

INNOVIVA, INC.

FORM 8-K (Current report filing)

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**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): **February 8, 2018**

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)

(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))

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.

Item 2.02. Results of Operations and Financial Condition.

On February 8, 2018, 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 and full year ended December 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 February 8, 2018.](#)

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: February 8, 2018

By: /s/ Eric d'Esparbes

Eric d'Esparbes

Interim Principal Executive Officer



Innoviva Reports Record Fourth Quarter and Full Year 2017 Financial Results

- Royalties earned of \$70.5 million in the fourth quarter of 2017, up 51% from the fourth quarter of 2016.
- Royalties earned in 2017 reached \$227.9 million, up 56% from 2016.
- Net income attributable to Innoviva stockholders of \$58.4 million for the fourth quarter of 2017 (up 129% from the fourth quarter of 2016), or \$0.55 per basic share.
- *Management to host a conference call and webcast today at 5:00 p.m. eastern time.*

BRISBANE, Calif., February 8, 2018 — Innoviva, Inc. (NASDAQ: INVA) (the Company) today reported financial results for the fourth quarter and full year 2017. Gross royalties earned on net sales of RELVAR[®]/BREO[®] ELLIPTA[®], ANORO[®] ELLIPTA[®] and TRELEGY[®] ELLIPTA[®] from Glaxo Group Limited (GSK) during the fourth quarter of 2017 were \$70.5 million, up 51% from \$46.8 million in the fourth quarter of 2016.

Income from operations for the fourth quarter of 2017 was \$66.4 million, compared with \$37.7 million for the same period in 2016. Adjusted EBITDA rose 65% to \$72.3 million for the fourth quarter of 2017, from \$43.7 million in the fourth quarter of 2016.

Net cash and cash equivalents, short-term investments and marketable securities totaled \$129.1 million as of December 31, 2017. During the fourth quarter, Innoviva completed its previously announced capital return program through the repurchase of \$80.0 million in Innoviva common stock through an accelerated share repurchase (ASR) program. Royalties receivable from GSK totaled \$70.5 million at December 31, 2017.

“We had a successful fourth quarter of 2017 that included strong commercial performance of RELVAR[®]/BREO[®] ELLIPTA[®], ANORO[®] ELLIPTA[®], the initiation of sales by GSK in the U.S. market of TRELEGY[®] ELLIPTA[®], the completion of our 2017 \$150 million capital return plan with the successful execution of our ASR program, and the continued growth in our income from operations and adjusted EBITDA, which reached \$183.6 million and \$207.5 million in 2017, respectively” said Eric d’Esparbes, interim Principal Executive Officer of Innoviva. “We remain confident in the trajectory of our respiratory portfolio and our financial performance.”

Recent Highlights

- GSK Net Sales:
 - Fourth quarter 2017 net sales of RELVAR[®]/BREO[®] ELLIPTA[®] by GSK were \$405.3 million, up 48% from \$273.0 million in the fourth quarter of 2016, with \$241.6 million in net sales from the U.S. market and \$163.7 million from non-U.S. markets.
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- Fourth quarter 2017 net sales of ANORO[®] ELLIPTA[®] by GSK were \$147.3 million, up 62% from \$90.7 million in the fourth quarter of 2016, with \$103.3 million of sales from the U.S. market and \$44.0 million from non-U.S. markets.
- Fourth quarter 2017 net sales of TRELEGY[®] ELLIPTA[®] by GSK were \$2.8 million in the U.S. market.
- Product Updates:
 - Announced positive data from a study comparing ANORO[®] ELLIPTA[®] and Stiolto Respimat, for symptomatic patients with chronic obstructive pulmonary disease (COPD).
 - Announced in November 2017 the filing of a supplemental New Drug Application with the U.S. Food and Drug Administration for an expanded indication for the use of TRELEGY[®] ELLIPTA[®] in COPD.
- Capital Return Program:
 - Completed in December 2017 the \$80.0 million ASR program by purchasing 6.1 million shares of common stock at an average price of \$13.09 per share.
 - In 2017, in the aggregate, Innoviva repurchased \$97.5 million of common stock or 7.4 million shares (7% of outstanding shares at the beginning of the year), and repaid \$85.9 million of its long term debt.

