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 6, 2016**

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
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:

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))

Item 7.01. Regulation FD Disclosure.

On September 6, 2016, GlaxoSmithKline plc (GSK) and Innoviva, Inc. issued a press release announcing further data presented by GSK at the European Respiratory Society (ERS) International Congress from a pivotal phase III study with investigational closed triple combination therapy fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI 100/6.2 5/25 mcg) in patients with chronic obstructive pulmonary disease (COPD). The poster presented by GSK at the ERS International Congress and the press release are furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and are incorporated by reference herein. UMEC/VI has been developed under the LABA collaboration agreement between GSK and Innoviva, Inc.

The information disclosed in this Item 7.01 is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Poster: Single inhaler triple therapy (ICS/LAMA/LABA) in patients with advanced COPD; results of the FULFIL trial
99.2	Press Release dated September 6, 2016.

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 6, 2016

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

PA4629

Single inhaler triple therapy (ICS/LAMA/LABA) in patients with advanced COPD: results of

Lomas D[1], Lipson D[2,3], Barnacle H[4], Birk R[4], Brealey N[4], Zhu C-Q[5], Tabberer M[6]

[1]UCL Respiratory, University College London, London, UK; [2]Respiratory Research and Development, GSK, King of Prussia, P
[4]Respiratory Clinical Development, GSK, Stockley Park, UK; [5]Clinical Sta

Introduction and objectives

- Treatment guidelines for patients with symptomatic advanced chronic obstructive pulmonary disease (COPD) at high risk of exacerbations recommend triple therapy using an inhaled corticosteroid (ICS), a long-acting muscarinic receptor antagonist (LAMA) and a long-acting β2-adrenergic receptor agonist (LABA).
- Triple pharmacologic therapy currently requires the use of multiple inhalers, including those delivering dual therapy, sometimes several times daily.[1]
- By offering a more practical dosing option, once-daily triple therapy via a single inhaler may offer clinically important improvements in lung function and health-related quality of life versus dual therapy with ICS/LABA.
- FULFIL (Lung FUnction and quality of LiFe assessment in COPD with closed trIpLe therapy) is the first study to examine once-daily triple combination treatment for up to 24 weeks (with a subset of patients treated for up to 52 weeks).

Methods

- FULFIL is a randomised, double-blind, double-dummy, parallel-group, multicentre study (NCT02345161, GSK study CTT116853) comparing 24 weeks of treatment with once-daily fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) inhalation powder delivered via a single ELLIPTA® inhaler or twice-daily budesonide/formoterol (BUD/FOR) delivered using the Turbohaler®.
- FULFIL enrolled patients with COPD aged ≥40 years with:
  - Forced expiratory volume in 1s (FEV_1) <50% and COPD Assessment Test (CAT) ≥10
  - Or patients with FEV_1 ≥50% to <80% with either ≥2 moderate exacerbations in the past year and CAT ≥10 or ≥1 severe exacerbation in the past year and CAT ≥10.
- Patients were randomised to receive 24 weeks of once-daily FF/UMEC/VI (100µg/62.5µg/25µg) inhalation powder delivered via a single ELLIPTA® inhaler or twice-daily BUD/FOR (400µg/12µg).
- A subset of patients remained on blinded study treatment for up to 52 weeks (extension population).

Outcomes

- The co-primary endpoints were:
  - Change from baseline in trough FEV_1 at Week 24
  - Change from baseline in St George's Respiratory Questionnaire (SGRQ) total score at Week 24.
- Secondary and other selected endpoints reported here:
  - Annual rate of on-treatment moderate and/or severe COPD exacerbations
  - Proportion of SGRQ total score responders (defined as an SGRQ total score of 4 units below baseline or lower) at Week 24.
- Baseline data were collected while patients were receiving current COPD medications.
- Safety data were analysed up to Week 24 in the intent-to-treat (ITT) population and up to Week 52 in the extension population.

Results

Patients

- FULFIL randomised 1810 patients (ITT population) who were treated with FF/UMEC/VI (n=911) or BUD/FOR (n=899)
  - The extension population included 430 of these patients.
- Of the 1810 patients, 90% (1622) completed the study and the study treatment. The most common reasons for discontinuation of study treatment were patient decision (4%), adverse event or lack of efficacy (both 3%).
- Demographic and baseline characteristics were similar between treatment arms in both the ITT (**Table 1**) and extension populations.

