

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

November 13, 1998
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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350 South Main Street
Doylestown, Pennsylvania 18901
(Address of principal executive offices)

(212) 340-4699
(Registrant's telephone number, including area code)

Item 5. Other Events

Attached as Exhibit 99.1 hereto is Discovery's November 1998 Interim Report to Shareholders.

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

(c) Exhibits:

99.1 Interim Report to Shareholders.

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: November 13, 1998

By: /s/ Robert J. Capetola, Ph.D.

Name: Robert J. Capetola, Ph.D.

Title: President and Chief Executive Officer

Exhibit Index

Exhibit Number

Description

99.1

Interim Report to Shareholders.

Interim Report to Shareholders

November 1998

Dear Discovery Laboratories, Inc. Investor:

1998 was a year of rapid progress for Discovery. We believe that the late stage clinical trials, initiated this year, will build the foundation for substantial growth in shareholder value over the years to come. In addition, FDA orphan drug designation and fast track status for Surfaxin(TM), our principal product in development, indicates the critical need for this groundbreaking therapy.

A Dedicated and Experienced Development Team

Discovery is led by a highly experienced drug development team, focused on reaching our ambitious goals. The management group was hand picked from among the best people that I have been acquainted with at Johnson & Johnson (J&J) and Ohmeda. We have all been involved in the discovery and successful clinical development of a variety of drugs on the market. We are driven by the belief that Surfaxin(TM) will one day save many lives.

As an indication of our faith in the future of our company, members of the management and the board of Discovery have invested a significant amount of their own money towards open market purchases of Discovery common stock.

A High Tech Drug with a Simple, Common Sense Approach

Discovery's lead product is Surfaxin(TM) (formerly known as KL(4)-Surfactant), a novel, peptide-containing synthetic lung surfactant. Lung Surfactant is the substance that lines the lungs and helps to keep them expanded. Surfaxin(TM) was invented at The Scripps Research Institute and initially developed by J&J. The novel peptide, KL4, is a 21-amino acid peptide modeled by Scripps' scientists after human surfactant protein B (SP-B). SP-B is considered to be the most important and functional protein of the human surfactant system.

Since licensing Surfaxin(TM) from J&J, the Discovery drug development team has added significant value to its existing proprietary base by developing a novel lavage technique. This technique can be best described as a "lung wash," and is designed to remove inflammatory and infectious infiltrates from patients' lungs, restoring their vital surfactant levels. In addition, Dr. Harry Brittain, Discovery's AACP-honored VP of Chemical Development, has developed a simple way to improve the viscosity of the original J&J formulation, rendering it more efficacious and easier to deliver.

Indications for Surfaxin(TM)

There are three disease states that are characterized by a lack of surfactant:

1. Meconium Aspiration Syndrome affecting full-term babies;
2. Idiopathic Respiratory Distress Syndrome affecting premature infants; and
3. Acute Respiratory Distress Syndrome/Acute Lung Injury affecting children and adults.

In addition, Surfaxin(TM) is being studied in a pivotal Phase 2/3 clinical trial in the US for the treatment of acute respiratory distress syndrome/acute lung injury (ARDS/ALI). ARDS/ALI afflicts approximately 220,000 patients annually. The company believes that it represents a \$1.8 billion market opportunity in the US alone (with a market of similar size in Europe). There are currently no drugs approved to treat ARDS/ALI, which has a mortality rate of approximately 50%. Discovery has the capability to produce Surfaxin(TM) in the commercial quantities required for the adult market.

Discovery is planning a Phase 3 trial in idiopathic respiratory distress syndrome (IRDS), which occurs in approximately 40,000 infants in the US each year who are born prematurely, prior to the development of the

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lung's natural surfactant. Proof of concept for Surfaxin(TM) in IRDS has already been demonstrated by J&J in a 47-patient Phase 2 clinical trial.

Meconium aspiration syndrome (MAS) is a condition afflicting approximately 25,000 newborns per year in the US. MAS results from the release of meconium, a greenish, pasty constituent of the fetal bowel, into the amniotic fluid. When

present in the amniotic fluid, babies can inhale meconium into their lungs, which can lead to pneumonitis and subsequent degradation of the lung surfactant. Discovery has recently completed a Phase 2a clinical trial in MAS.

FDA status of Surfaxin(TM)

Currently, there are no FDA-approved drugs for either MAS or ARDS/ALI. Both indications are therefore unmet market needs, and the FDA has granted Surfaxin(TM) fast track status and orphan drug designation for these indications. Fast track status facilitates the development and expedites the review of new drugs intended for the treatment of life-threatening conditions for which there is presently no medical option. In addition, the FDA Office of Orphan Products Development has awarded Discovery a renewable Orphan Products Development Grant, ranging from \$194,390 for the first year to \$583,170 over three years, to finance the Company's MAS clinical trials currently in progress.

FDA status of SuperVent(TM)

Discovery is also developing its aerosolized product, SuperVent(TM), for cystic fibrosis (CF). We recently completed a successful Phase 1 clinical trial in SuperVent(TM) for use of treating CF and are preparing for a Phase 2 trial in this indication. The current stage of development for Discovery compounds is summarized below:

An Aggressive Program for Development

COMPOUND	INDICATION	STAGE OF DEVELOPMENT
Surfaxin(TM)	ARDS/ALI	Phase 2/3 pivotal underway
Surfaxin(TM)	MAS	Phase 2a data under analysis
Surfaxin(TM)	IRDS	Phase 3 under development
SuperVent(TM)	CF	Phase 2 under development

Potential Product Markets

The following table summarizes our current views about the potential revenue stream from Surfaxin(TM). 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, we believe that under any realistic scenario, the potential market size for Surfaxin(TM) is very substantial.

INDICATION	PROJECTED SALES PRICE	PATIENTS/YEAR UNITED STATES	PATIENTS/YEAR REST OF WORLD	POTENTIAL MARKET SIZE
MAS	\$1,700	25,000	30,000	\$93,500,000
IRDS	\$1,000	40,000	50,000	\$90,000,000
ARDS/ALI	\$8,500	220,000	260,000	\$4,080,000,000
Total Potential Annual Market: \$4,263,500,000				

The numbers above represent the annual sales of the total potential Surfaxin(TM) market. Discovery's management is evaluating what penetration it might expect in these markets post approval.

Discovery's management continues to believe strongly that the value of Discovery's products under development is not reflected in its current market capitalization of roughly \$20 million. As I have noted in the past, the equity markets have often proven to be inaccurate and inadequate predictors of the intrinsic value of the clinical products under development by biotechnology companies. But with the help of our outside advisors, Mr. Fred Frank, Vice Chairman of Lehman Brothers and Dr. Marc Ostro of KPMG Health Sciences division, we are working hard to steadily increase the profile of Discovery within the investment community.

In conclusion, I would like to thank you on behalf of myself, the Board of Directors, the management and the employees of Discovery, for your past and continued support. I want to assure you that the Board and management of Discovery feel confident that the next year will be a fruitful one. I look forward to reporting to you on the progress that we make in moving Surfaxin(TM) closer to a New Drug Application and, ultimately, final FDA approval.

Sincerely,

/s/ Robert Capetola, Ph.D.

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.