

**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): **October 25, 2017**

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 October 25, 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 September 30, 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.

(d) Exhibits

99.1 [Press Release dated October 25, 2017.](#)

2

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: October 25, 2017

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

3



Innoviva Reports Third Quarter 2017 Financial Results and Provides Business Updates

- Royalties earned in the third quarter of 2017 of \$51.9 million, up 42% from the third quarter of 2016.
- Completed the full refinancing of the 9% non-recourse term notes due 2029.
- Plans to repurchase up to \$80 million of common stock, pursuant to an accelerated share repurchase (ASR) plan, which will complete the company's \$150 million capital return plan for 2017.
- *Management to host a conference call and webcast today at 5:00 p.m. eastern time.*

BRISBANE, Calif., October 25, 2017 — Innoviva, Inc. (NASDAQ: INVA) (the Company) today reported financial results for the third quarter of 2017. Gross royalties earned on net sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® from Glaxo Group Limited (GSK) during the third quarter of 2017 were \$51.9 million, up 42% from \$36.5 million in the third quarter of 2016.

Income from operations for the third quarter of 2017 was \$23.8 million (including \$2.5 million in litigation costs resulting from proxy contest), compared with \$15.0 million for the same period in 2016. Adjusted EBITDA rose 39% to \$46.0 million for the third quarter of 2017, from \$33.2 million in the third quarter of 2016.

Net cash and cash equivalents, short-term investments and marketable securities totaled \$168.2 million as of September 30, 2017. Royalties receivable from GSK totaled \$51.9 million at September 30, 2017.

“We had a very successful third quarter of 2017 that included strong commercial performance of RELVAR/BREO ELLIPTA and ANORO ELLIPTA, positive regulatory outcome in the U.S. and Europe for TRELEGY ELLIPTA, a successful refinancing of our 9% non-recourse term notes, and completion of the Board of Directors expense review.” said Michael W. Aguiar, President and Chief Executive Officer of Innoviva. “We remain confident in the trajectory of our respiratory portfolio as TRx market share for both marketed products achieved new records in the U.S. of 18.4% and 15.0%, respectively during the week of October 13. As a result, we plan to continue to execute on our previously announced 2017 capital return plan through the launch of an \$80 million accelerated share repurchase program.”

Recent Highlights

- **GSK Net Sales:**
 - Third quarter 2017 net sales of RELVAR®/BREO® ELLIPTA® by GSK were \$297.4 million, up 40% from \$212.2 million in the third quarter of 2016, with \$164.4 million in net sales from the U.S. market and \$133.0 million from non-U.S. markets.
 - Third quarter 2017 net sales of ANORO® ELLIPTA® by GSK were \$111.9 million, up 57% from \$71.2 million in the third quarter of 2016, with \$74.7 million of sales from the U.S. market and \$37.2 million from non-U.S. markets.
- **Product Updates:**
 - Received in September 2017 positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use for TRELEGY ELLIPTA for the treatment of chronic obstructive pulmonary disease (COPD) in appropriate patients.
 - Received in September 2017 U.S. Food and Drug Administration approval of TRELEGY ELLIPTA for the treatment of COPD in appropriate patients.
 - Announced in September 2017 positive headline results from the IMPACT study.
- **Capital Structure:**
 - Completed in August the full refinancing of Innoviva's 9% non-recourse term notes due 2029.
 - Issued in August 2017 \$192.5 million in aggregate principal of 2.50% convertible senior notes due 2025.
 - Closed in August 2017 a \$250 million 5 year Term B loan, paying LIBOR + 4.5% interest rate.
 - Repurchased \$17.5 million in Innoviva common stock in August 2017.
- **Cost Reduction Initiative:**
 - A special committee of the Company's independent directors and the Compensation Committee completed a comprehensive review of the Company's spending, including executive and board compensation structures, outside services, T&E and other expenses.
 - Reduced cash interest spending by more than \$18 million on an annual run rate basis following the refinancing in August 2017 of the Company's 9% non-recourse term notes due 2029.
 - Reduced full year 2017 cash operating costs by \$2.2 million versus prior 2017 expense guidance, a reduction of more than 10%.
 - The Compensation Committee and the full Board reviewed executive and Board compensation plans. Details of the changes to those plans will be disclosed in the Company's 2018 Proxy Statement.

Additional Financial Results for the Third Quarter of 2017

Total net royalty revenue for the third quarter of 2017 was \$48.4 million, compared with \$33.1 million in the third quarter of 2016. Gross royalty revenues for the third quarter of 2017 included royalties of \$44.6 million from global net sales of RELVAR®/BREO® ELLIPTA® and royalties of \$7.3 million from global net sales of ANORO® ELLIPTA®.

Total operating expenses for the third quarter of 2017 were \$8.6 million compared with \$5.4 million in the third quarter of 2016, an increase of \$3.2 million. The majority of the increase during the third quarter was due to \$2.5 million of litigation costs resulting from the proxy contest.

Net income in the third quarter of 2017 was \$23.8 million, including \$6.4 million of write offs associated with the debt refinancing completed in the quarter, or \$0.22 per basic share, compared with net income of \$15.0 million, or \$0.14 per share, in the third quarter of 2016. Adjusted earnings per share for the third quarter of 2017 totaled \$0.31 per share, compared with \$0.17 per share in the third 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:2272916. A live webcast of the call will be available at: <https://edge.media-server.com/m6/p/abjk7qxo> 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 for seven days, through November 1, by dialing (404) 537-3406 and entering Conference ID: 2272916.

