

**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 3, 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
(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:

- 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))
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Item 2.02. Results of Operations and Financial Condition

On February 3, 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 and full year ended December 31, 2015. 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 3, 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: February 3, 2016

By: /s/ Eric d'Esparbes

Eric d'Esparbes
Chief Financial Officer



Innoviva reports Fourth Quarter and Full Year 2015 Financial Results

Company reports its first quarterly net income, generating \$4.3 million in Q4 2015

Repurchased approximately \$37 million of stock through the end of January 2016

Company to host conference call and webcast today at 5:00 p.m. EDT

SOUTH SAN FRANCISCO, Calif., February 3, 2016 — Innoviva, Inc. (NASDAQ: INVA) today reported financial results for the fourth quarter and full year ended December 31, 2015. Net income for the fourth quarter of 2015 was \$4.3 million or \$0.04 per share, representing the Company's first quarterly net income since inception. This is compared to a net loss of \$4.6 million in the third quarter or \$(0.04) per share.

Royalties from sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® earned from Glaxo Group Limited (GSK) during the fourth quarter of 2015 grew by 55 percent quarter over quarter to reach \$26.1 million. Income from operations increased to \$17.3 million in the fourth quarter of 2015, compared to \$8.4 million in the third quarter, while adjusted EBITDA for the fourth quarter of 2015 increased to \$22.4 million compared to \$13.4 million in the third quarter of 2015. Cash and cash equivalents, short-term investments, and marketable securities totaled \$187.3 million as of December 31, 2015.

“This is an exciting time for Innoviva. We’ve generated our first quarterly profit since the creation of the company, maintained positive growth trends in prescriptions and market share for both RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, and ended the year in a strong position for continued growth in 2016,” said Michael W. Aguiar, President and Chief Executive Officer of Innoviva. “Following the spin-off of our research and development activities in 2014, we expected Innoviva to have a short path to profitability due to its lower cost profile and high revenue growth prospects. We are pleased to have achieved our goal this quarter. In addition, we repurchased approximately \$37.3 million of stock through Friday, January 29, 2016 under our share repurchase program, further demonstrating our commitment to generating long-term stockholder value.”

Recent Highlights

- In January 2016, the Company announced its corporate name change from Theravance, Inc. to Innoviva, Inc.
- Through January 29, 2016, Innoviva repurchased \$37.3 million of stock under its previously announced \$150 million share repurchase program through a combination of a “modified Dutch auction” tender offer (completed in December 2015) and open market purchases, with an average purchase price of \$9.49 per share.

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- In the fourth quarter of 2015, net sales of RELVAR®/BREO® ELLIPTA® by GSK were \$154.7 million, comprised of \$72.5 million in the U.S. market (an increase 79 percent from the prior quarter in the U.S.) and \$82.2 million in non-U.S. markets (an increase of 43 percent from the prior quarter).
 - As of December 31, 2015, RELVAR®/BREO® ELLIPTA® has been launched in 45 countries.
 - In the fourth quarter of 2015, sales of ANORO® ELLIPTA® by GSK were \$45.4 million, an increase of 44 percent compared to the prior quarter. Sales were \$31.2 million in the U.S. market (an increase of 42 percent from the prior quarter) and \$14.2 million in non-U.S. markets (an increase of 48 percent from the prior quarter).
 - As of December 31, 2015, ANORO® ELLIPTA® has been launched in 38 countries.

Key Clinical and Regulatory Events for 2016

- Initial results from the Salford Lung Study in COPD are expected in the first half of 2016.

Financial Results for the Fourth Quarter and Year Ended December 31, 2015

Total revenue for the fourth quarter of 2015 was \$22.8 million, which primarily resulted from royalties of \$26.1 million from net sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, representing a 55 percent quarter over quarter increase. The majority of royalties were driven by sales of RELVAR®/BREO® ELLIPTA®.

Research and development expenses for the fourth quarter of 2015 were \$0.7 million compared with \$0.5 million for the third quarter of 2015. General and administrative expenses for the fourth quarter of 2015 were \$4.8 million compared with \$4.6 million in the third quarter of 2015.

Income from operations reached \$17.3 million in the fourth quarter of 2015, an increase of more than 100 percent over the previous quarter. Adjusted EBITDA was \$22.4 million for the fourth quarter of 2015 compared to \$13.4 million for the third quarter of 2015. The Company generated a net profit of \$4.2 million or \$0.04 per share in the fourth quarter of 2015, compared to a net loss of \$4.6 million or \$(0.04) per share in the third quarter.

