

**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): **November 18, 2016**

INNOVIVA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation)

000-30319

(Commission File Number)

94-3265960

(I.R.S. Employer Identification
Number)

**2000 Sierra Point Parkway, Suite 500
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:

- 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))

Item 5.02. Departure of Directors or Principal Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 18, 2016, based upon the recommendation of the Nominating/Corporate Governance Committee of the Board of Directors (the "Board") of Innoviva, Inc. ("Innoviva"), the Board elected Barbara G. Duncan as a director, to serve until the next annual meeting of stockholders or until her successor has been duly elected and qualified. In connection with Ms. Duncan's election, and pursuant to Innoviva's bylaws, the Board has increased the number of directors from six (6) to seven (7). Ms. Duncan will also serve on the Audit Committee of the Board.

Pursuant to Innoviva's non-employee director compensation program, Ms. Duncan received (i) a restricted stock unit award covering 22,914 shares of Innoviva common stock (the "Initial RSU") and (ii) restricted stock unit award covering 9,547 shares of Innoviva common stock (the "Pro Rata RSU"). The Initial RSU vests in two equal annual installments and the Pro Rata RSU vests in a single installment at the sooner of the next annual stockholder meeting or one-year grant anniversary, in each case subject to Ms. Duncan's continuous service through the applicable vesting date, except that in the event of Ms. Duncan's death or in the event of a change of control prior to the termination of Ms. Duncan's services the Initial RSU and the Pro Rata RSU will immediately vest in full. Ms. Duncan will also receive an annual cash retainer of \$50,000 for her role as a board member and \$10,000 for her role on the Audit Committee of the Board.

Ms. Duncan and Innoviva have entered into an indemnification agreement requiring Innoviva to indemnify her to the fullest extent permitted under Delaware law with respect to her services as a director. The indemnification agreement will be in the form entered into with Innoviva's other directors and executive officers. This form is attached hereto as Exhibit 99.1.

The Board has determined that Ms. Duncan is an independent director in accordance with applicable rules of the Securities and Exchange Commission and The Nasdaq Stock Market, Inc.

Item 8.01. Other Events.

On November 21, 2016, GlaxoSmithKline plc ("GSK") and Innoviva issued a press release announcing that GSK has filed a New Drug Application with the United States Food and Drug Administration for the once-daily, closed triple combination therapy, fluticasone furoate/umeclidinium/vilanterol ("FF/UMEC/VI"), for patients with chronic obstructive pulmonary disease.

The press release is filed as Exhibit 99.2 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Form of Indemnification Agreement between Innoviva, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.11 to Innoviva Inc.'s Registration Statement on Form S-1 (SEC File No. 333-116384) filed with the SEC on June 10, 2004.

99.2 Press Release dated November 21, 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: November 21, 2016

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

PRESS
RELEASE



Issued: Monday, 21 November 2016, London UK — LSE Announcement

GSK files regulatory submission in US for once-daily closed triple combination therapy FF/UMEC/VI for patients with COPD

GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced the filing by GSK of a regulatory submission with the US Food and Drug Administration for the once-daily, closed triple combination therapy fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI 100/62.5/25 mcg) for patients with chronic obstructive pulmonary disease (COPD). This follows the announcement earlier this year of plans to bring forward the timing of the US filing from the first half of 2018.

The closed triple combination therapy comprises three medicines: fluticasone furoate, an inhaled corticosteroid (ICS), umeclidinium, a long-acting muscarinic antagonist (LAMA) and vilanterol, a long-acting beta₂-adrenergic agonist (LABA), delivered once-daily in GSK's Ellipta[®] dry powder inhaler.

The US regulatory submission of the closed triple therapy comprises a New Drug Application for the maintenance treatment of patients with COPD, including chronic bronchitis and emphysema. It is based on data from the closed triple combination therapy development programme, as well as data from studies with FF, UMEC and VI either alone or in combination.

Dave Allen, Head of Respiratory R&D, said, "COPD is a progressive disease and its impact on patients can worsen over time. As reflected in the recently updated GOLD COPD Strategy*, for those patients with advanced disease, multiple therapies such as ICS/LAMA/LABA combinations are often required and are typically delivered via two or more inhalers with potentially differing dose regimens. This first regulatory submission of our closed triple therapy brings us a step closer to providing a once-daily treatment in a single Ellipta inhaler as an alternative option for those patients who require multiple therapies."

Mike Aguiar, CEO of Innoviva, Inc., added "We are delighted that the US submission has been achieved some 18 months earlier than planned. If approved, FF/UMEC/VI as a once daily triple combination in a single inhaler could be a meaningful addition to the treatment options available for advanced COPD patients."

A regulatory filing in the EU is planned in the coming weeks and is expected to be followed by submissions in other countries beginning in 2017. The closed triple combination of FF/UMEC/VI is not approved for use anywhere in the world.

*The Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017. Available from: <http://goldcopd.org>. Accessed: November 2016

About COPD

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. COPD is thought to affect 329 million people worldwide.

Long-term exposure to lung 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.

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., 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.

RELVAR[®], BREO[®], ANORO[®] and ELLIPTA[®] are trademarks of the GlaxoSmithKline group of companies.

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GSK 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, 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, 2015 and Quarterly Report on Form 10-Q for the quarter ended September 30, 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. 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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