as planned and that the interim results provide us the information necessary to conclude at this point that AEOL 10150 is well tolerated in ALS patients, noted Richard P. Burgoon, Jr., Aeolus chief executive officer. Mr. Burgoon further noted, The fact that the data to date indicate that we are able to dose ALS patients at least 3 to 10 times above the presumed efficacious dose is very encouraging with respect to our planned multiple-dose study of AEOL 10150 in ALS patients, which we anticipate initiating and completing before the end of the third calendar quarter of this year. Mr. Burgoon also noted that the results from the single-dose study are also expected to be used for the design of a Phase 2 efficacy study of AEOL 10150 in stroke patients (based upon pre-clinical studies, the presumed efficacious dose in humans suffering from stroke is 3-8 mg.)

Mr. Burgoon additionally commented that, Recent events within our industry strongly indicate the need for carefully planned, executed and evaluated safety studies of new therapeutic opportunities. We believe that there are times in our industry when the rush to determine efficacy of new compounds overcomes the important need for safety determination, and this rush can at times provide false hope for both patients and investors. While efficacy is of course a key hallmark of opportunity for any clinical compound, patients and investors must always be mindful of the need for a study sponsor to carefully assess safety parameters as the clinical evaluation process moves forward. Aeolus is committed to focusing its attention at this stage on the safety and tolerability of AEOL 10150 such that upon the anticipated initiation of Phase 2 efficacy studies, we will have sufficient confidence that we have appropriately managed and addressed the required Phase 1 single and multiple-dose safety and tolerability issues regarding AEOL 10150.

Pharmacokinetic Parameters for AEOL 10150:

Interim Results Summary

	AEOL 10150		
Pharmacokinetic Parameter	**3 mg N = 3**	**12 mg N = 4**	**30 mg N = 3**
AUC(0-∞) (hr ng/mL)	354.2 ± 100.0	1493.8 ± 386.3	4579.9 ± 1828.3
Tmax (0-48) (hr)	0.5 ± 0.0	1.3 ± 0.5	1.3 ± 0.3
Cmax (0-48) (ng/mL)	114.8 ± 38.2	267.1 ± 40.0	733.4 ± 165.7
T1/2 (hr)	2.61 ± 0.60	3.97 ± 1.09	5.25 ± 1.65

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. 12 is March 29, 2005.