

**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): **July 28, 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)

951 Gateway Boulevard

South San Francisco, California 94080

(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 (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 2.02. Results of Operations and Financial Condition.

On July 28, 2016, Innoviva, Inc. (the "Company") issued a press release and is holding a conference call regarding its results of operations and financial condition for the quarter ended June 30, 2016. A copy of the press release, which includes information regarding the Company's use of non-GAAP financial measures, is furnished as Exhibit 99.1 to this Current Report.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of 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 a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated July 28, 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: July 28, 2016

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



Innoviva Reports Second Quarter 2016 Financial Results

- Royalty revenues rose 157% compared to Q2 2015, to \$35.7 million
- U.S. TRx market share recently reached all-time highs of 10% for BREO and 8% for ANORO
- Net income of \$14.6 million, or \$0.13 per share, and Adjusted Cash EPS of \$0.17 per share
- Management will host a conference call and webcast today at 5:00 p.m. EDT

BRISBANE, Calif., July 28, 2016 — Innoviva, Inc. (NASDAQ: INVA) today reported financial results for the second quarter ended June 30, 2016. Royalties earned on net sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® from Glaxo Group Limited (GSK) during the second quarter of 2016 were \$35.7 million, up from \$13.9 million in the second quarter of 2015.

Income from operations for the second quarter of 2016 was \$25.9 million, compared with \$5.1 million in the same period in 2015. Adjusted EBITDA was \$33.9 million, compared with \$10.4 million in the second quarter of 2015. Net cash and cash equivalents, short-term investments, and marketable securities totaled \$153.9 million and reflected the repurchase of \$19.0 million in Innoviva common stock and \$7.7 million of net cash used for the purchase of Innoviva convertible subordinated notes due 2023 (\$10.0 million face value) during the second quarter of 2016. Royalties receivable from GSK totaled \$35.7 million at June 30, 2016.

“We are very pleased with the performance of the company during the second quarter which included growth in revenues, prescriptions, and market share for RELVAR/BREO ELLIPTA and ANORO ELLIPTA. According to IMS, U.S. market share recently reached 10% for BREO TRx and 8% for ANORO, an all-time high for both products,” said Michael W. Aguiar, President and Chief Executive Officer of Innoviva. “Additionally during the quarter, we returned approximately \$26.7 million of capital through repurchases of our common stock and convertible notes. This brings total capital returns through dividends and the purchase of shares and debt to over \$223.4 million since the spin-off in June 2014, consistent with our goal of providing long-term returns to our stockholders and strategically optimizing our capital structure. Looking forward, we remain optimistic about the significant growth prospects for our respiratory portfolio and for the company.”

Recent Highlights

- In the second quarter of 2016, net sales of RELVAR®/BREO® ELLIPTA® by GSK were \$209.9 million, up 156% from \$82.0 million in the second quarter of 2015, with \$112.2 million net sales in the U.S. and \$97.7 million from non-U.S. markets.
- In the second quarter of 2016, net sales of ANORO® ELLIPTA® by GSK were \$65.0 million, up 174% from \$23.7 million in the second quarter of 2015, with \$44.1 million of sales generated in the U.S. and \$20.9 million from non-U.S. markets.
- During the second quarter and up to July 27, 2016, Innoviva repurchased \$21.4 million of stock. During the quarter, the company also repurchased \$10.0 million face value of its convertible subordinated notes due 2023 for net cash consideration of \$7.7 million.

Additional Financial Results for the Second Quarter of 2016

Total revenue for the second quarter of 2016 was \$32.5 million, which primarily resulted from royalties of \$35.7 million from global net sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, compared with \$10.7 million in the second quarter of 2015. The majority of royalties earned were driven by sales of RELVAR®/BREO® ELLIPTA®. The impact of currency fluctuations on revenues was only approximately negative 2% between the first quarter of 2016 and the second quarter of 2016 due to limited exposure to the British pound. British pound denominated sales account for approximately 2% of second quarter 2016 revenues.

Operating expenses for the second quarter of 2016 were \$6.6 million, compared with \$5.5 million in the second quarter of 2015.

Net income in the second quarter of 2016 was \$14.6 million, or \$0.13 per share, which includes a gain of \$1.7 million associated with the repurchase of \$10.0 million face value of our convertible subordinated notes due 2023. This compares with a net loss of \$7.8 million or (\$0.07) per share in the second quarter of 2015. Adjusted EBITDA was \$33.9 million for the second quarter of 2016, compared with \$10.4 million in the second quarter of 2015 (a 226% increase). Adjusted Cash EPS for the second quarter of 2016 was \$0.17 per share, compared with (\$0.02) per share in the second quarter of 2015.

Conference Call and Webcast Information

To participate in Innoviva’s conference call at 5:00 p.m. EDT today, please dial (877) 837-3908 from the U.S., or (973) 890-8166 for international callers. The conference call will also be webcast live by visiting Innoviva’s website at www.inva.com or <http://edge.media-server.com/m/p/st9jxoig> and will be available for 30 days. An audio replay will also be available through August 4 by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 49092758.

