

INCARA PHARMACEUTICALS CORP
Form 424B3
June 07, 2004

Prospectus Supplement filed pursuant to Rule 424(b)(3)
in connection with Registration Statement No. 333-115523

Incara Pharmaceuticals Corporation

Prospectus Supplement No. 1 dated June 7, 2004

(To Prospectus dated May 27, 2004)

61,560,000 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 61,560,000 shares of common stock of Incara Pharmaceuticals Corporation. This Prospectus Supplement is not complete without, and may not be delivered or used except in connection with, the original Prospectus.

Issuance of Press Release

The following paragraphs are hereby added to the disclosure, to be inserted after the paragraph under the heading "Our Business - Oxygen Stress and Disease - Submission of IND" on page 14 of the Prospectus:

On June 7, 2004, we issued a press release stating as follows:

Research Triangle Park, N.C., June 7, 2004 - Incara Pharmaceuticals Corporation (OTC Bulletin Board:ICRA) announced today that following discussions with the Food and Drug Administration (FDA), it was mutually agreed that Incara would quickly revise the Phase 1 (safety) clinical trial protocol submitted with Incara's April 30, 2004 AEOL 10150 Investigational New Drug application (the April 30 IND) and proceed directly into patients with amyotrophic lateral sclerosis (also known as ALS or Lou Gehrig's disease).

Under the clinical plan of the April 30 IND, Incara proposed conducting three Phase 1 clinical studies: a single dose escalation study in healthy volunteers; a multiple dose study in healthy volunteers; and a multiple dose study in patients diagnosed with ALS. This plan would have required the ALS safety arm to begin after successful completion of the first two studies, with ALS patient dosing in the Phase 1 study estimated to begin in late 2004 or early 2005.

Incara expects to revise and submit to the FDA the revised protocol in the next two weeks. Incara anticipates that the revised initial Phase 1 clinical trial will seek to evaluate a series of single doses of AEOL 10150 in patients diagnosed with ALS to evaluate the safety, tolerability and pharmacokinetics of AEOL 10150. Following satisfactory completion of this first study, Incara expects to initiate a multiple dose per patient

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study arm. Assuming that the revised protocol being prepared by Incara is acceptable to the FDA, the Phase 1 study in ALS patients is anticipated to now begin no later than the end of September of this year.

Incara is committed to advancing AEOL 10150 for the treatment of ALS, stated Shayne C. Gad, Ph.D., Incara's President. During the review of our April 30 IND, the FDA requested that Incara conduct Phase 1 safety testing of AEOL 10150 directly in the target patient group, ALS patients, and we are more than pleased to accept the suggestions made by the FDA. The revised approach will allow AEOL 10150 to be evaluated in ALS patients first, and several months sooner than we had originally proposed, noted Dr. Gad.

Resignation of Executive Officer

On June 7, 2004, we announced the resignation of Richard E. Gammans, Sr., our Executive Vice President, Research and Development. Mr. Gammans' resignation will be effective on June 11, 2004.

Investing in our common stock involves a high degree of risks. 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. 1 is June 7, 2004.