

# INNOVIVA, INC.

## **FORM 8-K** (Current report filing)

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Address	2000 SIERRA POINT PARKWAY SUITE 500 BRISBANE, CA 94005
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SIC Code	2834 - Pharmaceutical Preparations
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Fiscal Year	12/31

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**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): **April 27, 2017**

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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)

**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.)

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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):

- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02. Results of Operations and Financial Condition.**

On April 27, 2017, 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 March 31, 2017. 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 April 27, 2017.

**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: April 27, 2017

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



### Innoviva Reports First Quarter 2017 Financial Results

- *Royalties earned in Q1 2017 of \$43.7 million, up 60% from Q1 2016*
- *Net income for Q1 2017 of \$16.8 million (up 280% from Q1 2016), or \$0.16 basic earnings per share, and adjusted earnings per share of \$0.19 per share*
- *Management will host a conference call and webcast today at 5:00 p.m. eastern time.*

**BRISBANE, Calif., April 27, 2017** — Innoviva, Inc. (NASDAQ: INVA) today reported financial results for the first quarter of 2017. Gross royalties earned on net sales of RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> and ANORO<sup>®</sup> ELLIPTA<sup>®</sup> from Glaxo Group Limited (GSK) during the first quarter of 2017 were \$43.7 million, up 60% from \$27.4 million in the first quarter of 2016.

Income from operations for the first quarter of 2017 was \$29.3 million (including \$4.2 million in proxy contest costs), compared with \$17.5 million for the same period in 2016. Adjusted EBITDA rose 55% to \$35.4 million, from \$22.8 million in the first quarter of 2016.

Net cash and cash equivalents, short-term investments and marketable securities totaled \$169.8 million as of March 31, 2017. Royalties receivable from GSK totaled \$43.7 million at March 31, 2017. Innoviva recently announced that on May 15, 2017, the next interest payment date under its non-recourse royalty notes due 2029 (the 2029 Notes), Innoviva will prepay \$50 million in outstanding principal, along with the required principal repayment of \$6.7 million.

“We are very pleased with the continued progress that was made during the first quarter in the ongoing global commercialization of RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> and ANORO<sup>®</sup> ELLIPTA<sup>®</sup>. Consistent with historic patterns, U.S. wholesaler inventory levels decreased in the first quarter of the year following increases in Q4 2016. As a result, TRx market share remains our primary analytical measure of commercial progress in the U.S. According to IMS, BREO and ANORO gained 3.9% and 2.7% in TRx market share respectively since the beginning of 2017 to reach all-time highs of 16.1% and 12.3% respectively, for the week ended April 14, 2017,” said Michael W. Aguiar, President and Chief Executive Officer of Innoviva. “We also continued to execute on our capital return plan, with the announcement of a \$50 million early redemption of our 2029 Notes, representing a third of our 2017 capital return plan of \$150 million.”

## Recent Highlights

- GSK Net Sales:
  - First quarter 2017 net sales of RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> by GSK were \$257.9 million, up 59% from \$ 161.9 million in the first quarter of 2016, with \$137.2 million in net sales from the U.S. market and \$120.7 million from non-U.S. markets.
  - First quarter 2017 net sales of ANORO<sup>®</sup> ELLIPTA<sup>®</sup> by GSK were \$77.5 million, up 61% from \$48.1 million in the first quarter of 2016, with \$49.1 million of sales from the U.S. market and \$28.4 million from non-U.S. markets.
- Capital Returns:
  - Announced the early redemption payment of \$50 million on the 2029 Notes to be paid on May 15, 2017.
- Corporate Update:
  - Board of Directors has appointed a special committee comprised of independent directors to undertake a fresh, comprehensive review of all Company costs, including executive compensation structures. Innoviva expects to provide shareholders with the outcome of the review in the third quarter of 2017.
- Product Updates:
  - Announced in February 2017, the positive headline results from a non-inferiority lung function study, which demonstrated that patients with well-controlled asthma were able to switch to the once-daily Relvar<sup>®</sup> Ellipta<sup>®</sup> (fluticasone furoate/vilanterol, FF/VI) 100/25, an inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) combination, from the twice-daily Seretide<sup>®</sup> Accuhaler<sup>®</sup> (fluticasone propionate /salmeterol, FP/SAL) 250/50, without compromising their lung function.

