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 5, 2017**

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)

2000 Sierra Point Parkway
Brisbane, California 94005
(650) 238-9600
(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933(§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Item 8.01. Other Events.

On May 5, 2017, GlaxoSmithKline plc and Innoviva, Inc. (Innoviva) distributed a press release announcing positive results from the Salford Lung Study (SLS) of RELVAR® ELLIPTA® 100/25mcg or 200/25mcg (fluticasone furoate 'FF'/vilanterol 'VI' or 'FF/VI') in asthma. 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 initiating treatment with FF/VI with usual asthma maintenance therapy over a 52 week period.

FF/VI has been developed under the 2002 Long-Acting Beta$_2$ Agonist (LABA) collaboration between Glaxo Group Limited and Innoviva. FF/VI 100/25mcg, under the brand name RELVAR® ELLIPTA®, is indicated in Europe in the regular treatment of patients aged 12 and over with asthma, where use of a

combination product is appropriate. In the United States, FF/VI 100/25mcg, under the brand name BREO® ELLIPTA®, is indicated as a once-daily treatment of asthma in patients aged 18 years and older and is not indicated for the relief of acute bronchospasm.

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 5, 2017

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INNOVIVA, INC.

Date: May 5, 2017

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

PRESS RELEASE

Relvar Ellipta significantly improved asthma control in Salford Lung Study patients compared with their usual care

Significant improvement in asthma control was seen at all time points measured across the study

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva Inc. (NASDAQ: INVA) today announced positive results from the innovative Salford Lung Study (SLS) in asthma, carried out amongst 4,233 patients treated by their own General Practitioner in everyday clinical practice. This open-label, randomised study showed that significantly more asthma patients initiated on treatment with Relvar Ellipta 100/25mcg or 200/25mcg (fluticasone furoate 'FF'/vilanterol 'VI' or 'FF/VI') achieved an improvement in their asthma control compared with patients who continued to take their usual care medicines. Usual care treatment included inhaled corticosteroids (ICS) administered as monotherapy or as ICS/LABA (Long Acting Beta Agonist) combinations.

For the primary effectiveness analysis, at 24 weeks a significantly higher percentage of patients with uncontrolled asthma and initiated on treatment with FF/VI achieved better control of their asthma (71%) measured by the Asthma Control Test (ACT), compared with patients continuing usual care treatment (56%), (Odds ratio 2.00, 95% CI 1.70, 2.34; $p<0.001$). Improvement was defined as an ACT total score $\geq$20 or an increase from baseline of $\geq$3. This significant finding was also seen at 12, 40 and 52 weeks.

Lead Investigator, Ashley Woodcock, Professor of Respiratory Medicine and Clinical Director for Respiratory Medicine, University Hospital of South Manchester and University of Manchester said: "I am really excited to see the results from SLS asthma. Asthma control continues to be a real challenge for patients and the healthcare community. Poor control can have a major impact on the lives of asthma patients. The effectiveness of different treatments on asthma control is difficult to investigate in a traditional double-blind randomised control trial, where the study design and intrusive monitoring can influence the behaviour of patients. In SLS, patient relevant outcomes are the major endpoints. GSK should be congratulated for running this unique study, designed to understand how asthma medicines work in everyday clinical practice."

In the study for the intent-to-treat (ITT) population, the incidence of serious adverse events (SAE) was the same in both arms (FF/VI 13% and usual care 13%). Pneumonia was a safety endpoint of special interest and a regulatory post-authorisation requirement of the European Medicines Agency (EMA). A novel aspect of the study design was that it allowed patient's treatment to be modified throughout the study. Therefore two assessments relating to pneumonia have been performed, one based on the arm to which patients were randomised, the second based upon the treatment to which patients were exposed at the time of the event. Serious adverse events of pneumonia by randomised group were reported by 39 patients (FF/VI arm 23, 1%; usual care arm 16, <1%). These patients had 42 events and based on a pre-planned analysis non-inferiority of FF/VI to usual care was not confirmed. When these events were summarised according to the actual treatment patients were taking at the time of the event, 21 events were recorded for FF/VI and 21 events for usual care.

PRESS RELEASE

Eric Dube, Senior Vice President and Head, Global Respiratory Franchise GSK, said: "Despite medical advances, more than half of patients with asthma continue to experience poor control and significant symptoms. This positive study has demonstrated that patients initiated with Relvar Ellipta treatment by their doctor in their usual clinical practice, were able to achieve better control of their asthma than patients continuing on usual care; and this benefit was seen across all time points measured in the study from 12 to 52 weeks. . This study has been a tremendous partnership effort between healthcare professionals, patients, academics and GSK and we would like to thank everyone who has helped to make this unique study possible."

