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

July 29, 2011

Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(Address of principal executive offices)

(215) 488-9300
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On July 29, 2011, Discovery Laboratories, Inc. (the "Company") issued a press release announcing its plans to seek regulatory marketing authorization in the United States and the European Union to market a component of its proprietary patient interface technology under the trade name Afectair™. The Company will be hosting a conference call on Friday, July 29, 2011 at 10:00 am (EDT), to discuss its plans with respect to Afectair. The press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Background

The Company (referred to in this section as “we” or “us”) is a specialty biotechnology company focused on improving the standard of care in critical care settings for the treatment of respiratory diseases for which there frequently are few or no approved therapies. Our lead drug products are based on our KL_4 proprietary technology, which produces a synthetic, peptide-containing surfactant (KL_4 surfactant) that is structurally similar to pulmonary surfactant, a substance produced naturally in the lung and essential for normal respiratory function and survival focused initially on addressing the most significant respiratory conditions affecting neonatal populations. We have filed a New Drug Application (NDA) for Surfaxin® for the prevention of RDS in premature infants, and received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) in April 2009. We continue to focus primarily on Surfaxin and believe that we remain on track to file a Complete Response to the NDA for Surfaxin in the third quarter of 2011, which could lead to marketing authorization of Surfaxin for the prevention of RDS in premature infants in the first quarter 2012.

While working to gain regulatory marketing authorization for Surfaxin, as capital resources permit, we have continued to make measured investments in our other pipeline products, including our other lead programs to treat premature infants with or at risk for RDS: Surfaxin LS™, our initial lyophilized (dry powder) KL_4 surfactant; and Aerosurf®, our initial proprietary KL_4 surfactant in aerosolized form. Aerosurf combines our three proprietary technologies: KL_4 surfactant; our capillary aerosol-generating technology (capillary aerosolization technology), which produces a dense aerosol with a defined particle size to potentially deliver KL_4 surfactant to the lung; and our novel patient interface technology, which simplifies the delivery of aerosolized surfactant to the ventilatory stream and delivers it closer to the patient than conventional systems.

If approved, we believe that Aerosurf will make it possible to administer our KL_4 surfactant into the lung without subjecting patients to invasive procedures, including invasive endotracheal intubation and mechanical ventilation. Since available surfactants are currently administered using such invasive procedures, many infants (other than those with severe RDS) that might otherwise benefit from surfactant treatment currently are not treated because the benefits of surfactant therapy are believed to be outweighed by the risks of invasive administration. Unfortunately, a significant number of these infants do not respond adequately to the current standard of care (nasal continuous positive airway pressure, or nCPAP) and require subsequent surfactant administration. The delay in surfactant administration for these infants may result in less favorable clinical outcomes. We believe that Aerosurf, if approved, will address a significant unmet medical need by providing practitioners with the alternative of more promptly administering surfactants to currently untreated infants, which may result in a potentially significant increase in the number of infants who will benefit from surfactant therapy. By advancing the standard of care for treating these fragile patients, we believe that Aerosurf, if approved, may potentially expand the RDS estimated-worldwide annual market to a $1 billion market opportunity.

Afectair™

In developing Aerosurf, we focused on developing a patient interface and related componentry suitable for use with our capillary aerosolization technology in neonatal critical care units (NICUs). We have also recognized that our proprietary patient interface technology has potential application beyond the neonatal patient population and could potentially benefit neonatal, pediatric and adult patients receiving ventilatory support (intermittent mechanical ventilation or continuous positive airway pressure (CPAP)) who require aerosolized medicines in a critical care setting. We have recently undertaken efforts to assess whether a component of our patient interface technology is likely to gain market acceptance as a stand-alone product.

