UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): **May 24, 2016**

INNOVIVA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**000-30319**	**94-3265960**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

951 Gateway Boulevard
South San Francisco, California 94080
(650) 238-9600
(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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 (see General Instruction A.2. below):

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 May 24, 2016, GlaxoSmithKline plc ("GSK") and Innoviva, Inc. distributed a press release announcing headline data from the Salford Lung Study ("SLS") of RELVAR® ELLIPTA® 100/25mcg (fluticasone furoate/vilanterol or "FF/VI") in Chronic Obstructive Pulmonary Disease ("COPD"). SLS is a Phase IIIb multi-center, open label randomized controlled trial. The objective of SLS was to compare the effectiveness and safety profile of FF/VI 100/25mcg with existing COPD usual care.

SLS showed that for the primary effectiveness analysis in patients treated with FF/VI 100/25mcg there was a significant reduction of 8.4% (Cl 1.12, 15.17) in the rate of moderate or severe exacerbations compared with those receiving usual care (p=0.025).

FF/VI has been developed under the 2002 Long-Acting Beta $_2$ Agonist (LABA) collaboration between Glaxo Group Limited and Innoviva, Inc. FF/VI 100/25mcg, under the brand name RELVAR® ELLIPTA®, is approved in Europe for the symptomatic treatment of adults with COPD with a FEV1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy. In the United States, FF/VI 100/25mcg, under the brand name BREO® ELLIPTA®, is indicated for long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema and to reduce exacerbations of COPD in patients with a history of exacerbations.

The press release is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated May 24, 2016.

SIGNATURE

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.

INNOVIVA, INC.

Date: May 24, 2016

By: /s/ Eric d'Esparbes
Eric d'Esparbes
Chief Financial Officer

PRESS RELEASE

Salford Lung Study results show COPD patients treated with Relvar® Ellipta® achieve superior reduction in exacerbations compared to 'usual care'

Pioneering GSK study provides important new data on the effectiveness of Relvar Ellipta (FF/VI) when used in everyday clinical practice

May 24, 2016 - London and South San Francisco - GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced positive headline results from the innovative Salford Lung Study (SLS) in Chronic Obstructive Pulmonary Disease (COPD). The study showed that Relvar® Ellipta® 100/25mcg (fluticasone furoate 'FF'/vilanterol 'VI' or 'FF/VI', known as Breo® Ellipta® in the United States) achieved a superior reduction in exacerbations versus usual care, in patients with COPD, in an everyday clinical practice setting. Usual care included long-acting muscarinic antagonists (LAMA), long-acting beta$_2$-agonists (LABA), and inhaled corticosteroids (ICS) administered as monotherapy, dual or triple combinations.

For the primary effectiveness analysis, in patients treated with FF/VI 100/25mcg there was a statistically significant reduction of 8.41% (CI 1.12,15.17) in the rate of moderate or severe exacerbations compared with those receiving usual care (p=0.025).

Within the intent-to-treat (ITT) population, the incidence of serious adverse events (SAE) was similar between the groups (29% FF/VI, 27% usual care). For pneumonia, an SAE of special interest, FF/VI demonstrated non-inferiority versus usual care (7% FF/VI versus 6% usual care). This endpoint was a regulatory post-authorisation measure requested by the European Medicines Agency (EMA).

Patrick Vallance, President, Pharmaceuticals R&D, GSK, commented: "In this genuinely ground-breaking study we have worked closely with the local NHS clinical community to study patients in their everyday setting. To ensure the results from Salford were as robust as possible, we made a long term financial investment in the study, including supporting local infrastructure and training. Innovation often means you have to ask challenging questions to make significant advances, and I believe this is what we have achieved in these positive results announced today."

Eric Dube, SVP and Head, Global Respiratory Franchise, GSK, said: "The Salford Lung Study COPD results support the effectiveness of Relvar. As we move beyond the headline results, we will learn so much more about the medicine and disease management. We believe the results could transform understanding of how patients in everyday clinical practice respond to COPD treatments. We want to say a big thank you to everyone who has made this unique study possible."

