

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

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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**FORM 8-K**

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**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**

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**INNOVIVA, INC.**

(Exact Name of Registrant as Specified in its Charter)

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**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**

## Edgar Filing: Innoviva, Inc. - Form 8-K

(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

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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