Afectair™ – Proprietary Patient Interface Technology

The results of our efforts is Afectair, a series of novel patient interface adapters and related componentry that are based on our proprietary patient interface technology that simplifies the effective delivery of any aerosolized medication to critical-care patients requiring ventilatory support (either intermittent mechanical ventilation or continuous positive airway pressure) by introducing aerosolized medications into the ventilatory stream close to the patient and simplifying the connections to the ventilator circuitry without compromising ventilatory support. Afectair is being developed as a disposable aerosolized drug delivery interface with the following characteristics:

- The initial product will be designed for use with jet nebulizer aerosol generators,
- A subsequent product, Afectair™ Duo, will be designed for use with vibrating mesh nebulizers (VMN), metered dose inhalers (MDI) and other aerosol generator technologies, and
- Each product will be available in two sizes, one for infants and another one for pediatric and adult patients.

We believe that we potentially could gain marketing authorization (i) for the initial Afectair product, in the first half of 2012 in the U.S. and later in 2012 in the European Union; and (ii) for Afectair Duo, in late 2012 in the U.S. and in first half of 2013 in the European Union. If successful, we believe that the Afectair series of products has the potential to become a part of the standard of care for use in delivering aerosolized medicines to patients receiving ventilatory support in a critical care setting.

Business Strategy

In assessing Afectair as a potential pipeline product, we have considered whether introducing Afectair requires an unreasonable diversion of resources at a time when we are focused on securing marketing authorization for Surfaxin and on advancing our other lead products to address RDS in premature infants. We have concluded that it is appropriate to go forward based on a number of observations, including the following: (i) Afectair has not and will not involve a significant investment of funds to develop because it derives primarily from research and development efforts for Aerosurf and is advanced by work that will become an important element in the further development of our aerosolized KL_4 surfactant products, (ii) we believe that relatively modest additional expenditures will be required to complete the development of Afectair and file for regulatory marketing authorization, and that relatively modest additional expenditures will be required to launch Afectair if marketing authorization is granted, (iii) if marketing authorization is granted, Afectair would introduce to the critical care community an important component of Aerosurf, potentially enabling a more rapid and successful launch of Aerosurf, if approved, (iv) if marketing authorization is granted, Afectair would allow us to establish relationships with the pulmonary care medical community and, in particular, critical care practitioners, which relationships would be invaluable as we seek to launch our respiratory drug and drug-device combination products, if approved, and (v) over time, Afectair could potentially be a very important non-dilutive source of funds to support our KL_4 surfactant research and development programs (*see*, Regulatory Strategy, below). With both Afectair and Surfaxin potentially arriving on the market in 2012, we believe that we would greatly advance our goal of improving the standard of care for the treatment of patients suffering with a range of respiratory diseases in a critical care setting.

Market Analysis

We recently retained a leading life sciences marketing research firm to assist us in assessing the potential acceptance of Afectair among critical care medical professionals. This assessment included surveys of Respiratory Therapists and Physician Intensivists in the U.S. and the European Union to determine attitudes about the current systems used to deliver aerosolized medicines to patients receiving ventilatory support. Generally, the survey concluded that current methods of treatment are not very efficient, waste considerable amounts of drug, and may not deliver an optimal amount of aerosolized drug to the patient. Survey respondents indicated that they would welcome an aerosol delivery system that is simpler to use and introduces the aerosolized drug at a point in the delivery system that is closer to the patient. Since Afectair is both a patient interface adapter and a means of delivering the aerosolized drug into the ventilatory stream closer to the patient, rather than elsewhere in the ventilatory system, based on our review of the marketing survey data, we believe that it has the potential to gain broad market acceptance. In addition, we have demonstrated Afectair to professional groups and at medical congresses and have conducted our own surveys of medical professionals attending congresses, from which we also have received favorable responses.

Potential Market Opportunity

Our marketing research firm also assessed the potential market size and found that, in the United States and top five largest European Union countries (EU5), at any time, there are approximately 2.2 million patients in the hospital receiving ventilatory support. Of these patients, approximately 1.3 million patients currently are treated with aerosolized medicines (~0.9 million in the U.S. and ~0.4 in the EU5). Through comparisons to the introduction of other related medical products and after testing for price sensitivity and other factors, our marketing research firm estimated that, after an up-take period following introduction of Afectair, U.S. and EU5 revenues could potentially be between $50 million and $75 million in the fourth full year of sales, which could occur as early as 2016.