Lead investigator, Jørgen Vestbo, Professor of Respiratory Medicine at the Centre for Respiratory Medicine and Allergy, University Hospital South Manchester NHS Foundation Trust and the University of Manchester, said: "The Salford Lung Study is a very important trial to help us understand more about the medicines we prescribe on a day-to-day basis. This is an important finding; what we are seeing today is the tip of the iceberg. Over the coming months we will understand more about the day-to-day effectiveness of FF/VI and how treatment choice, patient behaviour, co-morbidities and other factors combine to influence COPD outcomes. This has been a highly collaborative effort to

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gather data that will help improve understanding about the effectiveness of respiratory medicines when used in usual clinical practice."

Michael W. Aguiar, President and Chief Executive Officer of Innoviva, said: "We are very pleased that Relvar Ellipta achieved superiority compared to usual care in SLS, a world-first effectiveness study in COPD. These data provide a significant body of evidence in everyday clinical practice and add to the data generated from other randomized controlled studies. These data are unique in the world of evidence generation in COPD. We look forward to disclosing further data and analyses, which we believe will be of significant value to both physicians and patients."

Analyses remain ongoing and will be the subject of future publications and presentations. A second Salford Lung Study is currently being conducted in asthma patients, with results expected in 2017.

Study Design

The Salford Lung Study is a Phase IIIb multi-centre, open label randomised controlled trial (RCT). The objective of the study was to compare the effectiveness and safety profile of FF/VI 100/25mcg with existing COPD usual care. All suitable patients with COPD at 80 primary care sites in and around Salford and South Manchester were identified from practice databases, and invited to participate in the study by their own GP.

In total, 2802 patients with COPD were randomised 1:1 to receive FF/VI 100/25mcg, with or without a LAMA, or to continue to receive usual care. FF/VI was administered once daily via the Ellipta inhaler. Patients who were taking a LAMA in addition to ICS/LABA therapy (triple therapy) who were randomised to the FF/VI group were able to continue to use LAMA therapy in addition to FF/VI. Usual care was taken as advised by the prescribing clinician, and could include single or dual long-acting bronchodilator therapy, inhaled corticosteroid either alone or in combination with a long acting bronchodilator or triple therapy of a LAMA, a LABA and an inhaled corticosteroid.

The Salford Lung Study had minimal exclusion criteria and involved a broad demographic of patients. At baseline patients had a mean age of 67 years (min 40 - max 93) and were equally split by gender (males vs. females 51/49%). To enrol in the study, patients were required to have a diagnosis of COPD and be receiving maintenance therapy; at baseline a total of 86% were receiving an ICS containing regimen, with a total of 52% on triple therapy. Patients were also required to have at least one exacerbation in the past 3 years: at baseline 47% of patients had $\geq$ 2 moderate exacerbations, 33% had 1 exacerbation and 20% had not reported an exacerbation in the prior 12 months.

Patients were followed for a period of 12 months in a normal clinical practice setting using a single electronic medical record (EMR), linking primary care, secondary care and pharmacy data. Throughout the duration of the study physicians were allowed to modify or switch treatment at any point in the study, as would happen in normal clinical practice, the only exception being a switch from usual care to FF/VI.

The study team were able to monitor all hospital admissions, outpatient and emergency department visits, as well as data from primary care (including all healthcare contacts, out-of-hours activity and prescriptions of antibiotics or oral steroids) via the electronic health-records.

The primary effectiveness endpoint is the mean annual rate of moderate or severe exacerbations, where a moderate exacerbation is defined as the subject receiving an exacerbation-related prescription (given to treat an acute worsening of COPD symptoms) of oral corticosteroid and/or antibiotic with or without NHS contact, not requiring hospitalisation. A severe exacerbation is defined as an exacerbation-related hospitalisation — a direct result of an acute worsening of symptoms of COPD or a prolonged hospitalization as a result of a COPD exacerbation.

For the primary effectiveness analysis the patient population was restricted to patients who had exacerbated in the previous 12 months prior to randomisation (2269), rather than in the previous three years prior to randomisation, as in the intention to treat (ITT) group (2799).