Additional Financial Results for the Fourth Quarter and Full Year 2017

Total net royalty revenue for the fourth quarter of 2017 was \$67.1 million, up 55% compared with \$43.4 million in the fourth quarter of 2016. Gross royalty revenues for the fourth quarter of 2017 included royalties of \$60.8 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®], royalties of \$9.5 million from global net sales of ANORO[®] ELLIPTA[®] and \$0.2 million from net sales of TRELEGY[®] ELLIPTA[®] in the U.S. market.

For the full year 2017, net royalty revenues were \$214.1 million, compared to \$132.7 million in 2016, an increase of 61% during the period.

Total operating expenses for the fourth quarter of 2017 were \$3.1 million (net of \$2.7 million in D&O insurance recovery for litigation costs resulting from proxy contest) compared with \$6.0 million in the fourth quarter of 2016.

For the full year 2017, total operating expenses were \$33.6 million (including \$8.1 million in net proxy contest and litigation costs) compared to \$24.6 million for the full year of 2016.

Net income attributable to Innoviva stockholders in the fourth quarter of 2017 was \$58.4 million (or \$0.55 per basic share), up 129% from the fourth quarter of 2016.

For the full year 2017, net income attributable to Innoviva stockholders was up 125% compared to 2016, reaching \$134.1 million (or \$1.25 per basic share), compared to \$59.5 million in 2016 (or \$0.54 per basic share). Adjusted earnings per share for the full year 2017 was \$1.40 per share, compared with \$0.66 per share in the full year 2016.

Adjusted EBITDA for the fourth quarter of 2017 was \$72.2 million, up 65% from the fourth quarter of 2016. Adjusted earnings per share for the fourth quarter of 2017 was \$0.55 per share, compared with \$0.26 per share in the fourth quarter of 2016.

Conference Call and Webcast Information

Innoviva management will host a webcast and conference call at 5:00 p.m. EDT/2:00 p.m. PDT to discuss the financial results. 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: 2397629. A live webcast of the call will be available by following this link: [INVA Earnings Call Webcast](#) or from the investor relations section of the company website at www.inva.com and will be archived for 30 days. A telephone replay of the call will be available through February 15, by dialing (404) 537-3406.

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 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, 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 attributable to Innoviva stockholders and adding back interest expense (income), taxes, stock-based compensation expense, write off of debt issuance costs, 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 attributable to Innoviva stockholders and adding back stock-based compensation expense, write off of debt issuance costs, amortization of debt discount, 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 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[®], ANORO[®] ELLIPTA[®] and TRELEGY[®] 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[®] and ANORO[®] ELLIPTA[®]. In addition, Innoviva retains a 15 percent economic interest in royalty payments made by GSK for TRELEGY[®] ELLIPTA[®] and earlier-stage programs partnered with Theravance BioPharma, Inc. For more information, please visit Innoviva's website at www.inva.com.

ANORO[®], RELVAR[®], BREO[®], TRELEGY[®] and ELLIPTA[®] 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. 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[®]/BREO[®] ELLIPTA[®], ANORO[®] ELLIPTA[®] and TRELEGY[®] ELLIPTA[®] 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 future 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 and Innoviva's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, 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 Annual Report on Form 10-K for the year ended December 31, 2017, to be filed with the SEC in the first quarter of 2018. 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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Interim Principal Executive Officer and Sr. Vice President and Chief Financial Officer
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INNOVIVA, INC.
Condensed Consolidated Statements of Operations
(in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Revenue:				
Royalty revenue from a related party, net	\$ 67,084	\$ 43,391	\$ 214,118	\$ 132,684
Revenue from collaborative arrangements from a related party	2,436	221	3,099	885
Total revenue ⁽¹⁾	<u>69,520</u>	<u>43,612</u>	<u>217,217</u>	<u>133,569</u>
Operating expenses:				
Research and development ⁽²⁾	342	345	1,355	1,393
General and administrative ⁽²⁾	5,690	5,606	24,147	23,188
General and administrative - proxy contest and litigation costs	(2,921)	—	8,111	—
Total operating expenses	<u>3,111</u>	<u>5,951</u>	<u>33,613</u>	<u>24,581</u>
Income from operations	66,409	37,661	183,604	108,988
Other income (expense), net	66	638	(7,042)	2,382
Interest income	393	171	1,311	582
Interest expense	(8,354)	(13,000)	(43,601)	(52,416)
Net income	<u>58,514</u>	<u>25,470</u>	<u>134,272</u>	<u>59,536</u>
Net income attributable to noncontrolling interest	129	—	129	—
Net income attributable to Innoviva stockholders	<u>\$ 58,385</u>	<u>\$ 25,470</u>	<u>\$ 134,143</u>	<u>\$ 59,536</u>
Basic earnings per share	\$ 0.55	\$ 0.24	\$ 1.25	\$ 0.54
Diluted earnings per share	\$ 0.50	\$ 0.22	\$ 1.17	\$ 0.53
Shares used in computing basic earnings per share	106,156	107,640	106,945	110,280
Shares used in computing diluted earnings per share	119,189	120,188	119,866	123,233