Capital Requirements

Much of the research and development activities for Afectair have occurred under the Aerosurf development program. We have leveraged those activities, which have been fully expensed and reported in our financial statements to date, to bring Afectair to this stage of development.

To complete the work necessary to meet the regulatory requirements for potentially gaining marketing authorization for the initial Afectair product in the U.S. and the European Union, we anticipate an investment of between $500,000 and $1 million, predominantly to register Afectair in the European Union. If marketing authorization is granted, we believe that preparing for the commercial launch will involve a further investment of approximately $1 million, primarily to initiate development of an in-house medical affairs and marketing management capability. This investment will be made only after marketing authorization is granted. We anticipate that our medical affairs personnel will also provide medical education support for Surfaxin, if approved, as both products will be of interest to many of the same medical practitioners and involve many of the same medical congresses, many of the same journals for publication and many of the same hospitals, providing certain economies for both of these products.

In 2012, we anticipate an additional investment of between $0.5 million and $1 million for the Afectair Duo product to potentially gain marketing authorization, and initiate manufacturing activities.

Regulatory Strategy

We currently expect to seek marketing authorization from the FDA to sell the initial Afectair product (in two sizes, for use with jet nebulizers) in the United States through a registration process applicable to exempt Class I medical devices (*see*, "Government Regulation – Exempt Class I Medical Device", below) in the fourth quarter of 2011, which could potentially lead to marketing authorization in the first half of 2012. We also expect to file with the European Union to potentially gain European Union marketing authorization for the initial Afectair product using the CE Mark clearance procedure (*see*, "Government Regulation – CE Mark Clearance Process", below) in the first quarter of 2012, which could lead to marketing authorization in 2012. Thereafter, we expect to file with both the FDA and EU applications to potentially gain marketing authorization for the Afectair Duo product (in two sizes, for use with VMN, MDI and other aerosol generators) in 2012, with potential marketing authorization in 2012 in the U.S. and in 2013 in the European Union. We continue to consult with our regulatory experts to confirm our expectation with respect to the required contents for our filings and the likely timing for marketing authorization, if any.

Manufacturing

To manufacture our Afectair products and related components, we expect to rely on third-party contract manufacturers, who will also provide quality systems, packaging and warehousing to support our planned commercialization of Afectair. We are currently engaged in discussions with several manufacturers that have a targeted expertise in medical device products. *See*, in our 2010 Annual Report on Form 10-K, which we filed with the SEC on March 31, 2011 ("2010 Annual Report"), "Item 1A – Risk Factors – Manufacturing problems potentially could cause us to delay preclinical or clinical programs, or, if our products are approved, product launch, or cause us to experience shortages of products inventories, which could have a material adverse effect on our business."

Commercialization and Distribution

To reduce the up-front investment required to commercialize Afectair, at least for the first few years, we plan to rely on third-party medical product distributors to support the launch and continued sales of Afectair. Based on our research and discussions with our expert consultants, we expect to enter into distribution agreements with distributors in each region of the U.S. and in each country in the European Union where we choose to sell our products. We have been in communication with a number of specialty medical product distributors that have experience in introducing respiratory medical products and have a sales force with established relationships with our target hospitals, who would also provide a variety of related services. We expect to sell Afectair products to the distributors at an agreed discount to the established retail price and the distributors will then sell directly to hospitals. In future years, to maximize financial returns and potentially eliminate the distributor fee, we may determine to develop our own distribution expertise and bring distribution activities in-house.

