INNOVIVA, INC.

FORM 8-K
(Current report filing)

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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): **September 15, 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)

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ 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 ☐

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. ☐

Item 8.01. Other Events.

On September 15, 2017, GlaxoSmithKline plc ("GSK") and Innoviva, Inc. (Innoviva) distributed a press release announcing that the European Medicines Agency's Committee for Medicinal Products for Human Use ("CHMP") issued a positive opinion recommending market authorization for the use of fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) as a maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist, under the proposed brand name Trelegy Ellipta.

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 September 15, 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: September 15, 2017

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

Exhibit 99.1

PRESS
RELEASE

Issued: 15 September 2017, London UK — LSE Announcement

Trelegy Ellipta once-daily single inhaler triple therapy receives positive opinion from the CHMP in Europe for appropriate patients with COPD

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending marketing authorisation for fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) as a maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist (for effects on symptom control see section 5.1). The proposed brand name is Trelegy Ellipta.

Trelegy Ellipta is a combination of an inhaled corticosteroid (ICS), a long-acting muscarinic antagonist (LAMA) and a long-acting beta2-adrenergic agonist (LABA), delivered once daily in GSK's Ellipta dry powder inhaler. It is the first once-daily single inhaler triple therapy to be granted a positive opinion by the CHMP. The proposed strength is FF/UMEC/VI 100/62.5/25 mcg.

Patrick Vallance, GSK's President, R&D, said, " We believe once-daily single inhaler triple therapy, if approved, would provide an important option for appropriate patients with COPD who are receiving ICS/LABA and require additional bronchodilation, avoiding the need for multiple inhalers."

Mike Aguiar, CEO of Innoviva, Inc . said, "This positive opinion will lead to a significant therapeutic convenience for those appropriate patients already on ICS/LABA treatment that require additional bronchodilation. Trelegy is the latest development in our collaboration with GSK and is testament to our ongoing efforts to advance respiratory medicine."

A CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission. A final decision by the European Commission is anticipated by around the end of 2017.

Regulatory applications have been submitted and are undergoing assessment in a number of other countries, including the US, Australia and Canada. FF/UMEC/VI is an investigational medicine not yet approved for use as a single inhaler triple therapy anywhere in the world. The proposed trade name 'Trelegy Ellipta' is subject to regulatory approval.

About COPD

COPD is a common but serious lung disease that is thought to affect around 384 million people worldwide. [1]

For people living with COPD, the inability to breathe normally can consume their daily lives and make simple activities, like walking up stairs, an everyday struggle.

Long-term exposure to inhaled irritants that damage the lungs and the airways are usually the cause of COPD. Cigarette smoke, breathing in second hand smoke, air pollution, chemical fumes or dust from the environment or workplace can all contribute to COPD. Most people who have COPD are at least 40 years old when symptoms begin. [2]

Every person with COPD is different, with different needs, different challenges and different goals. Understanding this and providing support to help meet these needs is the foundation of GSK's work.

About the once-daily single inhaler triple therapy clinical programme in COPD supporting the European Marketing Authorisation Application

The European Marketing Authorisation Application for Trelegy Ellipta is supported by efficacy and safety data from the FF/UMEC/VI development programme, as well as data from studies with the components either alone, or in combination. Positive top-line results of the phase 3 FULFIL (Lung **FU** nction and quality of **L** i **F** e assessment in COPD with closed tr **I** p **L** e therapy) study which investigated once-daily single inhaler triple therapy compared to twice-daily budesonide/formoterol were announced in June 2016 and published in 2017 (Lipson DA *et al* . Am J Resp Crit Care Med 2017).

Important Safety Information for FF/UMEC/VI in the EU

The following Important Safety Information is based on a summary of the Summary of Product Characteristics for Trelegy Ellipta (FF/UMEC/VI). Please consult the full Summary of Product Characteristics for all the safety information.

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

FF/UMEC/VI should not be used in patients with asthma since it has not been studied in this patient population. FF/UMEC/VI is not indicated for the treatment of acute episodes of bronchospasm.

In the event of deterioration of COPD during treatment with FF/UMEC/VI, a re-evaluation of the patient and of the COPD treatment regimen should be undertaken.

Administration of FF/UMEC/VI may produce paradoxical bronchospasm that may be life-threatening.

Cardiovascular effects, such as cardiac arrhythmias e.g. atrial fibrillation and tachycardia, may be seen after the administration of muscarinic receptor antagonists and sympathomimetics, including FF/UMEC/VI. Therefore, FF/UMEC/VI should be used with caution in patients with unstable or life-threatening cardiovascular disease.

Systemic steroids effects may occur with any inhaled corticosteroid (ICS), particularly at high doses prescribed for long periods. These effects are much less likely to occur than with oral corticosteroids. Patients with moderate to severe hepatic impairment receiving FF/UMEC/VI should be monitored for systemic corticosteroid-related adverse reactions.

If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

FF/UMEC/VI should be used with caution in patients with convulsive disorders or thyrotoxicosis, in patients who are unusually responsive to beta $_2$ -adrenergic agonists and in patients with pulmonary tuberculosis or in patients with chronic or untreated infection.

Consistent with its antimuscarinic activity, FF/UMEC/VI should be used with caution in patients with urinary retention or with narrow-angle glaucoma.

An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving ICS. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies. There is no conclusive clinical evidence for intra-class differences in the magnitude of the pneumonia risk among ICS products.

Beta $_2$ -adrenergic agonists may produce significant hypokalaemia in some patients, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. No clinically relevant effects of hypokalaemia were observed

in clinical studies with FF/UMEC/VI at the recommended therapeutic dose. Caution should be exercised when FF/UMEC/VI is used with other medicinal products that also have the potential to cause hypokalaemia.

Beta $_2$-adrenergic agonists may produce transient hyperglycemia in some patients. No clinically relevant effects on plasma glucose were observed in clinical studies with FF/UMEC/VI at the recommended therapeutic dose. Upon initiation of treatment with FF/UMEC/VI, plasma glucose should be monitored more closely in diabetic patients.

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take FF/UMEC/VI.

The most frequently reported adverse reactions with FF/UMEC/VI were nasopharyngitis (7%), headache (5%) and upper respiratory tract infection (2%). Other common adverse reactions (reported with a frequency of $\geq$ 1/100 to <1/10) include: pneumonia, pharyngitis, rhinitis, influenza, cough, arthralgia and back pain.

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.

Trade marks are owned by or licensed to the GSK group of companies.

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.

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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, including the development, regulatory and commercial plans for closed triple combination therapy and the potential benefits and mechanisms of action of closed triple combination therapy. 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 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, 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. 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).

Registered in England & Wales:
No. 3888792

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References (accessed September 2017)

1. Global Initiative for Chronic Obstructive Lung Disease Global Initiative for Chronic Obstructive Lung Disease. 2017. Pocket guide to COPD diagnosis, management, and prevention. Available at: http://goldcopd.org/wp-content/uploads/2016/12/wms-GOLD-2017-Pocket-Guide.pdf
2. Diagnosis of COPD. World Health Organisation. Available at: http://www.who.int/respiratory/copd/diagnosis/en/