Cash and cash equivalents, short-term investments and marketable securities totaled \$187.3 million as of December 31, 2015.

Conference Call and Webcast Information

Innoviva has scheduled a conference call for today at 5:00 p.m. Eastern Standard Time. To participate in the live call by telephone, please dial (877) 837-3908 from the U.S., or (973) 890-8166 for international callers. Those interested in listening to the conference call live via the Internet may do so by visiting Innoviva's website at www.inva.com. To listen to the live call via the Internet, please go to the website 15 minutes prior to its start to register, download and install any necessary audio software.

A replay of the conference call will be available on Innoviva's website for 30 days. An audio replay will also be available by dialing (855) 859-2056 from the U.S., or (404) 537-3406 for international callers, and entering confirmation code 36373209.

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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 measure of adjusted EBITDA. A reconciliation of this non-GAAP financial measure to the closest GAAP financial measure is presented in the financial table below 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 is used as a supplemental financial measure by Innoviva's management and also occasionally by external users of its financial statements, such as investors, commercial banks, research analysts and others, to assess:

- 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 return on investment as compared to those of other companies, without regard to financing or capital structures.

Adjusted EBITDA is determined by taking GAAP net income from operations and adding back stock-based compensation expense from continuing operations, depreciation expense from continuing operations and amortization of capitalized fees paid to a related party. Innoviva's method of computing adjusted EBITDA may not be the same method used to compute similar measures reported by other companies.

Adjusted EBITDA should not be considered in isolation or as a substitute to net income (loss), income (loss) from operations, cash flows from operating activities or any other measure of financial performance presented in accordance with GAAP. Adjusted EBITDA is not intended to represent cash flow and does not represent the measure of cash available for distribution. The principal limitation of this non-GAAP financial measure 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.

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About Innoviva

Innoviva, formerly known as Theravance, Inc., 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 companies.

Note Regarding Share Repurchase Program

The company's discussion of its share repurchase program does not obligate the company to repurchase any specific dollar amount or number of its shares of common stock. The company will determine when, if and how to proceed with any repurchase transactions under the program, as well as the amount of any such repurchase transactions, based upon, among other things, the results of the tender offer and the company's evaluation of its liquidity and capital needs (including for strategic and other opportunities), its business, results of operations, and financial position and prospects, general financial, economic and market conditions, prevailing market prices for the company's shares of common stock, corporate, regulatory and legal requirements, and other conditions and factors deemed relevant by the company's management and Board of Directors from time to time. The share repurchase program may be suspended or discontinued at any time. There can be no assurance as to the actual volume of share repurchases in any given period or over the term of the program, if any, or as to the manner or terms of any such repurchases. This press release does not constitute an offer to sell or the solicitation of an offer to buy any securities in any jurisdiction.

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: payor coverage, the strategies, plans and objectives of the company, 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 seeking 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

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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, 2014 and Innoviva’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, 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, 2015, to be filed with the SEC in the first 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 Information:

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

(INVA-F)

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

	Three Months Ended	
	December 31, 2015	September 30, 2015
	(unaudited)	
Revenue:		
Royalty revenue from a related party, net	\$ 22,615	\$ 13,341
Revenue from collaborative arrangements from a related party, net	221	221
Total revenue	22,836	13,562
Operating expenses:		
Research and development	722	547
General and administrative	4,821	4,581
Total operating expenses	5,543	5,128
Income from operations	17,293	8,434
Other income (expense), net	3	(45)
Interest income	52	90
Interest expense	(13,047)	(13,063)
Net income (loss)	<u>\$ 4,301</u>	<u>\$ (4,584)</u>
Basic earnings per share	\$ 0.04	\$ (0.04)
Shares used in computing basic earnings per share	115,184	115,787
Cash dividends declared per share	\$ —	\$ 0.25