Michael W. Aguiar, President and Chief Executive Officer of Innoviva said: "We are delighted to see the positive results from a second SLS study with Relvar Ellipta, the first being in chronic obstructive pulmonary disease. Asthma control remains a significant unmet medical need in the daily lives for many patients. We believe that this positive real world data successfully builds upon the previous clinical data to provide strong evidence of the benefits of Relvar Ellipta for the treatment of asthma. "

These data will be presented in future publications and will be made available on clinicaltrials.gov.

Study Design

The Salford Lung Study is a Phase III multi-centre, open label randomised controlled trial (RCT). The objective of this study was to compare the effectiveness and safety profile of initiating treatment with FF/VI with usual asthma maintenance therapy over a 52 week period. All suitable patients with asthma at 74 primary care sites in and around Salford and South Manchester, UK, were identified from practice databases and invited to participate in the study by their own GP. The primary endpoint of the study was measured at week 24 in the primary effectiveness analysis population.

In total, 4,233 patients with asthma who were taking an inhaled corticosteroid (ICS) with or without a long acting $beta_2$-agonist (LABA) were randomised to receive either FF/VI or to continue on their existing asthma maintenance therapy (usual care).

Usual care was prescribed by the patients GP and included ICS either alone or in a combination with a LABA. In the usual care arm 36% of patients were on an ICS alone and 64% were on an ICS/LABA combination at the time of commencing study medication.

The Salford Lung Study had minimal exclusion criteria and involved a broad demographic of patients. At baseline patients had a mean age of 49.8 (min 18 years) and were split by gender (males vs. female 41/59%). To enrol in the study, patients were required to have a GP diagnosis of asthma as their primary respiratory disease and be receiving maintenance therapy with an ICS with or without LABA for at least 4 weeks prior to visit 2. At baseline 72% of patients had uncontrolled asthma with an ACT total score of 5 to 19.

Patients were followed for a period of 52 weeks in a normal clinical practice setting using their electronic medical record (EMR), linking primary care, secondary care and pharmacy data to collect study data. Throughout the duration of the study physicians were allowed to modify or switch treatment at any point as this would happen in normal clinical practice, the only exception being a switch from usual care to FF/VI.

At weeks 12, 24, and 40 patients were telephoned to enquire about whether they had experienced any serious adverse events or non-serious adverse drug reactions. On these telephone calls patients were asked to provide responses to the ACT. At month 12 a face to face visit was carried out. The Standardised Asthma Quality of Life Questionnaire (AQLQ[S]) was also conducted at week 24 and week 52 by telephone.

The study team was 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 Intent-to-Treat (ITT) population is defined as all patients who have been randomised and received at least one prescription of study medication (e.g., FF/VI or usual asthma maintenance therapy). The primary effectiveness analysis (PEA) population is defined as all ITT patients who have an ACT total score of < 20 at baseline (Randomisation Visit).

The study design protocol paper can be found on clintrials.gov

The odds ratio expressed in the results is calculated as the ratio of the odds of achieving better asthma control as a patient initiated with Relvar Ellipta and the odds of achieving better asthma control as a patient continuing on usual care. This value is adjusted for any imbalances between the treatment arms in certain key characteristics.

The Asthma Control Test (ACT)

The ACT is a well recognised instrument that is used globally in asthma treatment guidelines to assess asthma control. It is self-administered utilising 5 questions to assess asthma control during the past 4 weeks on a 5-point categorical scale (1 to 5). By answering all five questions, a patient with asthma can obtain a score that may range between 5 and 25, with higher scores indicating better control.

An ACT total score of 5 to 19 suggests that a patient's asthma is poorly or not well controlled. A score of 20 to 25 suggests that a patient's asthma is likely to be well controlled. The total score is calculated as the sum of the scores from all 5 questions, provided all scores are non-missing; if any individual scores are missing then the overall score will be set to missing. A change of 3 points is clinically meaningful for the patient.

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 double blind 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.

The Salford Lung Study in COPD reported findings in May 2016. This is the second of the two Salford Lung Studies to report.

About asthma

Asthma is a chronic lung disease that inflames and narrows the airways. Asthma affects 358 million people worldwide.

The causes of asthma are not completely understood but likely involve an interaction between a person's genetic make-up and the environment

About Relvar Ellipta (fluticasone furoate + vilanterol)

Relvar Ellipta is a once-daily dual combination treatment comprising fluticasone furoate, an inhaled corticosteroid and vilanterol, a long-acting beta$_2$-agonist, in a single inhaler, the Ellipta.