Table 1. Baseline demographics for 24 Week ITT population

Characteristic	FF/UMEC/VI 100/62.5/25 (n=911)	BUD/FOR 400/12 (n=899)
Mean age, years (SD)	64.2 (8.56)	63.7 (8.71)
Female, n (%)	233 (26)	236 (26)
Current smokers, n (%)	400 (44)	394 (44)
Mean smoking pack-years (SD)	39.5 (21.87)	39.2 (22.15)
CV risk factors*, n (%)	599 (66)	602 (67)
Moderate/severe COPD exacerbation in previous 12 months, n (%)		
1	252 (28)	253 (28)
≥2	346 (38)	329 (37)
History of pneumonia, n (%)	87 (10)	99 (11)
FEV, absolute, L (SD)	1.349 (0.46)	1.339 (0.48)
FEV, predicted, % (SD)	45.5 (12.97)	45.1 (13.64)
Reversibility, % (SD)	8.17 (11.13)	9.20 (11.97)

CV, cardiovascular; SD, standard deviation
*CV risk factors included, but were not limited to, hypertension, hypercholesterolaemia, coronary heart disease and diabetes mellitus

Primary endpoints

- At 24 weeks, there was a clinically meaningful and statistically significant (p<0.001) benefit for FF/UMEC/VI compared with BUD/FOR for the co-primary endpoints of mean change from baseline in trough FEV_1 and mean change from baseline in SGRQ total score (**Table 2**)
  - The benefit of treatment with FF/UMEC/VI continued in patients who maintained treatment up to Week 52 (extension population).

Secondary and other selected endpoints

- There were statistically significant reductions in the annual rates of moderate/severe and mild/moderate/severe exacerbations with FF/UMEC/VI versus BUD/FOR, up to Week 24 and up to Week 52 (**Table 3**).
- The proportion of responders assessed by SGRQ total score up to Week 24 was higher with FF/UMEC/VI (50%) than with BUD/FOR (41%; odds ratio 1.41; p<0.001).

Table 2. Co-primary endpoints at 24 weeks (ITT population)

Endpoint		FF/UMEC/VI 100/62.5/25 (n=911)	BUD/FOR 400/12 (n=899)
Trough FEV_1	**n**	836	781
	Mean change (SE)	0.142 (0.0083)	-0.029 (0.0085)
	Difference (95% CI)	0.171 (0.148 to 0.194)	
	p-value	<0.001	
SGRQ total	**n**	846	791
	Mean change (SE)	-6.6 (0.45)	-4.3 (0.46)
	Difference (95% CI)	-2.2 (-3.5 to -1.0)	
	p-value	<0.001	

SE, standard error

Table 3. On-treatment annual COPD exacerbation rates

Annual rate of COPD exacerbations	Up to 24 weeks		Up to 52 weeks	
	FF/UMEC/VI 100/62.5/25 (n=911)	BUD/FOR 400/12 (n=899)	FF/UMEC/VI 100/62.5/25 (n=210)	BUD/FOR 400/12 (n=220)
Population, n	907	892	210	219
Moderate and severe exacerbations				
Mean rate	0.22	0.34	0.20	0.36
Ratio (95% CI); p-value	0.65 (0.49 to 0.86); 0.002		0.56 (0.37 to 0.85); 0.006	
Reduction in rate, % (95% CI)	35 (14 to 51)		44 (15 to 63)	
Mild, moderate and severe exacerbations				
Mean rate	0.25	0.39	0.22	0.40
Ratio (95% CI); p-value	0.65 (0.50 to 0.84); <0.001		0.55 (0.37 to 0.81); 0.003	
Reduction in rate, % (95% CI)	35 (16 to 50)		45 (19 to 63)	