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

	Three Months Ended December 31,		Fiscal Years Ended December 31,	
	2015	2014	2015	2014
	(unaudited)		(unaudited)	
Revenue:				
Royalty revenue from a related party, net	\$ 22,615	\$ 7,009	\$ 53,064	\$ 7,351
Revenue from collaborative arrangements from a related party, net	221	271	885	1,082
Total revenue (1)	22,836	7,280	53,949	8,433
Operating expenses:				
Research and development (2)	722	777	2,619	7,498
General and administrative (2)	4,821	6,373	19,750	34,864
Total operating expenses	5,543	7,150	22,369	42,362
Income (Loss) from operations	17,293	130	31,580	(33,929)
Other income (expense), net	3	(3,607)	1,120	(3,272)
Interest income	52	117	343	563
Interest expense	(13,047)	(12,566)	(51,803)	(36,892)
Income (loss) from continuing operations before income taxes	4,301	(15,926)	(18,760)	(73,530)
Income tax benefit	—	—	—	—
Income (loss) from continuing operations, net of tax	4,301	(15,926)	(18,760)	(73,530)
Loss from discontinued operations	—	—	—	(94,934)
Net income (loss)	\$ 4,301	\$ (15,926)	\$ (18,760)	\$ (168,464)
Basic earnings per share:				
Continuing operations	\$ 0.04	\$ (0.14)	\$ (0.16)	\$ (0.66)
Discontinued operations	—	—	—	(0.84)
Shares used in computing basic earnings per share	115,184	114,342	115,372	112,059
Cash dividends declared per common share	\$ —	\$ 0.25	\$ 0.75	\$ 0.50

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

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	Three Months Ended December 31,		Fiscal Years Ended December 31,	
	2015	2014	2015	2014
	(unaudited)		(unaudited)	
Royalties from a related party	\$ 26,071	\$ 10,464	\$ 66,887	\$ 18,417
Amortization of capitalized fees paid to a related party	(3,456)	(3,455)	(13,823)	(11,066)
Royalty revenue	22,615	7,009	53,064	7,351
Strategic alliance - MABA program	221	271	885	1,082
Total revenue from a related party	\$ 22,836	\$ 7,280	\$ 53,949	\$ 8,433

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

	Three Months Ended December 31,		Fiscal Years Ended December 31,	
	2015	2014	2015	2014
	(unaudited)		(unaudited)	
Research and development	\$ 349	\$ 192	\$ 1,036	\$ 2,781
General and administrative	1,301	1,185	5,837	12,980
Discontinued operations	—	—	—	11,629
Total stock-based compensation expense	\$ 1,650	\$ 1,377	\$ 6,873	\$ 27,390

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	<u>2015</u> <u>(unaudited)</u>	<u>2014</u> <u>(1)</u>
Assets		
Cash, cash equivalents and marketable securities	\$ 187,283	\$ 283,354
Other current assets	27,042	11,684
Property and equipment, net	221	324
Capitalized fees paid to a related party, net	194,368	208,191
Other assets	15,158	18,101
Total assets	<u>\$ 424,072</u>	<u>\$ 521,654</u>
Liabilities and stockholders' deficit		
Other current liabilities	\$ 4,695	\$ 4,067
Payable to Theravance Biopharma, Inc.	—	1,056
Accrued interest payable	7,911	7,551
Deferred revenue	3,984	4,870
Convertible subordinated notes	255,109	255,109
Non-recourse notes payable, due 2029	493,162	470,527
Other long-term liabilities	1,856	1,823
Stockholders' deficit	<u>(342,645)</u>	<u>(223,349)</u>
Total liabilities and stockholders' deficit	<u>\$ 424,072</u>	<u>\$ 521,654</u>

(1) The selected consolidated balance sheet amounts at December 31, 2014 are derived from audited financial statements.

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

	<u>Three Months Ended</u>	
	<u>December 31, 2015</u>	<u>September 30, 2015</u>
	<u>(unaudited)</u>	
Reconciliation from GAAP net income from operations to adjusted EBITDA:		
GAAP net income from operations	\$ 17,293	\$ 8,434
Non-GAAP adjustments:		
Stock-based compensation	1,650	1,468
Depreciation	28	28
Amortization of capitalized fees paid to a related party	3,456	3,455
Adjusted EBITDA	<u>\$ 22,427</u>	<u>\$ 13,385</u>

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

	<u>Three Months Ended</u> <u>December 31,</u>		<u>Fiscal Years Ended</u> <u>December 31,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
	<u>(unaudited)</u>		<u>(unaudited)</u>	
Reconciliation from GAAP net income (loss) from operations to adjusted EBITDA:				
GAAP net income (loss) from operations	\$ 17,293	\$ 130	\$ 31,580	\$ (33,929)
Non-GAAP adjustments:				
Stock-based compensation from continuing operations	1,650	1,377	6,873	15,761
Depreciation from continuing operations	28	—	110	—
Amortization of capitalized fees paid to a related party	3,456	3,455	13,823	11,066
Adjusted EBITDA	<u>\$ 22,427</u>	<u>\$ 4,962</u>	<u>\$ 52,386</u>	<u>\$ (7,102)</u>