We plan to support our network of distributors with an in-house medical affairs staff that will be focused on medical education activities, publications and congresses. Data from a study conducted using Afectair were presented at the 2011 International Society for Aerosols in Medicine Annual Meeting and the 2011 Pediatric Academic Societies Annual Meeting and we anticipate that further studies will be conducted and presented at congresses in late 2011 and beyond.

Intellectual Property

We hold exclusive rights to Afectair. In March 2009, we filed an international patent application (PCT US/2009/037409), directed to improvements of an aerosol delivery system and ventilation circuit adaptor, in the United States, Europe and Japan, among other countries, and our application is currently pending. *See*, 2010 Annual Report, "– Item 1 – Business – Licensing, Patents and Other Proprietary Rights and Regulatory Designations – Patents and Proprietary Rights," and "– Proprietary Platform – Surfactant and Aerosol Technologies – Our Aerosolization Device Technology – Novel Patient Interfaces and Related Componentry." The status of our patent will be "patent pending" until a patent is or is not issued, which we anticipate could be in late 2012, or later. We have conducted a series of reviews with patent experts and anticipate that a patent will issue; however, the various authorities have broad discretion in connection with the issuance of patents and there can be no assurance that a patent will issue within that time frame, if at all, in any or all of the jurisdictions in which we have filed applications.

Government Regulation

Afectair is a medical device that is subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our medical devices. To assure our continued compliance with these requirements, we plan on hiring medical device quality assurance personnel as well as engaging regulatory and clinical consultants to provide detailed advice on complying with the different requirements.

The FDA has established classifications for different generic types of medical devices and has assigned each to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements which apply to them are: (i) Class I General Controls, with exemptions and without exemptions, (ii) Class II General Controls and Special Controls, with exemptions and without exemptions, and (iii) Class III General Controls and Premarket Marketing authorization. The class to which a device is assigned determines the process that applies for gaining marketing authorization. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Marketing authorization.

Exempt Class I Medical Device

Prior to marketing an exempt Class I medical device, the manufacturer must register its establishment, list the generic category or classification name of the medical device being marketed and pay a registration fee. We have consulted with our regulatory experts and believe that Afectair qualifies as an exempt Class I medical device. We therefore plan to comply with the registration requirements applicable to Class I medical devices. Once registered, we would be required to update and renew our registration annually.

510(k) Clearance Process

If for any reason, the FDA determines that Afectair is a Class II medical device, we would have to obtain FDA clearance, before marketing Afectair in the U.S., through the 510(k) clearance process. We believe that if we are required to seek marketing authorization using the 510(k) clearance process, we will be able to complete the process and launch Afectair within the time frames set forth above. The 510(k) clearance process is available if we can demonstrate that Afectair is substantially equivalent to a legally marketed medical device. In this process, we would be required to submit data that supports our equivalence claim. We must receive an order from the FDA finding substantial equivalence to another legally marketed medical device before we can commercially distribute Afectair. Modifications to cleared medical devices can be made without using the 510(k) process if the changes do not significantly affect safety or effectiveness.

Pre-market Marketing Authorization

A more rigorous and time-consuming process applicable to Class III medical devices, known as pre-market marketing authorization (PMA), would require us to independently demonstrate that Afectair is safe and effective. We would do this by collecting data regarding design, materials, bench and animal testing, and human clinical data for the medical device. The FDA will authorize commercial release of a Class III medical device if it determines there is reasonable assurance that the medical device is safe and effective. This determination is based on benefit outweighing risk for the population intended to be treated with the device. This process is much more detailed, time-consuming and expensive than the 510(k) clearance process. We do not believe that we will be required to file an application for PMA.

CE Mark Clearance Process

The European Union has comparable regulations to the FDA for the registration or marketing authorization of medical devices. We believe that in the European Union Afectair will be classified as a Class IIa device, which will require us to obtain a “CE mark” by filing a statement of registration. We must first seek a review of a third-party “Notified Body” that will conduct an audit to ensure that we and our manufacturers are in compliance with applicable quality regulations, and, if the audit is successful, will certify the product for a CE mark. We are working with a regulatory services firm to obtain the CE mark. The regulatory services firm will assist us with compiling the required technical file, labeling review, a clinical evaluation report to support CE mark, design control and quality system implementation, subcontractor audit and general regulatory consulting.

