#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

#### CURRENT REPORT

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

Date of Report (Date of Earliest Event Reported) January 27, 2000 Discovery Laboratories, Inc.

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(Exact Name of Registrant as Specified in its Charter)

Delaware 000-26422 13-3711775 \_ \_\_\_\_\_ (State or Other (Commission (I.R.S. Employer Jurisdiction of File Number) Identification incorporation) No.)

350 Main Street, Suite 307, Doylestown, Pennsylvania 18901 (Address of Principal Executive Offices) (Zip Code)

(Registrant's Telephone Number, Including Area Code) (215) 240-4699

\_\_\_\_\_\_ (Former Name or Former Address, If Changed Since Last Report.)

914917.1

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#### ITEM 5. Other Events.

Attached is a press release issued by Discovery Laboratories, Inc. (the "Company") on January 27, 2000 with respect to a pivotal Phase III Trial on Surfaxin(R) for Meconium Aspiration Syndrome and discontinuance of a Phase II/III clinical trial on Surfaxin(R) for acute respiratory distress syndrome and a press release issued on January 12, 2000 with respect to grant of a patent.

Financial Statements, Pro Forma Financial Information and Exhibits. ITEM 7.

## (c) Exhibits.

Exhibit Description

- 1.1 Press release issued by the Company on January 27, 2000
- Press release issued by the Company on January 12, 2000 1.2

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# 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.

By: /s/ Robert Capetola

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Name: Robert Capetola

Title: President and Chief Executive

Officer

Date: February 7, 2000

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### EXHIBIT INDEX

Exhibit 1.1	Press	release	issued	by	the	Company	on	January	27,	2000
Exhibit 1.2	Press	release	issued	by	the	Company	on	January	12,	2000
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FOR IMMEDIATE RELEASE:

Contact: Christopher J. Schaber

Executive Vice President,

Drug Development and Regulatory Compliance

Discovery Laboratories, Inc. 215.340.4699, Ext. 130

Dian Griesel, Ph.D., CEO/

Shayne Payne

The Investor Relations Group

212.736.2650

DISCOVERY LABORATORIES, INC. TO BEGIN PIVOTAL PHASE 3 STUDY OF SURFAXIN(R) IN MECONIUM ASPIRATION SYNDROME

Doylestown, PA, January 27, 2000 - Discovery Laboratories, Inc. (Discovery) (Nasdaq small cap: DSCO, DSCOU) announces the initiation of a pivotal Phase 3 trial to evaluate the efficacy of the company's novel pulmonary surfactant, Surfaxin(R) (lucinactant), in the treatment of full-term infants with Meconium Aspiration Syndrome (MAS). The trial will enroll approximately 200 newborn infants at more than thirty medical centers throughout the United States in order to compare Surfaxin(R)-lavage (lung wash) with standard care.

Approximately 13% of babies pass a bowel movement (known as meconium) while still inside their mothers' uterus. Some fetuses and newborns will inhale this substance into their lungs and subsequently develop MAS. This disorder is characterized by the presence of meconium, inflammatory cells, inflammatory mediators, edema fluid, protein, and other noxious debris in the lungs. Inhaled meconium can inactivate the infants' own natural surfactant (the substance that keeps lung air sacs open) and make breathing difficult. Many of the affected babies develop severe respiratory distress, necessitating the need for mechanical ventilation. There are no approved therapies for this disorder worldwide.

Previously, Surfaxin(R) was shown to be safe and well tolerated in a similar open label Phase 2 trial that used the novel surfactant to cleanse the lungs (using bronchoalveolar lavage or lung wash) of MAS patients requiring mechanical ventilation. In order to assess the safety and potential efficacy of Surfaxin(R) therapy, fifteen of twenty-two patients randomized to receive Surfaxin(R)-lavage were compared to seven patients randomized to standard of care. Surfaxin(R)-lavaged newborns had more rapid and more persistent improvements in oxygenation compared to standard of care patients. Lavaged infants were, on average, weaned from mechanical ventilation 3 days sooner than controls. These promising preliminary results prompted the initiation of the new Phase 3 trial.

Surfaxin(R), which contains sinapultide (a peptide mimic of the human surfactant protein B), was granted fast track designation by the U.S. Food and Drug Administration (FDA) on October 8, 1998 for the treatment of MAS. Fast track status facilitates the development and expedites the review of new drugs intended for the treatment of life-threatening conditions for which there are

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no current medical options. The FDA has also granted Discovery orphan drug designation for this indication and has awarded the Surfaxin(R) MAS development program a three-year orphan drug grant totaling approximately \$560,000.