Ratios and p-values are calculated for FF/UMEC/VI vs BUD/FOR

Safety

- The safety profile of FF/UMEC/VI reflects the safety findings from the FF/VI and UMEC/VI dual therapy and UMEC monotherapy development programmes in COPD.
- Up to 24 and 52 weeks (ITT and extension populations), the most common adverse events in both treatment arms were nasopharyngitis, headache and COPD.
- The incidences of serious adverse events (SAEs) for FF/UMEC/VI and BUD/FOR respectively were 5.4% and 5.7% up to 24 weeks (ITT population), and 10% and 12.7% up to 52 weeks (extension population).
- Less than 1% of the SAEs were drug-related and there were no drug-related deaths.
- Up to 24 weeks (ITT population), the incidence of pneumonia events was higher in the FF/UMEC/VI arm than in the BUD/FOR arm; up to 52 weeks (extension population) there was no difference between the arms in the incidence of pneumonia events (**Table 4**).

Presented at the ERS International Congress, London, UK, 3–7 September 2016

PRESS RELEASE

Issued: Tuesday, 6 September 2016, London UK — LSE Announcement

GSK presents positive results from phase III FULFIL study of closed triple combination therapy FF/UMEC/VI versus Symbicort® Turbohaler® in COPD at ERS International Congress

- **Improvements in lung function and health-related quality of life supported by statistically significant reductions in exacerbations**

London and Brisbane, Calif. — September 6, 2016 — GlaxoSmithKline plc (LSE/NYSE: GSK) and Innoviva, Inc. (NASDAQ: INVA) today announced the presentation of further data from the pivotal phase III FULFIL study with investigational closed triple combination therapy fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI 100/62.5/25 mcg) in patients with chronic obstructive pulmonary disease (COPD), at the European Respiratory Society International Congress taking place in London this week.

The FULFIL study was designed to evaluate the effects of once daily FF/UMEC/VI compared with twice daily Symbicort® Turbohaler® (budesonide/formoterol 400/12 mcg) in patients with advanced COPD.

The study, which reported headline results in June 2016, met its two co-primary endpoints. At 24 weeks, there was a clinically meaningful and statistically significant ($p<0.001$) benefit for FF/UMEC/VI in both lung function, measured as mean change from baseline in trough FEV_1 (171mL, 95% confidence interval [148, 194]) and health-related quality of life, measured as mean change from baseline in St George's Respiratory Questionnaire (SGRQ) total score (-6.6 units for closed triple versus -4.3 units for budesonide/formoterol, difference of -2.2 units, 95% confidence interval [-3.5, -1.0]). In addition, the proportion of patients who responded with the minimum clinically important difference in SGRQ (-4 units) was 50% on closed triple and 41% on budesonide/formoterol (odds ratio 1.41; $p<0.001$).

This benefit of treatment with closed triple therapy was also observed in the subset of patients who received treatment for up to 52 weeks, with a statistically significant improvement of 179mL in trough FEV_1 and a numerical improvement of -2.7 units in SGRQ total score at Week 52 with closed triple therapy compared with budesonide/formoterol.

The study also showed a statistically significant and clinically meaningful reduction in the annual rate of moderate/severe exacerbations with closed triple therapy compared to budesonide/formoterol, with closed triple therapy showing a 35% reduction versus budesonide/formoterol based on data up to 24 weeks ($p=0.002$) and a 44% reduction in the subset of patients that received treatment for up to 52 weeks ($p=0.006$).

The safety profile of the closed triple combination up to 24 weeks and in the subset of patients up to 52 weeks was consistent with the known profile of the individual medicines and their combinations. Up to both 24 weeks and 52 weeks, the most common adverse events in both treatment arms were nasopharyngitis, headache and COPD worsening.

The incidence of investigator-reported serious adverse events for closed triple and budesonide/formoterol, respectively, was 5.4% and 5.7% up to 24 weeks, and 10.0% and 12.7% up to 52 weeks. Up to 24 weeks, the incidence of pneumonia was 1.0% in the closed triple arm and 0.3% in the budesonide/formoterol arm. Up to 52 weeks, it was 1.9% in the closed triple arm and 1.8% in the budesonide/formoterol arm.