In addition, in the European Union we will have to designate a single Authorized Representative located in the European Union to interact with the local authorities and respond to technical document requests. The Authorized Representative will be responsible for preparing supplemental submissions to member states that have additional requirements for marketing authorization.

Other Regulatory Requirements

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements may apply. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;

- Quality System Regulation ("QSR"), which is the medical device term for good manufacturing practices, requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;

- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a significant change in the safety or efficacy of our cleared devices;

- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

- post-approval or post-clearance restrictions or conditions, including post-approval or post-clearance study commitments;

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and

- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of certain companies have been the subject of enforcement action brought under health care reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the U.S., which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired. In addition to this domestic US regulatory scheme, there are numerous additional regulatory considerations pertaining to medical devices in foreign jurisdictions.

Note Regarding Forward-looking Statements

Our estimates of market size and business opportunities included in this Current Report on Form 10-K and in the press release attached hereto are based in part on our analysis of data derived from the following sources, among others: HCUP Hospital Discharge data, 2008; Hospital Insurance Claim Database, 2009; Market Intelligence Report on Number of ICU Beds in EU5 Countries; Primary Market Research, December 2010 and May 2011; as well as our analysis of the SELECT and STAR trials described below. In addition, our analysis and assumptions take into account estimated patient populations, expected adoption rates of our products, current pricing, economics and anticipated potential pharmaco-economic benefits of our drug products, if marketing authorization is granted. We provide estimates and projections to give the reader an understanding of our strategic priorities, but we caution that the reader should not rely on our estimates and projections. These estimates and projections are forward-looking statements, which we intend to be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. For a discussion of forward-looking statements, *see* "Forward-Looking Statements" on page iii of our 2010 Annual Report, "Item 1A – Risk Factors," and the Risk Factors associated with Afectair, below.

Risk Factors Related to Afectair

Afectair will require FDA and international regulatory marketing authorization which may be costly and may not occur.

Afectair is not registered with or approved by the FDA and may require regulatory pre-marketing approval in the United States before commercialization can commence. Whether or not regulatory pre-marketing approval is required is based on whether or not Afectair is classified as an exempt Class I medical device. Although we currently believe that Afectair qualifies as an exempt Class I medical device, there can be no assurance that it will be subject to registration only. If a specific marketing approval is required, the regulatory process can be a costly, time consuming, lengthy and uncertain process and no assurances can be given as to the classification, timing or expenses involved not whether any Afectair product ultimately will receive the required regulatory marketing authorizations**.**

In order to market products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory marketing authorizations and comply with numerous and varying regulatory requirements. We may not obtain foreign regulatory marketing authorizations on a timely basis, if at all. Marketing authorization by the FDA would not ensure marketing authorization by regulatory agencies in foreign countries. A failure or delay in obtaining marketing authorization in one jurisdiction may have a negative effect on the marketing authorization process in other jurisdictions, including the FDA. The failure to obtain regulatory marketing authorization in domestic or foreign jurisdictions could harm our business.

Delays in gaining regulatory marketing authorization can be extremely costly in terms of lost sales and marketing opportunities, as well as increased regulatory costs. Moreover, even if the regulatory marketing authorization of Afectair is achieved, the marketing authorization will be limited to specific indications or uses or limited with respect to its distribution. Expanded or additional indications for an approved device may not be approved, which could limit our potential revenues. Foreign regulatory authorities may apply different or similar limitations or may refuse to grant any marketing authorization. Consequently, even if we believe that our submissions are sufficient to support regulatory marketing authorization for Afectair, the FDA and foreign regulatory authorities may not ultimately grant marketing authorization for commercial sale in any jurisdiction. If Afectair is not approved, our ability to generate revenues will be limited and our business will be adversely affected.