Relvar Ellipta is indicated in Europe in the regular treatment of patients aged 12 and over with asthma, where use of a combination product (long-acting ß2—agonist, LABA, and inhaled corticosteroid, ICS) is appropriate: Patients not adequately controlled on both ICS and 'as-needed' short-acting ß$_2$-agonist (SABA).

Full EU prescribing information is available at: EU Prescribing Information for Relvar Ellipta.

Important safety information for Relvar Ellipta in Europe

FF/VI is contraindicated in patients with hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients.

FF/VI should not be used to treat acute asthma symptoms or an acute exacerbation in COPD, for which a short-acting bronchodilator is required. Increasing use of short-acting bronchodilators to relieve symptoms indicates deterioration of control and patients should be reviewed by a physician.

Patients should not stop therapy with FF/VI in asthma or COPD, without physician supervision since symptoms may recur after discontinuation.

Asthma-related adverse events and exacerbations may occur during treatment with FF/VI. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of treatment with FF/VI.

Paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with a short-acting inhaled bronchodilator. FF/VI should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary.

Cardiovascular effects, such as cardiac arrhythmias e.g. supraventricular tachycardia and extrasystoles may be seen with sympathomimetic medicinal products including FF/VI. Therefore fluticasone furoate/vilanterol should be used with caution in patients with severe cardiovascular disease.

For patients with moderate to severe hepatic impairment, the 92/22 mcg dose should be used and patients should be monitored for systemic corticosteroid-related adverse reactions. FF/VI 184/22 mcg is not indicated for patients with COPD. There is no additional benefit of the 184/22 mcg dose compared to the 92/22 mcg dose and there is a potential increased risk of pneumonia and systemic corticosteroid-related adverse reactions.

An increase in the incidence of pneumonia has been observed in patients with COPD receiving FF/VI. There was also an increased incidence of pneumonias resulting in hospitalisation. In some instances these pneumonia events were fatal.

The incidence of pneumonia in patients with asthma was common at the higher dose. In a previous study of FF/VI in asthma the incidence of pneumonia in patients with asthma taking FF/VI 184/22 mcg was numerically higher compared with those receiving FF/VI 92/22 mcg or placebo.

Hyperglycaemia: There have been reports of increases in blood glucose levels in diabetic patients and this should be considered when prescribing to patients with a history of diabetes mellitus.

Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, growth retardation in children and adolescents, cataract and glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

FF/VI should be administered with caution in patients with pulmonary tuberculosis or in patients with chronic or untreated infections. Data from large asthma and COPD clinical trials were used to determine the frequency of adverse reactions associated with FF/VI.

Very common adverse reactions (occurring in >1/10 patients) with FF/VI were headache and nasopharyngitis. Common adverse reactions (occurring in >1/100 to <1/10 patients) were pneumonia, upper respiratory tract infection, bronchitis, influenza, candidiasis of mouth and throat, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, fractures, and pyrexia and muscle spasms..Extrasystoles were observed as an uncommon adverse reaction (occurring in >1/1,000 to <1/100 patients). Rare adverse reactions (occurring in >1/10,000 to < 1/1,000) were hypersensitivity reactions (including anaphylaxis, angioedema, rash and urticaria), anxiety, tremor, palpitations, tachycardia and paradoxical bronchospasm. With the exception of pneumonia and fractures, the safety profile was similar in patients with asthma and COPD. During clinical studies, pneumonia and fractures were more frequently observed in patients with COPD.

PRESS
RELEASE

Relvar Ellipta is known as Breo Ellipta in the United States. Breo Ellipta is licensed in the US for:

· The once-daily treatment of asthma in patients aged 18 years and older.

Long-acting beta2-adrenergic agonists (LABA), such as vilanterol, one of the active ingredients in Breo Ellipta, increase the risk of asthma-related death. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe Breo Ellipta for patients not adequately controlled on a long-term asthma

control medication, such as an inhaled corticosteroid, or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and a LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue Breo Ellipta) if possible without loss of asthma control and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use BREO ELLIPTA for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids.

· Breo Ellipta 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 for Breo Ellipta.

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®. In addition, Innoviva retains a 15 percent economic interest in future payments made by GSK for earlier-stage programs partnered with Theravance Biopharma, Inc., including the closed triple combination therapy for COPD. For more information, please visit Innoviva's website at www.inva.com.

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.

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PRESS RELEASE

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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 Principal risks and uncertainties in the company's Annual Report on Form 20-F for 2016.

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. 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 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, 2016, which is on file with the U.S. Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Innoviva's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, to be filed with the SEC in the second quarter of 2017. 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. 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. The information in this press release is provided only as of the date hereof, and 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).