
**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 31, 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 October 31, 2018, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended September 30, 2018. A copy of the press release 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 October 31, 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: October 31, 2018

By: /s/ Geoffrey Hulme
Geoffrey Hulme
Interim Principal Executive Officer



Innoviva Reports Third Quarter 2018 Financial Results

- Total net revenue rose 26.8% to \$61.7 million compared with the third quarter of 2017.
- Net income attributable to Innoviva stockholders increased 98.1% from the third quarter of 2017 to \$47.1 million, or \$0.43 per diluted share.
- The Company made a partial repayment of \$110.0 million on its Term B loan.

BRISBANE, Calif., October 31, 2018 — Innoviva, Inc. (NASDAQ: INVA) (the Company) today reported financial results for the third quarter ended September 30, 2018.

- Gross royalty revenues of \$65.1 million from Glaxo Group Limited (GSK) for the third quarter of 2018 included royalties of \$51.7 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®], royalties of \$9.8 million from global net sales of ANORO[®] ELLIPTA[®] and \$3.6 million from global net sales of TRELEGY[®] ELLIPTA[®].¹
- Total operating expenses for the third quarter of 2018 were \$4.0 million (including \$2.5 million of cash severance expenses) compared with \$8.6 million (including \$2.5 million of proxy contest related litigation costs) in the third quarter of 2017. Total non-cash operating expenses for the third quarter of 2018 included (\$0.9) million in stock-based compensation compared to \$2.5 million in stock-based compensation for the third quarter of 2017.
- Net income attributable to Innoviva stockholders in the third quarter of 2018 was \$47.1 million or \$0.43 per diluted share, up 98.1% from the third quarter of 2017.
- Net cash and cash equivalents, short-term investments and marketable securities totaled \$55.5 million, and royalties receivable from GSK totaled \$65.1 million as of September 30, 2018.

Geoffrey Hulme, interim Principal Executive Officer, stated: “RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®] continued to achieve record TRx market share in the U.S., reaching 21.8% and 18.9% at the end of the third quarter of 2018, respectively. Net sales of BREO in the U.S. market returned to year-over-year growth. BREO’s rate of growth, however, was impacted by increased sales to segments with higher rebates and by reductions in distribution channel inventory. In non-US markets, RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®] continued their strong product sales growth.”

“During the quarter, Innoviva took additional actions to improve operations and reduce its long-term cost structure. The Company’s board of directors and management team remain focused on pursuing opportunities to optimize capital allocation and maximize shareholder value.”

Recent Highlights

- GSK Net Sales:
 - Third quarter 2018 net sales of RELVAR[®]/BREO[®] ELLIPTA[®] by GSK were \$345.0 million, up 16.0% from \$297.4 million in the third quarter of 2017, with \$180.4 million in net sales from the U.S. market and \$164.6 million from non-U.S. markets.
 - Third quarter 2018 net sales of ANORO[®] ELLIPTA[®] by GSK were \$150.8 million, up 34.7% from \$111.9 million in the third quarter of 2017, with \$99.7 million net sales from the U.S. market and \$51.1 million from non-U.S. markets.
 - Third quarter 2018 net sales of TRELEGY[®] ELLIPTA[®] by GSK were \$55.7 million with \$41.3 million in net sales from the U.S. market and \$14.4 million in net sales from non-U.S. markets. TRELEGY[®] ELLIPTA[®] was approved in September, 2017.
- Product Updates:
 - In September 2018, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion supporting the expanded label of TRELEGY[®] ELLIPTA[®] (fluticasone furoate/umeclidinium/ vilanterol 'FF/UMEC/VI') in chronic obstructive pulmonary disease (COPD).
- Capital Structure:
 - Made a partial prepayment in August 2018 of \$110.0 million on the principal amount outstanding under the Company's Term B loan.

¹ For TRELEGY[®] ELLIPTA[®], Innoviva is entitled to 15% of royalty payments made by GSK that are assigned to TRC, LLC.

About Innoviva

Innoviva, Inc. (referred to as "Innoviva", the "Company", or "we" and other similar pronouns) is focused on royalty management. Innoviva's portfolio includes the respiratory assets partnered with Glaxo Group Limited ("GSK"), including RELVAR[®]/BREO[®] ELLIPTA[®] (fluticasone furoate/ vilanterol, "FF/VI"), ANORO[®] ELLIPTA[®] (umeclidinium bromide/ vilanterol, "UMEC/VI") and TRELEGY[®] ELLIPTA[®] (the combination FF/UMEC/VI). Under the Long-Acting Beta2 Agonist ("LABA") Collaboration Agreement, Innoviva is eligible to receive the associated royalty revenues from RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®]. Innoviva is also entitled to 15% of royalty payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC ("TRC"), relating to TRELEGY[®] ELLIPTA[®] and any other product or combination of products that may be discovered and developed in the future under the LABA Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the "GSK Agreements"), which have been assigned to TRC other than RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®].