Afectair may be subject to varied and rigorous FDA regulatory pathways and procedures.

Our goal is to have Afectair regulated by the FDA as a Class I device. A Class I classification is designed for low risk devices in which sufficient information exists to establish general and specific controls that provide reasonable assurance of safety and effectiveness. If Afectair is classified as an exempt Class I medical device, marketing authorization is obtained through a registration process. If Afectair is classified as a non-exempt Class I or a Class II medical device, marketing authorization is obtained through a 510(k) clearance process. In a 510(k) application, applicants must demonstrate that the proposed device is substantially equivalent to an existing approved product, or “predicate device.” If a product employs new or novel technology such that no predicate device exists, the FDA will automatically classify the device as a Class III device under regulatory statute. The applicant may then request that a risk-based classification determination be made for the device under Section 513(f)(2) of the U.S. Food, Drug and Cosmetic Act . This process is also known as a “de novo” or “risk based” classification.

If the FDA determines that a predicate device does not exist for Afectair, we may be required to submit a request for Pre-Market Approval under the de novo protocol as required by the Section 513(f)(2) guidance document and be subject to significant regulatory delays. In addition, recent, widely-publicized events concerning the safety of certain drug, food and medical device products have raised concerns among members of Congress, medical professionals, and the public regarding the FDA’s handling of these events and its perceived lack of oversight over regulated products. The increased attention to safety and oversight issues could result in a more cautious approach by the FDA to clearances and marketing authorizations for devices such as Afectair.

There is no guarantee that the FDA will permit registration of Afectair as a Class I medical device or grant market clearance or designate Afectair as a Class II device in a timely manner, if at all. Even if FDA marketing clearance is received, we may encounter significant delays in receiving such clearance. If unexpected delays occur, it could have a material adverse effect on our business.

Marketing authorization to promote, manufacture and/or sell Afectair, if granted, will be limited and subject to continuing review.

Even if regulatory clearance of a product is granted, such clearance may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to serious regulatory enforcement actions, including some of those listed above. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Due to these legal constraints, our distributors' sales and marketing efforts will focus only on the general technical attributes and benefits of Afectair and the FDA cleared indications for use.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of Afectair, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with Afectair, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market or regulatory enforcement actions.

Product inadequacies could lead to recalls and harm our reputation, business and financial results.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining marketing authorization, if previously unknown problems with the product or its manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory clearance. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenues.

In addition, if approved for sale, we could be exposed to the risk of device failures and malfunctions, which might result in a recall of the product. Recalls of the product can occur at any time and can impact our business operations. Recalls can be both time consuming and costly. Recalls might also impact future sales through negative market perception, or might result in legal action against us by those affected by the recall or the regulatory authorities whose role it is to supervise the product.

Even if FDA marketing authorization is ultimately received for Afectair, which cannot be assured, the occurrence of subsequent, unforeseen medical complications or subsequent instances of noncompliance with FDA or other regulatory requirements could lead to enforcement action against us. Enforcement action may result in, among other things, withdrawal of marketing authorization, injunctions, suspension of production, recall or seizure of products, and fines or criminal prosecution, any and all of which could have a material adverse effect on our business and financial condition.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a mandatory recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, initiate a field correction or removal, known as a recall, for a product if any material deficiency in a device is found. A government mandated or voluntary recall by us or our third-party manufacturers or suppliers could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. We are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

Under the FDA medical device reporting regulation, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Product liability claims could hurt our reputation and finances.

Product liability claims could have a material adverse effect on our business. Our business may be exposed to an inherent risk of potential product liability claims relating to the development, manufacturing, testing, marketing and sale of the Afectair medical device. No assurance can be given that we will be able to secure, maintain or increase our product liability insurance on favorable terms, if at all, and such insurance might not provide adequate coverage against potential liabilities. A successful claim brought against us in excess or outside of our insurance coverage could not only have an adverse effect on our financial position, but could also hinder our ability to gain endorsement of the product by healthcare professionals.