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Royalties from a related party	\$ 70,539	\$ 46,847	\$ 227,941	\$ 146,507
Amortization of capitalized fees paid to a related party	(3,455)	(3,456)	(13,823)	(13,823)
Royalty revenue	67,084	43,391	214,118	132,684
Strategic alliance - MABA program	2,436	221	3,099	885
Total revenue from a related party	<u>\$ 69,520</u>	<u>\$ 43,612</u>	<u>\$ 217,217</u>	<u>\$ 133,569</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Research and development	\$ 164	\$ 142	\$ 697	\$ 632
General and administrative	2,263	1,732	9,136	7,665
Total stock-based compensation	<u>\$ 2,427</u>	<u>\$ 1,874</u>	<u>\$ 9,833</u>	<u>\$ 8,297</u>

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

	December 31, 2017 <u>(unaudited)</u>	December 31, 2016 <u>(1)</u>
Assets		
Cash, cash equivalents and marketable securities	\$ 129,075	\$ 150,433
Related party receivables from collaborative arrangements	70,540	46,847
Property and equipment, net	209	368
Capitalized fees paid to a related party, net	166,722	180,545
Other assets	791	803
Total assets	<u>\$ 367,337</u>	<u>\$ 378,996</u>
Liabilities and stockholders' deficit		
Other current liabilities	\$ 3,822	\$ 3,584
Accrued interest payable	5,920	7,828
Deferred revenue	—	3,099
Convertible subordinated notes, net	238,123	237,597
Convertible senior notes, net	124,158	—
Senior secured term loans, net	237,081	—
Non-recourse notes, net	—	478,496
Other long-term liabilities	940	1,383
Innoviva stockholders' deficit	(242,859)	(352,991)
Noncontrolling interest	152	—
Total liabilities and stockholders' deficit	<u>\$ 367,337</u>	<u>\$ 378,996</u>

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

INNOVIVA, INC.
Cash Flows Summary
(in thousands)

	Year Ended December 31,	
	2017	2016
	(unaudited)	
Net cash provided by operating activities	\$ 141,748	\$ 60,984
Net cash used in investing activities	(23,236)	(4,580)
Net cash used in financing activities	(163,192)	(97,568)

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Reconciliation from GAAP net income to adjusted EBITDA:				
GAAP net income attributable to Innoviva stockholders	\$ 58,385	\$ 25,470	\$ 134,143	\$ 59,536
Non-GAAP adjustments:				
Interest expense (income), net	7,961	12,829	42,290	51,834
Stock-based compensation	2,427	1,874	9,833	8,297
Write off of debt issuance costs	—	—	7,256	—
Depreciation	40	41	159	131
Amortization of capitalized fees paid to a related party	3,455	3,456	13,823	13,823
Adjusted EBITDA	<u>\$ 72,268</u>	<u>\$ 43,670</u>	<u>\$ 207,504</u>	<u>\$ 133,621</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Reconciliation from GAAP net income to adjusted net income for computing adjusted earnings per share:				
GAAP net income attributable to Innoviva stockholders	\$ 58,385	\$ 25,470	\$ 134,143	\$ 59,536
Non-GAAP adjustments:				
Stock-based compensation	2,427	1,874	9,833	8,297
Write off of debt issuance costs	—	—	7,256	—
Amortization of debt discount	1,434	—	2,268	—
Depreciation	40	41	159	131
Amortization of capitalized fees paid to a related party	3,455	3,456	13,823	13,823
Adjusted net income	<u>\$ 65,741</u>	<u>\$ 30,841</u>	<u>\$ 167,482</u>	<u>\$ 81,787</u>
Adjusted earnings per share	\$ 0.55	\$ 0.26	\$ 1.40	\$ 0.66
Shares used in computing diluted earnings per share	119,189	120,188	119,866	123,233