

Innoviva, Inc.
Form 8-K
June 20, 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): **June 20, 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

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

(650) 238-9600

(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):

- ☐ 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 8.01. Other Events.

On June 20, 2016, GlaxoSmithKline plc (GSK) and Innoviva, Inc. (Innoviva) distributed a press release announcing positive top-line results from the pivotal phase III FULFIL study of the investigational once-daily closed triple combination therapy, fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI: a combination inhaled corticosteroid, long-acting muscarinic antagonist, long-acting beta agonist), in patients with chronic obstructive pulmonary disease (COPD). The study met its two co-primary endpoints, demonstrating statistically significant improvements compared with twice-daily budesonide/formoterol 400/12mcg in both lung function as measured by trough FEV1 and health-related quality of life as measured by the St. George's Respiratory Questionnaire.

FULFIL (Lung FUnction and quality of LiFe assessment in COPD with closed triPLe therapy) was a randomised, double-blind, double-dummy, parallel group multicentre study evaluating once-daily FF/UMEC/VI (100mcg/62.5mcg/ 25mcg) inhalation powder versus twice-daily budesonide/formoterol (400mcg/12mcg) via the Turbohaler dry powder inhaler. In the study, 1,810 patients were treated across 162 study centres globally.

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 June 20, 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: June 20, 2016

By:

/s/ Eric d Esparbes
Eric d Esparbes
Chief Financial Officer