The cost of materials required for the manufacture of Afectair may increase or be higher than anticipated.

The components of Afectair are manufactured from high-quality medical grade materials that are generally recognized as safe. Suppliers of these materials, due to a change in their pricing policies or an increase in raw materials costs, might charge us increasingly higher than anticipated prices. In turn, we might experience diminishing profit margins or remain unprofitable indefinitely.

Our future results could differ significantly from the financial estimates included in this Current Report.

Our estimates of market size and business opportunities included in this Current Report on Form 8-K are based in part on our analysis of data derived from the following sources, among others: HCUP Hospital Discharge data, 2008; Hospital Insurance Claim Database, 2009; Market Intelligence Report on Number of ICU Beds in EU5 Countries; Primary Market Research, December 2010 and May 2011. In addition, our analysis and assumptions take into account estimated patient populations, expected adoption rates of Afectair, current pricing, economics and anticipated potential pharmaco-economic benefits of our drug and medical device products, if approved. We provide estimates and projections to give the reader an understanding of our strategic priorities, but we caution that the reader should not rely on our estimates and projections. These estimates and projections are forward-looking statements, which we intend be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Further, although we believe that the assumptions underlying these estimates and projections are reasonable, there can be no assurance that such assumptions will prove to be correct. Actual results will vary from the projected results, and such variations may be material and adverse. We also reserve the right to conduct business in a manner different from that set forth in the assumptions as changing circumstances require.

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of our product development or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in our filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Any forward-looking statement in this Current Report on Form 8-K speaks only as of the date on which it is made. We assume no obligation to update or revise any forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

99.1 Press release dated July 29, 2011

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/ W. Thomas Amick
Name: W. Thomas Amick
Title: Chairman of the Board and
Chief Executive Officer

Date: July 29, 2011

Exhibit 99.1

Discovery Labs Aerosolization Program Yields Potential New Product Offering: AFECTAIR™

Proprietary Patient Interface Technology Simplifies Delivery of Aerosolized Medications to Patients Requiring Ventilatory Support – Conference Call to be held today at 10:00 a.m. (EDT)

Warrington, PA — July 29, 2011 — Discovery Laboratories, Inc. (NASDAQ: DSCO), a specialty biotechnology company dedicated to improving the standard of respiratory critical care through its KL_4 surfactant and aerosolized drug delivery technology platform, today announced its intent to seek regulatory approval to market AFECTAIR, a potential new product offering. AFECTAIR originates from the AEROSURF® development program and is a proprietary disposable patient interface adapter that simplifies the delivery of any aerosolized medication to critical-care patients requiring ventilatory support from either intermittent mechanical ventilation or continuous positive airway pressure. According to national health statistics and market assessment data recently obtained from an independent consulting firm, it is estimated that more than 1.3 million patients annually in the United States and European Union receive aerosolized medications while requiring ventilator support. Discovery Labs will host a conference call today at 10:00 AM EDT to introduce AFECTAIR and provide additional insight into the utility and commercial potential of this technology. Conference call details are below.

"We are excited about the prospect of expanding the Discovery Labs' pipeline through our AFECTAIR patient interface technology, a product that emerged as a result of the outstanding work being done to advance AEROSURF," said W. Thomas Amick, Chairman of the Board and Chief Executive Officer, Discovery Labs. "With both AFECTAIR and SURFAXIN potentially arriving on the market in 2012, we are making great progress toward our goal of improving the standard of respiratory critical care."