Dave Allen, Head of Respiratory R&D at GSK, commented: "Exacerbations are a major cause of morbidity in COPD and reducing these symptomatic and potentially life-threatening episodes is a priority for physicians. To observe such significant reductions in exacerbations with closed triple therapy versus budesonide/formoterol is encouraging and supports our belief that a convenient, once-daily triple therapy dosing option delivered via a single inhaler could provide compelling and clinically important treatment benefits in this more severe patient population."

Mike Aguiar, CEO of Innoviva, Inc, added: "The results of the FULFIL study confirm that the closed triple therapy of FF/UMEC/VI is superior to dual therapy of budesonide/formoterol on the key measures of lung function, quality of life and exacerbation reduction. These results contribute to the medicine's positive benefit/risk profile and increase understanding of the clinical value of triple therapy in those patients that physicians decide would benefit from triple therapy versus dual therapy alone."

GSK's plans are on schedule for regulatory submissions of the closed triple combination therapy for COPD in the US and Europe by the end of 2016.

About the closed triple therapy

The closed triple therapy is a combination of three medicines: fluticasone furoate (FF), an inhaled corticosteroid (ICS), umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA) and vilanterol (VI), a long-acting $beta_2$-adrenergic agonist (LABA) delivered once-daily in GSK's Ellipta® inhaler. The FULFIL study compared FF/UMEC/VI with budesonide and formoterol, an ICS/LABA combination delivered twice-daily in the Turbohaler dry powder inhaler.

About FULFIL

FULFIL (Lung **FU**nction and quality of **L**i**F**e assessment in COPD with closed tr**I**p**L**e 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 (911 on FF/UMEC/VI and 899 on budesonide/formoterol). The population included symptomatic COPD patients (COPD assessment test $\geq$ 10) with either an FEV_1 of less than 50% predicted, or FEV_1 of 50% to less than 80% of predicted and two moderate or one severe exacerbation in the prior year.

The co-primary endpoints were: change from baseline in trough FEV_1 and SGRQ total score after 24 weeks of treatment. Other endpoints included the effect of FF/UMEC/VI on the annual rate of moderate/severe exacerbations compared with budesonide/formoterol, and the safety profile of FF/UMEC/VI compared with budesonide/formoterol over 24 weeks and 52 weeks of treatment. To provide additional longer term safety data, a sub-set of 430 patients remained on blinded study treatment for up to a total of 52 weeks.

About the ongoing clinical programme in COPD

In addition to FULFIL, the IMPACT (InforMing the PAthway of COPD Treatment) study, which began in 2014 and is expected to complete in 2017, is investigating whether FF/UMEC/VI can reduce the rate of exacerbations compared with two, once-daily dual therapies from GSK's existing portfolio: Relvar/Breo (FF/VI), an ICS/LABA combination, and Anoro (UMEC/VI), a LAMA/LABA combination.

The closed triple combination of FF/UMEC/VI is not approved for use anywhere in the world.

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.

About Symbicort Turbohaler - http://www.medicines.org.uk/emc/medicine/11882

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.

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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. 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. Examples of such statements include statements relating to: the development, regulatory and commercial plans for closed triple combination therapy, the commercialization of RELVAR®/BREO®ELLIPTA® and ANORO® ELLIPTA® in the jurisdictions in which these products have been approved; the strategies, plans and objectives of the company (including the company's growth strategy and corporate development initiatives beyond the existing respiratory portfolio); the timing, manner, amount and planned growth of anticipated potential capital returns to stockholders (including, without limitation, statements regarding the company's expectations of future share purchases and future cash dividends); the status and timing of clinical studies, data analysis and communication of results; the potential benefits and mechanisms of action of product candidates; expectations for product candidates through development and commercialization; the timing of regulatory approval of product candidates; and projections of revenue, expenses and other financial items;. 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 include, among others, risks related to: lower than expected future royalty revenue from respiratory products partnered with GSK, delays or difficulties in commencing or completing clinical studies, the potential that results from clinical or non-clinical studies indicate product candidates are unsafe or ineffective, dependence on third parties to conduct its clinical studies, delays or failure to achieve and maintain regulatory approvals for product candidates, and risks of collaborating with third parties to discover, develop and commercialize products. Other risks affecting Innoviva 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 June 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. 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)

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