AEOLUS PHARMACEUTICALS, INC.
Form 424B3
September 12, 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. 14 dated September 12, 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 Reports on Form 8-K

On September 7, 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, today announced results for its multi-center, double-blind, randomized, placebo-controlled, Phase 1 clinical trial. This escalating single dose study was conducted 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).

We are very pleased with the results from our Phase 1 single dose study of AEOL 10150 and we are looking forward to moving this exciting and potential therapeutic into multiple dose evaluation, noted Richard P. Burgoon, Jr., Aeolus chief executive officer. Mr. Burgoon further stated that

Although the Phase 1 single and multiple dose studies are being conducted in patients diagnosed with ALS, these Phase 1 safety studies can also support human efficacy studies of AEOL 10150 in other clinical indications for which AEOL 10150 has shown pre-clinical efficacy. On this point, Mr. Burgoon noted that in addition to efficacy in the scientifically recognized ALS model, AEOL 10150 also has demonstrated efficacy in models of other neurodegenerative disorders, autoimmune diabetes, stroke, chronic obstructive pulmonary disease, pancreatic islet cell preservation, radiation-induced lung fibrosis, and inflammation.

Phase 1 Single Dose Clinical Trial Details

In the study, 4-5 patients diagnosed with ALS were utilized in each dosage cohort (3 or 4 receiving AEOL 10150 and 1 receiving placebo). Each dose cohort was evaluated at a separate clinical center. In total, seven separate cohorts were evaluated for the study, and 25 ALS patients received AEOL 10150.

Based upon an analysis of the data, it was concluded that single doses of AEOL 10150 ranging from 3 mg to 75 mg were well tolerated. In addition, no serious adverse clinical events were reported, nor were there any significant laboratory abnormalities. Based upon extensive cardiovascular monitoring (*i.e*. frequent electrocardiograms and continuous Holter recordings for up to 48 hours following dosing), there were no compound-related cardiovascular abnormalities.

Following administration of single doses of AEOL 10150 (3, 12, 30, 45, 60 and 75 mg), pharmacokinetic analysis demonstrated plasma area under the curve (AUC) values ranging from 354 ng hr/mL in the 3 mg

group to 12,167 ng hr/mL in the 75 mg group. Correspondingly, Cmax ranged from 114.8 ng/mL to 1584 ng/mL, and Tmax ranged from 1 to 2 hours in these same groups. The mean half-life of AEOL 10150 ranged from 2.6 (3 mg cohort) to 6.4 hours (75 mg cohort). Linear dose response, and dose proportionality, were documented. A summary of these results is provided below in table form below.

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. All cohorts exhibited dose-related peak plasma drug concentrations and consistent disappearance half-lives.

Taken together, the pharmacokinetic data indicate that accumulation of AEOL 10150 with multiple dosing is unlikely.

Launch of Phase 1 Multi-dose Clinical Trial

Based on these data, and in consultation with the Phase 1 single dose principal investigators, Aeolus will initiate a multiple dose study of AEOL 10150 in patients diagnosed with ALS in the fourth quarter of this year. The dosing study is expected to be completed in the fourth quarter of this year.

Under the multiple dose protocol, three groups of six ALS patients (four receiving AEOL 10150; two receiving placebo, 18 total patients) will be recruited, based upon patients who meet the El Escorial criteria for 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). Each patient will receive twice daily subcutaneous injections of AEOL 10150 or placebo for six days, followed by a single subcutaneous administration on the seventh day, for a total of 13 injections. In the first cohort, each injection will be 40 mg (i.e., 80 mg daily for six days and 40 mg on the seventh day). In the second cohort, each injection will be 70 mg (i.e., 140 mg daily for six days and 70 mg on the seventh day). In the third cohort, each injection will be 100 mg (i.e., 200 mg daily for six days and 100 mg on the seventh day). Each patient will complete follow-up evaluation by 14 days.

The study is planned to be conducted at six clinical ALS centers, with each center enrolling three patients. Male and female ALS patients, 18 to 70 years of age, will be eligible for study participation. Patients must be ambulatory (with the use of a walker or cane, if needed) and capable of orthostatic blood pressure assessments. Clinical signs/symptoms, laboratory values, cardiac assessments, and pharmacokinetics (PK) will be performed.

Pharmacokinetic Parameters for AEOL 10150:

Result Summary, Phase I Single Dose Evaluation

Pharmacokinetic Parameter	**AEOL 10150**						
	3 mg	**12 mg**	**30 mg**	**45 mg**	**45 mg**	**60 mg**	**75 mg**
	N = 3	**N = 4**	**N = 3**	**N = 4**	**N = 4**	**N = 4**	**N = 3**

					(repeat, different patients)		
AUC(0-∞) (hr ng/mL)	354 ± 100	1,494 ± 386	4,580 ± 1828	7,116 ± 1010	5,922 ± 1307	9,087 ± 2180	12,167 ± 1543
Tmax (0-48) (hr)	1 ± 0	1 ± 1	1 ± 0	1 ± 0	2 ± 1	2 ± 0	2 ± 1
Cmax (0-48) (ng/mL)	115 ± 38	267 ± 40	733 ± 166	1,245 ± 247	962 ± 333	1,330 ± 226	1,584 ± 378
T1/2 (hr)	2.61 ± 0.60	3.97 ± 1.09	5.25 ± 1.65	6.31 ± 2.54	5.28 ± 1.00	5.93 ± 0.90	6.36 ± 0.47

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

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

The date of this Prospectus Supplement No. 14 is September 12, 2005.