Non-GAAP Financial Measures

To supplement the consolidated financial statements presented in accordance with generally accepted accounting principles in the United States, or GAAP, Innoviva uses the non-GAAP financial measures of adjusted EBITDA and Adjusted Cash EPS. A reconciliation of these non-GAAP financial measures to the closest GAAP financial measure is presented in the accompanying financial table under the headings “Reconciliation of Non-GAAP Financial Measures to GAAP.”

Innoviva believes that the non-GAAP financial information provided in this release can assist investors in understanding and assessing Innoviva's on-going operations and prospects for the future and provides an additional tool for investors to use in comparing Innoviva's financial results with other companies in Innoviva's industry or with similar operating profiles. Adjusted EBITDA and Adjusted Cash EPS are used as supplemental financial measures by Innoviva's management and frequently discussed with external users of its financial statements, such as investors, commercial banks, research analysts and others, to assess:

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- the financial performance of Innoviva's assets without regard to financing methods, capital structure, or historical cost basis;
- the ability of Innoviva's assets to generate cash sufficient to pay interest costs and support its indebtedness; and
- Innoviva's operating performance and cash return on investment compared to those of other companies, without regard to financing or capital structures.

Adjusted EBITDA is determined by taking GAAP net income and adding back interest expense (income), taxes, stock-based compensation expense, depreciation expense and amortization of capitalized fees paid to a related party. Innoviva believes the non-GAAP measure of adjusted EBITDA is important as it measures the Company's ability to generate cash to pay interest costs and support its indebtedness, and it is also used currently in the Company's annual performance review process. Innoviva's method of computing adjusted EBITDA may not be the same method used to compute similar measures reported by other companies.

Adjusted Cash EPS is determined by taking GAAP net income and adding back stock-based compensation expense, depreciation expense and amortization of capitalized fees paid to a related party, and dividing the total by the fully diluted number of shares outstanding used to calculate the GAAP diluted EPS. Innoviva believes the non-GAAP measure of Adjusted Cash EPS provides useful information about the Company's core operating performance and cash return on investment, and enhances the overall understanding of the Company's past financial performance and its prospects for the future. Innoviva's method of computing Adjusted Cash EPS may not be the same method used to compute similar measures reported by other companies.

Adjusted EBITDA and Adjusted Cash EPS should not be considered in isolation or as a substitute to net income/loss, income/loss from operations, cash flows from operating activities, earnings per share or any other measure of financial performance presented in accordance with GAAP. Adjusted EBITDA and Adjusted Cash EPS are not intended to represent cash flow and do not represent a measure of cash available for distribution. The principal limitation of these non-GAAP financial measures is that it excludes significant elements that are required by GAAP to be recorded in Innoviva's consolidated financial statements. In addition, it is subject to inherent limitations as it reflects the exercise of judgments by management in determining these non-GAAP financial measures. In order to compensate for these limitations, management of Innoviva presents its non-GAAP financial measures in connection with its GAAP results. Investors are encouraged to review the reconciliation of Innoviva's non-GAAP financial measures to their most directly comparable GAAP financial measure.

About 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. For more information, please visit Innoviva's website at www.inva.com.

ANORO®, RELVAR®, BREO® and ELLIPTA® are trademarks of the GlaxoSmithKline group of

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companies.

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: prescription and market share trends, payor coverage, the strategies, plans and objectives of the Company, future purchases under the Company's share repurchase program or otherwise, 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 products, 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 March 31, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Innoviva's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, to be filed with the SEC in the third quarter of 2016. 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. Past performance is not necessarily indicative of future 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.

Contact:

Eric d'Esparbes
 Sr. Vice President and Chief Financial Officer
 650-238-9640
 investor.relations@inva.com

INNOVIVA, INC.
 CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
 (in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(unaudited)		(unaudited)	
Revenue:				
Royalty revenue from a related party, net	\$ 32,251	\$ 10,434	\$ 56,206	\$ 17,108
Revenue from collaborative arrangements from a related party	221	221	442	443
Total revenue (1)	32,472	10,655	56,648	17,551
Operating expenses:				
Research and development (2)	370	638	762	1,350
General and administrative (2)	6,225	4,909	12,477	10,348
Total operating expenses	6,595	5,547	13,239	11,698
Income from operations	25,877	5,108	43,409	5,853
Other income (expense), net	1,719	(16)	1,687	1,162
Interest income	157	85	249	201
Interest expense	(13,156)	(12,987)	(26,313)	(25,693)
Net income (loss)	\$ 14,597	\$ (7,810)	\$ 19,032	\$ (18,477)
Basic and diluted earnings per share	\$ 0.13	\$ (0.07)	\$ 0.17	\$ (0.16)
Shares used in computing basic earnings per share	111,359	115,329	112,005	115,096
Shares used in computing diluted earnings per share	124,316	115,329	112,531	115,096
Cash dividend declared per common share	\$ —	\$ 0.25	\$ —	\$ 0.50