In addition to its ongoing efforts to gain approval from the U.S. Food and Drug Administration (FDA) to market SURFAXIN® for the prevention of respiratory distress syndrome (RDS) in premature infants, Discovery Labs has made advancements in the delivery of aerosolized KL_4 surfactant to critical care patients through the AEROSURF program. In connection with that program, Discovery Labs developed AFECTAIR, a disposable patient interface adapter that introduces aerosolized medications into the ventilator airflow close to the patient and reduces the number of connections to the ventilator circuitry without compromising ventilatory support. To date, studies suggest that the AFECTAIR technology is an effective option for delivering aerosolized medicine to all patients receiving ventilator support while providing healthcare professionals with a simplified alternative to conventional methods. Discovery Labs expects to file for market authorization of the initial AFECTAIR product in the United States in the fourth quarter of 2011, and in the European Union in the first half of 2012. If approved, Discovery Labs believes that it may be in a position to introduce the AFECTAIR product line in both markets in 2012.

"We have completed and are encouraged by our comprehensive assessment of the operational, regulatory, and commercial landscape for AFECTAIR", said John G. Cooper, President and Chief Financial Officer, Discovery Labs, "Through consultation with independent experts, we believe that AFECTAIR represents an incremental revenue opportunity of approximately $50-75 million, which could provide a source of non-dilutive funds to further support the development of our KL_4 surfactant pipeline."

AFECTAIR product attributes and performance data will be presented at multiple medical conferences in 2011 and 2012.

CONFERENCE CALL DETAILS

Discovery Labs will hold a conference call today at 10:00 AM EDT to further discuss the foregoing. The call in number is (866) 332-5218. The international call in number is (706) 679-3237. This audio webcast will be available through a live broadcast on the Internet at https://us.meeting-stream.com/discoverylaboratories_072811 and www.discoverylabs.com. The replay number to hear the conference call is (855) 859-2056 or (404) 537-3406. The passcode is 86703037.

ABOUT SURFAXIN

SURFAXIN® (lucinactant intratracheal suspension) is Discovery Labs' lead product based on its proprietary KL4 surfactant technology and represents the first synthetic, peptide-containing surfactant that, if approved, will provide healthcare practitioners with an alternative therapy to the currently-approved, animal-derived surfactants that are standard of care today. The safety and efficacy of SURFAXIN for the prevention of RDS has previously been demonstrated in a comprehensive Phase 3 clinical program. Discovery Labs filed a New Drug Application (NDA) for SURFAXIN for the prevention of RDS in premature infants and received a Complete Response Letter from the FDA in April 2009. Discovery Labs anticipates filing response to the Complete Response Letter in the third quarter of 2011, which after a six-month FDA review period, could lead to the potential approval of Surfaxin as early as the first quarter of 2012.

ABOUT AEROSURF

AEROSURF® (lucinactant for inhalation), the company's initial aerosolized KL4 surfactant product, is under development for the prevention of RDS in premature infants. Through effective delivery of aerosolized KL4 surfactant using Discovery Labs' proprietary capillary aerosolization technology and related patient interface technology, AEROSURF may significantly expand the surfactant-eligible treatment population by providing neonatologists with a means of administering surfactant without the risks currently associated with surfactant administration, which requires invasive endotracheal intubation and mechanical ventilation.

ABOUT DISCOVERY LABS

Discovery Laboratories, Inc. is a specialty biotechnology company with one focus – to create life-saving products for patients with respiratory disease and improve the standard of care for pulmonary medicine. Discovery Labs' novel proprietary KL4 surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, lyophilized and aerosol formulations. Discovery Labs is also developing its proprietary drug delivery technologies – capillary aerosol generator and novel patient interface adapters – to enable efficient, targeted upper respiratory or alveolar delivery of aerosolized KL4 surfactant. Discovery Labs believes that its proprietary technology makes it possible, for the first time, to develop a significant pipeline of surfactant products to address a variety of respiratory diseases for which there frequently are few or no approved therapies. For more information, please visit our website at www.Discoverylabs.com.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Examples of such risks and uncertainties, including those related to AFECTAIR, are described in Discovery Labs' filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Any forward-looking statement in this release speaks only as of the date on which it is made. The Company assumes no obligation to update or revise any forward-looking statements.

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