

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) October 12, 1999

Discovery Laboratories, Inc.

-----  
(Exact Name of Registrant as Specified in its Charter)

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

350 Main Street, Suite 307, Doylestown, Pennsylvania 18901

-----  
(Address of Principal Executive Offices) (Zip Code)

(Registrant's Telephone Number, Including Area Code) (215) 340-4699

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

883253.1

ITEM 5. Other Events.

Attached is an Interim Report to Shareholders dated October 1999 sent by Discovery Laboratories Inc, a Delaware Corporation (the "Registrant"), to its shareholders, updating them on the Registrant's developments.

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

(c) Exhibits.

Exhibit	Description
1	Interim Report to Shareholders, dated October 1999.

883253.1

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

-----  
Name: Robert Capetola  
Title: President and Chief Executive  
Officer

Date: October 15, 1999

883253.1

EXHIBIT INDEX

Exhibit 1  
-----

883253.1

October 1999

Dear Discovery Laboratories, Inc. Investor:

I would like to take this opportunity to update you on developments at Discovery Laboratories, Inc. 1999 has been a year of strong progress for your company in which we released positive clinical results which set the basis for additional Phase 3 trials of Surfaxin(R), as well as the initiation of a phase 2 trial of SuperVent™.

#### Status of Surfaxin(R)

Earlier this year, we released positive Phase 2 data on Surfaxin(R) for the treatment of meconium aspiration syndrome (MAS). This data demonstrated the safety and tolerability of Surfaxin(R), while showing a clinical benefit in the treated patients' oxygenation index as compared to controls. In addition, a savings of an average of 3 days on mechanical ventilation was seen in the babies treated with Surfaxin(R) as compared to control patients. At an average cost nationwide of \$4,000 per day in the neonatal intensive care unit, this suggests a strong pharmacoeconomic rationale for the use of Surfaxin(R).

During the summer, Discovery received a notice of allowance from the US patent office for its surfactant lavage application. This patent covers the use of all surfactants, including Surfaxin(R), for the novel lavage technique pioneered by Discovery for treatment of pulmonary diseases. This technique can be best described as a "lung wash" and is designed to remove inflammatory and infectious infiltrates from patients' lungs, and restore their vital surfactant levels. This complements Discovery's extensive patent portfolio both in the US and in Europe.

Discovery currently has a new clinical protocol under review by the FDA. This new trial is intended to be a pivotal Phase 3 study that would enable Discovery to file an NDA in MAS upon its completion. Since there are currently no FDA approved treatments for MAS, Discovery has been granted Fast Track status by the FDA, which provides for an expedited review period of no more than 6 months.

In addition, Discovery has recently had its MAS Orphan Drug Grant expanded.

#### New IRDS Initiative

In addition to the MAS and ALI/ARDS development, Discovery is also planning a pivotal Phase 3 trial in respiratory distress syndrome of premature infants (IRDS). The study design is currently under review at the FDA. Although there are animal derived products on the market to treat IRDS patients, we believe that they are pharmaceutically inferior to Surfaxin(R) due to the relative lack of protein B found in them. Protein B is the protein which gives mammalian surfactants the majority of their surface-active properties by which they keep alveoli expanded. Without it mammalian life can not exist. Surfaxin(R) was engineered to be an excellent model of human surfactant protein B. Various published transgenic-knockout studies demonstrate that surfactants work without other surfactant proteins, but not without protein B. Further, there is a well-documented condition of protein B mutations in which babies born without protein B require lung transplants or else they die.

## Status of SuperVent™

Discovery has recently begun its Phase 2 clinical trial of its aerosolized product, SuperVent™, for cystic fibrosis (CF). Discovery expects to have results from this trial around the first quarter of 2000. Discovery is developing SuperVent™ as a multidimensional therapy for cystic fibrosis and chronic bronchitis. Preclinical tests have shown that tyloxapol, the active ingredient in SuperVent™ Aerosol Solution, is a potent anti-oxidant and anti-inflammatory agent that also reduces the viscosity of sputum. Further studies have shown that tyloxapol is a potent inhibitor of the transcription factor NF-(kappa)B, which is currently the subject of much pharmaceutical research. In addition, Discovery has received a grant from the CF Foundation, which will cover a significant portion of the costs associated with this trial. If successful in CF, Discovery will begin to develop SuperVent™ for chronic bronchitis, a much larger and unaddressed market.

The current stage of development for Discovery compounds is summarized below:

### An Aggressive Program for Development

COMPOUND	INDICATION	STAGE OF DEVELOPMENT
Surfaxin(R)	ARDS/ALI	Phase 2/3 pivotal; another clinical trial contemplated
Surfaxin(R)	MAS	Phase 3 to begin shortly <sup>1</sup>
Surfaxin(R)	IRDS	Phase 3 to begin shortly <sup>1</sup>
SuperVent™	CF	Phase 2 underway

<sup>1</sup> Dependant on outcome of discussion with FDA.

### Potential Product Markets

The following table summarizes Discovery's current views about the potential revenue stream from its products. These views are, of course, dependent on the projected sale prices set forth in the table, which in turn are subject to variation based on numerous factors (such as competition from animal-derived surfactant replacement therapies and any other competing therapies that may be developed). Nevertheless, it is believed that under any realistic scenario, the potential market size for Surfaxin(R) is very substantial.

INDICATION	PATIENTS/YEAR UNITED STATES	PATIENTS/YEAR REST OF WORLD	POTENTIAL MARKET SIZE
MAS	25,000	30,000	\$209,000,000
IRDS	45,000	55,000	\$220,000,000
ARDS/ALI	222,000	263,000	\$4,122,500,000
CF	23,000	27,000	\$365,000,000
Total Potential Annual Market:			\$4,916,500,000

### Building Blocks

Discovery was also very pleased to announce this year the completion of small private placements totaling \$3.45 million in proceeds primarily from one of the premier biotech institutional investors, OrbiMed of New York City, as well as several existing Discovery investors. In addition, Discovery completed its first corporate partnership with YuYu Industrial of Korea for its vitamin D analog, DSC-103, for the treatment of postmenopausal osteoporosis. Management continues to work diligently towards completion of other licensing collaborations and has retained Mr. Fred Frank, Sr. Vice Chairman of Lehman Brothers to assist with this effort.

Discovery's management believes very strongly in the value of its products under development and to demonstrate this, members continue to invest a significant amount of their private funds towards open market purchases of Discovery common stock.

As we progress into the next millenium, we intend to continue the aggressive development of our lifesaving products. The year 2000 provides a fitting backdrop for our technology that will revolutionize the way critically ill patients will be cared for, further solidifying Discovery's role as an innovator in the critical care arena.

In conclusion, I would like to thank you on behalf of myself, your Board of Directors, the management and the employees of Discovery, for your past and continued support.

Sincerely,

Robert Capetola, Ph.D.  
President and Chief Executive Officer

To the extent that statements in this letter are not strictly historical, including statements as to future financial conditions 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.