(1) Revenue is comprised of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(unaudited)		(unaudited)	
Royalties from a related party	\$ 35,707	\$ 13,890	\$ 63,118	\$ 24,020
Amortization of capitalized fees paid to a related party	(3,456)	(3,456)	(6,912)	(6,912)
Royalty revenue	32,251	10,434	56,206	17,108
Strategic alliance - MABA program	221	221	442	443
Total revenue from a related party	\$ 32,472	\$ 10,655	\$ 56,648	\$ 17,551

(2) Amounts include stock-based compensation expense as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(unaudited)		(unaudited)	
Research and development	\$ 172	\$ 232	\$ 347	\$ 467
General and administrative	2,669	1,590	4,358	3,288
Total stock-based compensation	\$ 2,841	\$ 1,822	\$ 4,705	\$ 3,755

INNOVIVA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Three Months Ended	
	June 30, 2016	March 31, 2016
	(unaudited)	
Revenue:		
Royalty revenue from a related party, net	\$ 32,251	\$ 23,955
Revenue from collaborative arrangements from a related party	221	221
Total revenue	<u>32,472</u>	<u>24,176</u>
Operating expenses:		
Research and development	370	392
General and administrative	6,225	6,252
Total operating expenses	<u>6,595</u>	<u>6,644</u>
Income from operations	25,877	17,532
Other income (expense), net	1,719	(32)
Interest income	157	92
Interest expense	(13,156)	(13,157)
Net income	<u>\$ 14,597</u>	<u>\$ 4,435</u>
Basic and diluted earnings per share:	\$ 0.13	\$ 0.04
Shares used in computing basic earnings per share	111,359	112,482
Shares used in computing diluted earnings per share	124,316	113,178

INNOVIVA, INC.
Consolidated Balance Sheet
(in thousands)

	June 30, 2016	December 31, 2015
	(unaudited)	(1)
Assets		
Cash, cash equivalents and marketable securities	\$ 153,866	\$ 187,283
Other current assets	36,555	27,042
Property and equipment, net	174	221
Capitalized fees paid to a related party, net	187,456	194,368
Other assets	58	18
Total assets	<u>\$ 378,109</u>	<u>\$ 408,932</u>
Liabilities and stockholders' deficit		
Other current liabilities	\$ 2,655	\$ 4,695
Accrued interest payable	7,823	7,911
Deferred revenue	3,541	3,984
Convertible subordinated notes	241,408	250,992
Non-recourse notes payable, due 2029	484,145	482,139
Other long-term liabilities	1,639	1,856
Stockholders' deficit	(363,102)	(342,645)
Total liabilities and stockholders' deficit	<u>\$ 378,109</u>	<u>\$ 408,932</u>

(1) The selected consolidated balance sheet amounts at December 31, 2015 are derived from audited financial statements.

INNOVIVA, INC.
Reconciliation of GAAP to Non-GAAP Operating Results
(in thousands)

Three Months Ended		Six Months Ended	
June 30,		June 30,	
2016	2015	2016	2015
(unaudited)		(unaudited)	

Reconciliation from GAAP net income (loss) to adjusted EBITDA:								
GAAP net income (loss)	\$	14,597	\$	(7,810)	\$	19,032	\$	(18,477)
Non-GAAP adjustments:								
Interest expense (income), net		12,999		12,902		26,064		25,492
Stock-based compensation		2,841		1,822		4,705		3,755
Depreciation		28		28		55		55
Amortization of capitalized fees paid to a related party		3,456		3,456		6,912		6,912
Adjusted EBITDA	\$	<u>33,921</u>	\$	<u>10,398</u>	\$	<u>56,768</u>	\$	<u>17,737</u>

INNOVIVA, INC.
Reconciliation of GAAP to Non-GAAP Operating Results
(in thousands)

	Three Months Ended			
	June 30, 2016	March 31, 2016		
	(unaudited)			
Reconciliation from GAAP net income to adjusted EBITDA:				
GAAP net income	\$	14,597	\$	4,435
Non-GAAP adjustments:				
Interest expense (income), net		12,999		13,065
Stock-based compensation		2,841		1,864
Depreciation		28		28
Amortization of capitalized fees paid to a related party		3,456		3,456
Adjusted EBITDA	\$	<u>33,921</u>	\$	<u>22,848</u>

INNOVIVA, INC.
Reconciliation of GAAP to Non-GAAP Operating Results
(in thousands, except per share data)

	Three Months Ended		Six Months Ended					
	June 30,		June 30,					
	2016	2015	2016	2015				
(unaudited)								
Reconciliation from GAAP net income (loss) to adjusted net income (loss) for computing Adjusted Cash EPS:								
GAAP net income (loss)	\$	14,597	\$	(7,810)	\$	19,032	\$	(18,477)
Non-GAAP adjustments:								
Stock-based compensation		2,841		1,822		4,705		3,755
Depreciation		28		28		55		55
Amortization of capitalized fees paid to a related party		3,456		3,456		6,912		6,912
Adjusted net income (loss)	\$	<u>20,922</u>	\$	<u>(2,504)</u>	\$	<u>30,704</u>	\$	<u>(7,755)</u>
Adjusted Cash EPS	\$	0.17	\$	(0.02)	\$	0.27	\$	(0.07)
Shares used in computing diluted earnings per share		124,316		115,329		112,531		115,096