

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

December 10, 1997  
Date of Report (Date of earliest event reported)

DISCOVERY LABORATORIES, INC.  
(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	000-26422 (Commission File Number)	94-3171943 (IRS Employer Identification Number)
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509 Madison Avenue  
14th Floor  
New York, NY 10022  
(Address of principal executive offices)

(212) 223-9504  
(Registrant's telephone number, including area code)

Item 5. Other Events

Discovery Laboratories, Inc. ("Discovery") announced today that its majority-owned privately held subsidiary, Acute Therapeutics, Inc. ("ATI"), has completed enrollment of its Phase IB clinical trial in acute respiratory distress syndrome. The Phase IB clinical trial is designed to determine the safety and tolerability of a bronchoscopic lavage procedure incorporating Surfaxin(TM). ATI has exclusively licensed worldwide distribution rights to Surfaxin(TM) from Johnson & Johnson.

Reference is made to Discovery's related press release attached hereto as Exhibit 99.1 and incorporated by reference herein.

Item 7. Financial Statements, Pro Forma Financial Statements and Exhibits

(c) Exhibits:

99.1 Press Release dated December 10, 1997.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DISCOVERY LABORATORIES, INC.

Date: December 10, 1997

By: /s/ James S. Kuo, M.D.

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Name: James S. Kuo, M.D.  
Title: President and Chief Executive Officer

Exhibit Index

Exhibit Number

Description

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99.1

Press Release dated December 10, 1997.

## DISCOVERY LABORATORIES, INC.

FOR IMMEDIATE RELEASE

Contact:  
James S. Kuo, M.D.  
President and Chief Executive Officer  
Discovery Laboratories, Inc.  
(212) 223-9504

Dan Griesel, Ph.D.  
The Investor Relations Group, Inc.  
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Discovery Laboratories, Inc. Announces Completion of Enrollment of Patients in a Phase IB Acute Respiratory Distress Syndrome Clinical Trial by Its Subsidiary, Acute Therapeutics, Inc.

NEW YORK, NEW YORK, Dec. 10, 1997--Discovery Laboratories, Inc. (NASDAQ: DSCO and DSCOU) announced that its majority-owned privately held subsidiary, Acute Therapeutics, Inc., has completed enrollment of its Phase IB clinical trial in acute respiratory distress syndrome (ARDS). The Phase IB clinical trial is designed to enroll 12 ARDS patients and determine the safety and tolerability of a bronchoscopic lavage procedure incorporating Surfaxin(TM). Patients with ARDS are assigned to receive one of three dosing regimens of Surfaxin(TM) with 28 days of follow-up. The open label study is being conducted at seven academic hospitals in the United States. Dr. Robert Capetola, chairman and CEO of Acute Therapeutics, stated, "The completion of patient enrollment in this Phase IB clinical trial in ARDS marks a major milestone for the Company. We would expect to announce results of this Phase IB clinical trial in the two or three months, if not sooner."

Surfaxin(TM) is a novel, proprietary, peptide-containing lung surfactant invented at The Scripps Research Institute. The peptide is KL4, a 21 amino acid peptide, modeled after the important SP-B protein in the human surfactant system. Lung surfactants are protein-lipid complexes that coat the airsacs of the lung and facilitate oxygen exchange with blood. ARDS is an acute generalized inflammatory disease of the lung which can lead to the degradation of lung surfactants. Common conditions that can cause ARDS are pneumonia, aspiration of gastric contents, smoke inhalation and trauma. The human and economic cost of ARDS is significant with a reported incidence of 150,000 cases per year in the United States and a mortality rate of approximately 50 percent. There are no Food and Drug Administration (FDA) approved therapies for ARDS.

Surfaxin(TM) is also currently in a Phase II trial for meconium aspiration syndrome (MAS). MAS results from the release of meconium, a greenish, pasty constituent of the fetal bowel, into the amniotic fluid. When present in amniotic fluid, babies can inhale the meconium into their lungs, which can lead to pneumonitis and subsequent degradation of lung surfactant. MAS affects approximately 26,000 newborn babies per year in the United States and an equal number in Europe. There are no specific FDA approved therapies. Surfaxin(TM) has been successfully tested in a Phase II trial in infant respiratory distress syndrome (IRDS) by Johnson & Johnson prior to the licensure of the technology. Acute Therapeutics is planning to develop Surfaxin(TM) in IRDS in the near future.

Discovery Laboratories, Inc. is a New York City based development stage pharmaceutical company that is clinically developing proprietary pharmaceuticals to treat post-menopausal osteoporosis, adult respiratory distress syndrome, meconium aspiration syndrome and cystic fibrosis. Discovery's strategy is

to accelerate and lower the risk of drug development by acquiring and developing proprietary pharmaceuticals for which significant animal or human testing has already been completed. In addition, Discovery seeks to minimize the cost of drug development by outsourcing preclinical development and manufacturing. Hospital based pharmaceuticals are developed at Discovery's majority-owned privately held subsidiary, Acute Therapeutics, Inc., located in Doylestown, Pa. More information about Discovery is available on the company's web site at [www.discoverylabs.com](http://www.discoverylabs.com).

To the extent that statements in this press release are not strictly historical, including statements as to future financial conditions, events conditioned on

stockholder or other approval, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Securities Litigation Reform Act of 1995. The forward-looking statements contained in this release are subject to certain risks and uncertainties that could cause results to differ materially from the statements made. Among the factors which could affect the company's actual results and could cause results to differ from those from those contained in the forward-looking statements contained herein are the risk that financial conditions may change, risks relating to the progress of the company's research and development and the development of competing therapies and/or technologies by other companies. Those associated risks and others are further described in the company's filings with the Securities and Exchange Commission.