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.

3

Adjusted EBITDA is determined by taking GAAP net income 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 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 future 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® and ELLIPTA® are trademarks of the GlaxoSmithKline group of companies.

4

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®/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 its capital return programs including the accelerated share repurchase plan 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 June 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, to be filed with the SEC in the fourth 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Revenue:				
Royalty revenue from a related party, net	\$ 48,422	\$ 33,088	\$ 147,034	\$ 89,294
Revenue from collaborative arrangements from a related party	221	221	663	663
Total revenue ⁽¹⁾	48,643	33,309	147,697	89,957
Operating expenses:				
Research and development ⁽²⁾	311	286	1,013	1,048
General and administrative ⁽²⁾	5,822	5,105	18,457	17,582
General and administrative - proxy contest and litigation costs	2,488	—	11,032	—
Total operating expenses	8,621	5,391	30,502	18,630
Income from operations	40,022	27,918	117,195	71,327
Other income (expense), net	(6,369)	56	(7,108)	1,743
Interest income	376	162	918	411
Interest expense	(10,262)	(13,103)	(35,247)	(39,416)
Net income	\$ 23,767	\$ 15,033	\$ 75,758	\$ 34,065
Basic earnings per share	\$ 0.22	\$ 0.14	\$ 0.71	\$ 0.31
Diluted earnings per share	\$ 0.21	\$ 0.13	\$ 0.67	\$ 0.31
Shares used in computing basic earnings per share	106,841	109,282	107,236	111,128
Shares used in computing diluted earnings per share	119,796	121,993	120,120	111,583

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

Three Months Ended September 30,	Nine Months Ended September 30,
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	2017 (unaudited)		2016 (unaudited)	
Royalties from a related party	\$ 51,878	\$ 36,544	\$ 157,402	\$ 99,662
Amortization of capitalized fees paid to a related party	(3,456)	(3,456)	(10,368)	(10,368)
Royalty revenue	48,422	33,088	147,034	89,294
Strategic alliance - MABA program	221	221	663	663
Total revenue from a related party	\$ 48,643	\$ 33,309	\$ 147,697	\$ 89,957

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017 (unaudited)	2016 (unaudited)	2017 (unaudited)	2016 (unaudited)
Research and development	\$ 180	\$ 143	\$ 533	\$ 490
General and administrative	2,292	1,575	6,873	5,933
Total stock-based compensation	\$ 2,472	\$ 1,718	\$ 7,406	\$ 6,423

6

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

	September 30, 2017 (unaudited)	December 31, 2016 (1)
Assets		
Cash, cash equivalents and marketable securities	\$ 168,192	\$ 150,433
Other current assets	52,317	47,613
Property and equipment, net	249	368
Capitalized fees paid to a related party, net	170,177	180,545
Other assets	37	37
Total assets	\$ 390,972	\$ 378,996
Liabilities and stockholders' deficit		
Other current liabilities	\$ 3,433	\$ 3,584
Accrued interest payable	3,566	7,828
Deferred revenue	2,436	3,099
Convertible subordinated notes, net	237,988	237,597
Convertible senior notes, net	122,605	—
Senior secured term loans, net	242,856	—
Non-recourse notes payable, net	—	478,496
Other long-term liabilities	1,049	1,383
Stockholders' deficit	(222,961)	(352,991)
Total liabilities and stockholders' deficit	\$ 390,972	\$ 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)

	Nine Months Ended September 30,	
	2017 (unaudited)	2016
Net cash provided by operating activities	\$ 93,890	\$ 39,898
Net cash provided by (used in) investing activities	2,644	(27,900)
Net cash used in financing activities	(76,133)	(77,984)

7

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016

	(unaudited)		(unaudited)	
Reconciliation from GAAP net income to adjusted EBITDA:				
GAAP net income	\$ 23,767	\$ 15,033	\$ 75,758	\$ 34,065
Non-GAAP adjustments:				
Interest expense (income), net	9,886	12,941	34,329	39,005
Stock-based compensation	2,472	1,718	7,406	6,423
Write off of debt issuance costs	6,426	—	7,256	154
Depreciation	40	35	119	90
Amortization of capitalized fees paid to a related party	3,456	3,456	10,368	10,368
Adjusted EBITDA	<u>\$ 46,047</u>	<u>\$ 33,183</u>	<u>\$ 135,236</u>	<u>\$ 90,105</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(unaudited)		(unaudited)	
Reconciliation from GAAP net income to adjusted net income for computing adjusted earnings per share:				
GAAP net income	\$ 23,767	\$ 15,033	\$ 75,758	\$ 34,065
Non-GAAP adjustments:				
Stock-based compensation	2,472	1,718	7,406	6,423
Write off of debt issuance costs	6,426	—	7,256	154
Amortization of debt discount	834	—	834	—
Depreciation	40	35	119	90
Amortization of capitalized fees paid to a related party	3,456	3,456	10,368	10,368
Adjusted net income	<u>\$ 36,995</u>	<u>\$ 20,242</u>	<u>\$ 101,741</u>	<u>\$ 51,100</u>
Adjusted earnings per share	\$ 0.31	\$ 0.17	\$ 0.85	\$ 0.46
Shares used in computing diluted earnings per share	119,796	121,993	120,120	111,583