## Additional Financial Results for the First Quarter of 2017

Total net revenue for the first quarter of 2017 was \$40.5 million, compared with \$24.2 million in the first quarter of 2016. Gross royalty revenues for the first quarter of 2017 included royalties of \$38.7 million from global net sales of RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> and royalties of \$5.0 million from global net sales of ANORO<sup>®</sup> ELLIPTA<sup>®</sup>.

Total operating expenses for the first quarter of 2017 were \$11.1 million, which included \$4.2 million of proxy contest costs, compared with \$6.6 million of operating expenses in the first quarter of 2016.

Net income in the first quarter of 2017 was \$16.8 million, or \$0.16 basic earnings per share, compared with a net income of \$4.4 million, or \$0.04 basic earnings per share, in the first quarter of 2016. Adjusted earnings per share for the first quarter of 2017 totaled \$0.19 per share, compared with \$0.09 per share in the first quarter of 2016.

## Conference Call and Webcast Information

To participate in the live call, dial (877) 837-3908 from the U.S., or (973) 890-8166 for international callers, and enter Conference ID: 4743061. A live webcast of the call will be available at: <http://edge.media-server.com/m/p/7vf4ydi7> or from the investor relations section of the company website at [www.inva.com](http://www.inva.com) and will be archived for 30 days. A telephone replay of the call will be available through May 3, by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers and entering Conference ID: 4743061.

## 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 earnings per share. Generally, a non-GAAP financial measure is a numerical measure of a company's operating performance or financial position that either excludes or includes amounts that are not normally included or excluded in the most directly comparable measure calculated and presented in accordance with GAAP. A reconciliation of these non-GAAP financial measures to the closest GAAP financial measures 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, research analysts and others in understanding and assessing Innoviva's on-going operations, financial performance and prospects for the future and provides an additional tool to use in comparing Innoviva's financial results with other companies in Innoviva's industry or with similar operating profiles, without regard to financing or capital structures. Adjusted EBITDA and adjusted earnings per share are used as supplemental financial operating measures by Innoviva's management and frequently discussed with external users of its financial statements.

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 earnings per share is determined by taking adjusted net income and dividing the total by the fully diluted number of shares outstanding used to calculate the GAAP diluted EPS. Adjusted net income 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. Innoviva believes the non-GAAP measure of adjusted earnings per share provides useful information about the Company's core operating performance, and enhances the overall understanding of the Company's past financial performance and its prospects for the future. Innoviva's method of computing adjusted earnings per share may not be the same method used to compute similar measures reported by other companies.

Adjusted EBITDA, adjusted net income and adjusted earnings per share should not be considered in isolation or as a substitute to net income, income from operations, cash flows from operating activities, earnings per share or any other measure of financial performance presented in accordance with GAAP. Adjusted earnings per share is not intended to represent cash flow per share and does not represent a measure of liquidity or 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 measures.

## 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<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> and ANORO<sup>®</sup> ELLIPTA<sup>®</sup>, which were jointly developed by Innoviva and GSK. Under the agreement with GSK, Innoviva is eligible to receive associated royalty revenues from RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup>, ANORO<sup>®</sup> ELLIPTA<sup>®</sup>. 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](http://www.inva.com).

ANORO<sup>®</sup>, RELVAR<sup>®</sup>, BREO<sup>®</sup> and ELLIPTA<sup>®</sup> are trademarks of the GlaxoSmithKline group of 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, including expected cost savings. 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. The words "anticipate", "expect", "goal", "intend", "objective", "opportunity", "plan", "potential", "target" and similar expressions are intended to identify such forward-looking statements. Such forward-looking statements involve substantial risks, uncertainties and assumptions. 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: expected cost savings, lower than expected future royalty revenue from respiratory products partnered with GSK, the commercialization of RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> and ANORO<sup>®</sup> ELLIPTA<sup>®</sup> in the jurisdictions in which these products have been approved; the strategies, plans and objectives of Innoviva (including Innoviva'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 shareholders (including, without limitation, statements regarding Innoviva's expectations of future purchases under its capital return programs 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. 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, 2016, which is on file with the Securities and Exchange Commission ("SEC") and available on the SEC's website at [www.sec.gov](http://www.sec.gov). Additional factors may be described in those sections of Innoviva's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, to be filed with the SEC in the second quarter of 2017. 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. The information in this press release is provided only as of the date hereof, and 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:

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INNOVIVA, INC.  
Condensed Consolidated Statements of Operations  
(in thousands, except per share data)

	Three Months Ended March 31,	
	2017	2016
	(unaudited)	
<b>Revenue:</b>		
Royalty revenue from a related party, net	\$ 40,271	\$ 23,955
Revenue from collaborative arrangements from a related party	221	221
Total revenue <sup>(1)</sup>	40,492	24,176
<b>Operating expenses:</b>		
Research and development <sup>(2)</sup>	354	392
General and administrative <sup>(2)</sup>	6,558	6,252
General and administrative - proxy contest costs	4,237	—
Total operating expenses	11,149	6,644
Income from operations	29,343	17,532
Other income (expense), net	47	(32)
Interest income	236	92
Interest expense	(12,781)	(13,157)
Net income	\$ 16,845	\$ 4,435
Basic earnings per share	\$ 0.16	\$ 0.04
Diluted earnings per share	\$ 0.15	\$ 0.04
Shares used in computing basic earnings per share	107,487	112,482
Shares used in computing diluted earnings per share	120,336	113,178

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

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
	<b>(unaudited)</b>	
Royalties from a related party	\$ 43,727	\$ 27,411
Amortization of capitalized fees paid to a related party	(3,456)	(3,456)
Royalty revenue	40,271	23,955
Strategic alliance - MABA program	221	221
Total revenue from a related party	<u>\$ 40,492</u>	<u>\$ 24,176</u>

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

	<b>Three Months Ended March 31,</b>	
	<b>2017</b>	<b>2016</b>
	<b>(unaudited)</b>	
Research and development	\$ 178	\$ 175
General and administrative	2,329	1,689
Total stock-based compensation	<u>\$ 2,507</u>	<u>\$ 1,864</u>

INNOVIVA, INC.  
Condensed Consolidated Balance Sheets  
(in thousands)

	<b>March 31, 2017</b>	<b>December 31, 2016</b>
	<b>(unaudited)</b>	<b>(1)</b>
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 169,811	\$ 150,433
Other current assets	44,607	47,613
Property and equipment, net	328	368
Capitalized fees paid to a related party, net	177,089	180,545
Other assets	37	37
Total assets	\$ 391,872	\$ 378,996
<b>Liabilities and stockholders' deficit</b>		
Other current liabilities	\$ 6,485	\$ 3,584
Accrued interest payable	6,400	7,828
Deferred revenue	2,878	3,099
Convertible subordinated notes, net	237,724	237,597
Non-recourse notes payable, net	471,304	478,496
Other long-term liabilities	1,267	1,383
Stockholders' deficit	(334,186)	(352,991)
Total liabilities and stockholders' deficit	\$ 391,872	\$ 378,996

(1) The selected consolidated balance sheet amounts at December 31, 2016 are derived from audited financial statements.

INNOVIVA, INC.  
Cash Flows Summary  
(in thousands)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2017</b>	<b>2016</b>
	<b>(unaudited)</b>	
Net cash provided by operating activities	\$ 27,761	\$ 7,250
Net cash provided by investing activities	22,395	11,693
Net cash used in financing activities	(8,364)	(26,345)

INNOVIVA, INC.  
Reconciliation of Non-GAAP Financial Measures to GAAP  
(in thousands)

	Three Months Ended March 31,	
	2017	2016
	(unaudited)	
Reconciliation from GAAP net income to adjusted EBITDA:		
GAAP net income	\$ 16,845	\$ 4,435
Non-GAAP adjustments:		
Interest expense (income), net	12,545	13,065
Stock-based compensation	2,507	1,864
Depreciation	40	28
Amortization of capitalized fees paid to a related party	3,456	3,456
Adjusted EBITDA	<u>\$ 35,393</u>	<u>\$ 22,848</u>

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

	Three Months Ended	
	2017	2016
	March 31,	
	(unaudited)	
Reconciliation from GAAP net income to adjusted net income for computing adjusted earnings per share:		
GAAP net income	\$ 16,845	\$ 4,435
Non-GAAP adjustments:		
Stock-based compensation	2,507	1,864
Depreciation	40	28
Amortization of capitalized fees paid to a related party	3,456	3,456
Adjusted net income	<u>\$ 22,848</u>	<u>\$ 9,783</u>
Adjusted earnings per share	\$ 0.19	\$ 0.09
Shares used in computing diluted earnings per share	120,336	113,178