

Innoviva, Inc.
Form 8-K
May 24, 2016

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
(State or Other Jurisdiction of
Incorporation)

000-30319
(Commission File Number)

94-3265960
(I.R.S. Employer Identification Number)

951 Gateway Boulevard
South San Francisco, California 94080

(650) 238-9600

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(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))
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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% (CI 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