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 known and unknown 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; 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, 2017 and Innoviva’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and for the quarter ended June 30, 2018, 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, 2018, to be filed with the SEC in the fourth quarter of 2018. 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
Royalty revenue from a related party, net	\$ 61,680	\$ 48,422	\$ 181,146	\$ 147,034
Revenue from collaborative arrangements from a related party	—	221	—	663
Total net revenue ⁽¹⁾	<u>61,680</u>	<u>48,643</u>	<u>181,146</u>	<u>147,697</u>
Operating expenses:				
Research and development	—	311	—	1,013
General and administrative	1,489	5,822	11,711	18,457
General and administrative - proxy contest and litigation costs	—	2,488	—	11,032
General and administrative - cash severance expenses	2,530	—	5,704	—
General and administrative - related party	—	—	2,700	—
Total operating expenses	<u>4,019</u>	<u>8,621</u>	<u>20,115</u>	<u>30,502</u>
Income from operations	57,661	40,022	161,031	117,195
Other expense, net	(2,626)	(6,369)	(5,686)	(7,108)
Interest income	370	376	1,141	918
Interest expense	(5,238)	(10,262)	(19,373)	(35,247)
Net income	<u>50,167</u>	<u>23,767</u>	<u>137,113</u>	<u>75,758</u>
Net income attributable to noncontrolling interest	3,078	—	5,817	—
Net income attributable to Innoviva stockholders	<u>\$ 47,089</u>	<u>\$ 23,767</u>	<u>\$ 131,296</u>	<u>\$ 75,758</u>
Basic net income per share attributable to Innoviva stockholders	\$ 0.47	\$ 0.22	\$ 1.30	\$ 0.71
Diluted net income per share attributable to Innoviva stockholders	\$ 0.43	\$ 0.21	\$ 1.19	\$ 0.67
Shares used to compute basic net income per share	100,936	106,841	100,806	107,236
Shares used to compute diluted net income per share	113,363	119,796	113,444	120,120

(1) Total net revenue is comprised of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
	(unaudited)		(unaudited)	
Royalties from a related party	\$ 65,136	\$ 51,878	\$ 191,514	\$ 157,402
Amortization of capitalized fees paid to a related party	(3,456)	(3,456)	(10,368)	(10,368)
Royalty revenue	61,680	48,422	181,146	147,034
Strategic alliance - MABA program license	—	221	—	663
Total net revenue	<u>\$ 61,680</u>	<u>\$ 48,643</u>	<u>\$ 181,146</u>	<u>\$ 147,697</u>

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

	September 30, 2018 (unaudited)	December 31, 2017 (1)
Assets		
Cash, cash equivalents and marketable securities	\$ 55,480	\$ 129,075
Other current assets	65,649	71,294
Property and equipment, net	173	209
Capitalized fees paid to a related party, net	156,354	166,722
Other assets	37	37
Total assets	\$ 277,693	\$ 367,337
Liabilities and stockholders' deficit		
Other current liabilities	\$ 2,524	\$ 3,822
Accrued interest payable	1,775	5,920
Convertible subordinated notes, net	238,525	238,123
Convertible senior notes, net	129,040	124,158
Senior secured term loans, net	13,437	237,081
Other long-term liabilities	668	940
Innoviva stockholders' deficit	(111,357)	(242,859)
Noncontrolling interest	3,081	152
Total liabilities and stockholders' deficit	\$ 277,693	\$ 367,337

(1) The selected consolidated balance sheet amounts at December 31, 2017 are derived from audited financial statements.

INNOVIVA, INC.
Cash Flows Summary
(in thousands)

	Nine Months Ended September 30,	
	2018	2017
	(unaudited)	
Net cash provided by operating activities	\$ 161,754	\$ 93,890
Net cash provided by investing activities	49,113	2,644
Net cash used in financing activities	(235,588)	(76,133)

Investor & Media Contacts:

Dan Zacchei / Alex Kovtun
Sloane & Company
212-446-9500
dzacchei@sloanep.com / akovtun@sloanep.com