In addition, Discovery has elected to halt its current ARDS clinical trial as a result of a breakthrough in the manufacturing process of Surfaxin(R). "We can now manufacture a less viscous formulation of Surfaxin(R)", said Robert J. Capetola, Ph.D., President and CEO of Discovery. "This new process will allow us to deliver a higher concentration of Surfaxin(R) through our patented lavage process. To that end we are planning to initiate a new clinical trial in ARDS/ALI with this less viscous product subject to appropriate funding. This should greatly benefit patients and further improve the chances of success for Surfaxin(R) in the ARDS clinical trials."

Discovery is a bio-pharmaceutical company whose mission is to develop and commercialize medically novel therapeutics for critical care. Presently, Discovery is developing proprietary pharmaceuticals to treat respiratory distress syndrome (RDS) in premature infants, MAS in full-term infants, direct acute respiratory distress syndrome (ARDS), and cystic fibrosis. More information about Discovery is available on the company's web site at: 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 actual 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 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.

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Contact: Christopher J. Schaber

Executive Vice President,

Drug Development and Regulatory Compliance

Discovery Laboratories, Inc. 215.340.4699, Ext. 130

Dian Griesel, Ph.D., CEO/

Shayne Payne

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# DISCOVERY LABORATORIES RECEIVES BROAD PATENT COVERING SURFACTANT LAVAGE

Patent covers all known surfactants for use in any form of pulmonary lavage.

Doylestown, PA, January 12, 2000 - Discovery Laboratories, Inc. (NASDAQ Small Cap: DSCO, DSCOU) today announced the issuance of United States Patent No. 6013619 entitled "Novel Pulmonary Surfactants and Therapeutics Uses, Including Pulmonary Lavage." The issued claims enable Discovery to broaden its protection of its prime development product, Surfaxin(R). This patent also covers all other known surfactants for use in any form of pulmonary lavage. This includes all synthetic, animal- or human-derived surfactants designed to treat a variety of respiratory distress syndromes, including respiratory distress syndrome (RDS) in premature infants, acute lung injury (ALI)/acute respiratory distress syndrome (ARDS), meconium aspiration syndrome (MAS), neonatal respiratory distress associated with acute hypoxemia, persistent pulmonary hypertension, or congenital diaphramatic hernia, as well as a variety of other conditions associated with pulmonary injury. Pulmonary lavage techniques (using any surfactant) include lavage via a bronchoscope as well as direct pulmonary lung lavage via an endotracheal tube.

"This completes the four sided intellectual property position of Surfaxin(R). In addition to our composition of matter, utility, and process technology patent portfolio on Surfaxin(R), this issuance positions us as the future global leader in surfactant therapy since the allowed claims cover all known surfactants," said Dr. Robert Capetola, CEO of Discovery Laboratories, Inc. "We now have what we consider to be a very complete proprietary position on our lead respiratory product."

Discovery pioneered the surfactant lavage technique, which is also known as "lung wash". Many respiratory diseases such as MAS and ALI/ARDS are associated with massive pulmonary inflammation, which includes white blood cells, edema, protein and debris. "The lungs are infiltrated with inflammatory material in these conditions and need to be drained just as an abscess would have to be. One way to safely drain them is with a surfactant lavage", added Capetola. Due to inflammation associated with respiratory distress syndromes such as MAS and

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ALI/ARDS, these patients have depleted or degraded endogenous surfactant in their lungs and thus require mechanical ventilation. Discovery's intent, with its lavage technique, is to rid the lung of the infectious and inflammatory debris, restore the alveoli to a more normal state and get patients off mechanical ventilation sooner.

Discovery has safely employed the surfactant lavage technique in two clinical trials thus far, a Phase 1B trial in ARDS/ALI patients and a Phase 2 trial in newborn MAS babies. Plans are currently underway to initiate a Phase 3 pivotal trial in MAS.

Surfaxin(R) (lucinactant) contains the novel, proprietary peptide sinapultide which was designed to completely mimic the human surfactant protein B (SP-B). Clinical proof of concept has been demonstrated in a Phase 2 trial in premature infants with respiratory distress syndrome (RDS), and in a Phase 2 trial of full-term babies with MAS. Existing surfactants are approved only for RDS in premature babies, with the most commonly-used surfactants being extracts from either cow or pig lungs. Discovery's synthetic humanized surfactant, Surfaxin(R), was designed to replace the animal-derived surfactants and to expand surfactant use into other pulmonary disorders.

Discovery is a bio-pharmaceutical company whose mission is to develop and commercialize medically novel therapeutics for critical care. Presently,

Discovery is developing proprietary pharmaceuticals to treat RDS in premature infants, MAS, direct ARDS, and cystic fibrosis. More information about Discovery is available on the company's web site at: www.discoverylabs.com.

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