About the Study

The Salford Lung Study is intended to enable healthcare professionals and decision makers to more fully assess the potential value of FF/VI by providing data collected in a normal clinical practice setting which is representative of how healthcare professionals and patients may use the medicine in everyday life. It will add to the existing data set from randomised clinical trials (RCTs) for the medicine which, while critical to establishing the safety and efficacy of a medicine, are conducted in a highly controlled environment and enrol a more highly selected patient population than would be expected in everyday clinical care.

The study is made possible through a unique collaboration between GSK, North West e-Health (NWEH), The University of Manchester, Salford Royal NHS Foundation Trust, University Hospital of South Manchester (UHSM), NHS Salford and GPs and community pharmacists in Salford, Trafford and South Manchester.

What is COPD?

Chronic obstructive pulmonary disease (COPD) is a disease of the lungs that includes chronic bronchitis, emphysema or both. COPD is characterised by obstruction to airflow that interferes with normal breathing. Cigarette smoke, breathing in second-hand smoke, air pollution including biomass fuels, chemical fumes and dust from the environment or workplace can all contribute to COPD.

People with COPD can experience a sudden worsening in symptoms, known as an exacerbation. Symptoms of an exacerbation can include an increase in breathlessness, coughing and mucus production, as well as fever. In these cases, the patient may need to change their medication or even, in some cases, be admitted to hospital. Exacerbations are common; one in three patients with severe COPD and almost half of patients with very severe COPD had frequent exacerbations (two or more in the first year following diagnosis). Every exacerbation can cause permanent lung damage and repeated exacerbations can accelerate the progression of the disease. People with frequent exacerbations have a poorer quality of life and may have an increased risk of death.

The study is listed on www.clinicaltrials.gov.

Relvar® Ellipta® is known as Breo® Ellipta® in the United States.

About FF/VI 100/25

FF/VI 100/25mcg, under the brand name Breo® Ellipta® 100/25mcg is licensed in the US for:

- The long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema and to reduce exacerbations of COPD in patients with a history of exacerbations. Breo® Ellipta® 100/25mcg is the only strength indicated for the treatment of COPD.

- Breo Ellipta100/25mcg is not indicated for the relief of acute bronchospasm.

Full US prescribing information, including BOXED WARNING and Medication Guide is available at us.gsk.com or US Prescribing Information Breo Ellipta.

FF/VI 100/25mcg, under the brand name Relvar® Ellipta® is approved in Europe for:

- the symptomatic treatment of adults with chronic obstructive pulmonary disease (COPD) with a FEV_1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.

For the EU Summary of Product Characteristics for Relvar Ellipta, please visit: http://ec.europa.eu/health/documents/community-register/html/h886.htm

Important Safety Information (ISI) for FF/VI (Breo Ellipta) in the US

The following ISI is based on the Highlights section of the US Prescribing Information for Breo Ellipta. Please consult the full Prescribing Information for all the labelled safety information for Breo Ellipta.

Long-acting beta$_2$-adrenergic agonists (LABA), such as vilanterol, one of the active ingredients in BREO ELLIPTA, increase the risk of asthma-related death. A placebo-controlled trial with another LABA (salmeterol) showed an increase in asthma-related deaths. This finding with salmeterol is considered a class effect of all LABA. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids (ICS) or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA.

Breo Ellipta is contraindicated for primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required and in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients.

Breo Ellipta should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD or asthma, or used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled, short-acting beta$_2$-agonist.

Breo Ellipta should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medications containing LABAs, as an overdose may result.

Oropharyngeal candidiasis has occurred in patients treated with Breo Ellipta. Patients should be advised to rinse their mouth with water without swallowing after inhalation to help reduce this risk.

An increase in the incidence of pneumonia has been observed in subjects with COPD receiving the fluticasone furoate/vilanterol combination, including Breo Ellipta 100 mcg/25 mcg, in clinical trials. There was also an increased incidence of pneumonias resulting in hospitalisation. In some incidences these pneumonia events were fatal.

Patients who use corticosteroids are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients.

Particular care is needed for patients who have been transferred from systemically active corticosteroids to inhaled corticosteroids because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids.

Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage of inhaled corticosteroids in susceptible individuals.

Caution should be exercised when considering the coadministration of Breo Ellipta with long-term ketoconazole and other known strong CYP3A4 inhibitors because increased systemic corticosteroid and cardiovascular adverse effects may occur.

Breo Ellipta can produce paradoxical bronchospasm which may be life-threatening.

Hypersensitivity reactions such as anaphylaxis, angioedema, rash, and urticaria may occur after administration of Breo Ellipta.

Vilanterol, the LABA in Breo Ellipta, can produce clinically significant cardiovascular effects in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, and also cardiac arrhythmias. Breo Ellipta should be used with caution in patients with cardiovascular disorders.

Decreases in bone mineral density have been observed with long-term administration of products containing inhaled corticosteroids, as have glaucoma, increased intraocular pressure, and cataracts.

Breo Ellipta should be used with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines.

Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients. Beta-adrenergic agonist medicines may produce transient hyperglycemia in some patients.

For COPD, the most common adverse reactions (≥3% and more common than in placebo) reported in two 6-month clinical trials with Breo Ellipta 100/25 (and placebo) were nasopharyngitis, 9% (8%); upper respiratory tract infection, 7% (3%); headache, 7% (5%); and oral candidiasis, 5% (2%). In addition to the reactions reported in the 6-month studies, adverse reactions occurring in ≥3% of the subjects treated with Breo Ellipta 100/25 in two 1-year studies included back pain, pneumonia, bronchitis, sinusitis, cough, oropharyngeal pain, arthralgia, influenza, pharyngitis, and pyrexia.

GSK — one of the world's leading research-based pharmaceutical and healthcare companies — is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com.

Innoviva - Innoviva is focused on bringing compelling new medicines to patients in areas of unmet need by leveraging its significant expertise in the development, commercialization and financial management of bio-pharmaceuticals. Innoviva's portfolio is anchored by the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, which were jointly developed by Innoviva and GSK. Under the agreement with GSK, Innoviva is eligible to receive associated royalty revenues from RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and, if approved and commercialized, VI monotherapy, as well. In addition, Innoviva retains a 15 percent economic interest in future payments made by GSK for earlier-stage programs partnered with Theravance BioPharma, Inc. For more information, please visit Innoviva's website at www.inva.com. RELVAR®, BREO®, ANORO® and ELLIPTA® are trademarks of the GlaxoSmithKline group of companies.

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Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D 'Risk factors' in the company's Annual Report on Form 20-F for 2015.

Innoviva forward-looking statements

This press release contains certain "forward-looking" statements as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things, statements relating to goals, plans, objectives and future events. Innoviva intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve substantial risks, uncertainties and assumptions. Examples of such statements include statements relating to: the future use or importance of the SLS trial results, prescription and market share trends, payor coverage, the strategies, plans and objectives of the company, the timing, manner and amount of anticipated potential capital returns to stockholders (including without limitation, expectations of future share repurchases or cash dividends), the status and timing of clinical studies, data analysis and communication of results, the potential benefits and mechanisms of action of product candidates, expectations for products, and projections of revenue, expenses and other financial items. These statements are based on the current estimates and assumptions of the management of Innoviva as of the date of this press release and are subject to risks, uncertainties, changes in circumstances, assumptions and other factors that may cause the actual results of Innoviva to be materially different from those reflected in the forward-looking statements. Important factors that could cause actual results to differ materially from those indicated by such forward-looking statements include, among others, risks related to: lower than expected future royalty revenue from respiratory products partnered with GSK, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, dependence on third parties to conduct its clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, and risks of collaborating with third parties to discover, develop and commercialize products. Other risks affecting Innoviva are described under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Innoviva's Annual Report on Form 10-K for the year ended December 31, 2015 and Innoviva's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. In addition to the risks described above and in Innoviva's other filings with the SEC, other unknown or unpredictable factors also could affect Innoviva's results. Past performance is not necessarily indicative of future results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Innoviva assumes no obligation to update its forward-looking statements on account of new information, future events or otherwise, except as required by law. (INVA-G)

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