Innoviva Reports Fourth Quarter 2018 Financial Results

February 6, 2019

- Total net revenue rose 15% to $79.9 million in the fourth quarter of 2018 compared with the fourth quarter of 2017.[1]
- Income before income taxes increased 25% from the fourth quarter of 2017 to $73.1 million.

BRISBANE, Calif.--(BUSINESS WIRE)--Feb. 6, 2019-- Innoviva, Inc. (NASDAQ: INVA) (the Company) today reported financial results for the fourth quarter ended December 31, 2018.

- Gross royalty revenues of $83.3 million from Glaxo Group Limited ("GSK") for the fourth quarter of 2018 included royalties of $64.8 million from global net sales of RELVAR®/BREO® ELLIPTA®, royalties of $12.1 million from global net sales of ANORO® ELLIPTA® and $6.4 million from global net sales of TRELEGY® ELLIPTA®.[2]
- Total operating expenses for the fourth quarter of 2018 were $2.6 million compared with $3.1 million (including $2.9 million for insurance recovery and legal fee discount) in the fourth quarter of 2017. Total non-cash operating expenses for the fourth quarter of 2018 included $0.5 million in stock-based compensation compared to $2.4 million in stock-based compensation for the fourth quarter of 2017.
- In the fourth quarter of 2018, the Company recorded an income tax benefit of approximately $196.1 million related to the reversal of a valuation allowance on its deferred tax assets. This non-cash income tax benefit is non-recurring and relates primarily to $0.8 billion of U.S. federal net operating losses, and certain federal R&D credits which are expected to be utilized in the future. The Company expects to recognize income tax expense in 2019 and future periods, primarily based on the 21% federal tax rate, but it doesn't expect to use cash to pay income taxes until after it utilizes the available deferred tax assets.

- Net cash and cash equivalents, short-term investments and marketable securities totaled $114.9 million, and royalties receivable from GSK totaled $83.3 million, as of December 31, 2018.

"Global net sales of RELVAR®/BREO® ELLIPTA® increased 7% versus the fourth quarter of 2017 –U.S. net sales decreased 2% as increased pricing discounts in the respiratory sector offset volume growth while non-U.S. sales continued their strong growth and increased 19% compared to 2017. Global net sales of ANORO® ELLIPTA® grew 26% versus the fourth quarter of 2017 – U.S. net sales increased 22% due to continued growth of the LABA/LAMA class while non-U.S. sales were up 37%", stated Geoffrey Hulme, interim Principal Executive Officer.

Hulme continued, "With the efforts taken by the new board of directors and management in 2018, Innoviva enters 2019 with simplified operations, lower debt levels, and increasing cash balances. Although the exact timing of generic Advair in the U.S. was unknowable, the approval was expected. And, despite changing market dynamics in the U.S., we believe in the value proposition of Breo and the Ellipta device and are pleased by the continued strong growth of the respiratory products ex-U.S. in the face of generic Advair. Management and the board remain focused on optimizing capital allocation and maximizing shareholder value."

Recent Highlights

- GSK Net Sales:
  - Fourth quarter 2018 net sales of RELVAR®/BREO® ELLIPTA® by GSK were $431.6 million, up 7% from $405.3 million in the fourth quarter of 2017, with $236.4 million in net sales from the U.S. market and $195.2 million from non-U.S. markets.
  - Fourth quarter 2018 net sales of ANORO® ELLIPTA® by GSK were $186.2 million, up 26% from $147.3 million in the fourth quarter of 2017, with $125.7 million net sales from the U.S. market and $60.5 million from non-U.S. markets.
  - Fourth quarter 2018 net sales of TRELEGY® ELLIPTAby GSK were $99.0 million with $75.8 million in net sales from the U.S. market and $23.2 million in net sales from non-U.S. markets. TRELEGY® ELLIPTA® was approved in the U.S. in September 2017.
- Product Updates:
  - In November 2018, the European Commission authorized an expanded label of TRELEGY® ELLIPTA® (fluticasone furoate/umeclidinium/ vilanterol 'FF/UMEC/VI') for once daily use in patients with moderate to severe chronic obstructive pulmonary disease (COPD) not adequately treated with dual bronchodilators or with an inhaled corticosteroid (ICS) and a long-acting β2-agonist (LABA).

[1] The fourth quarter of 2017 included $2.4 million of revenue attributable to the completion of the company's performance obligations under the MABA program.

[2] 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 entitled to receive royalties from GSK on sales of 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®.

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, and amount of 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 quarters ended March 31, June 30 and September 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 Annual Report on Form 10-K for the year ended December 31, 2018, to be filed with the SEC in the first quarter of 2019. 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 December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenue:				
Royalty revenue from a related party, net	$ 79,858	$ 67,084	$ 261,004	$ 214,118
Revenue from collaborative arrangements from a related party	-	2,436	-	3,099
Total net revenue [1]	79,858	69,520	261,004	217,217
Operating expenses:				
Research and development	-	342	-	1,355
General and administrative	2,638	5,690	14,349	24,147
General and administrative - proxy contest and litigation costs	-	(2,921)	-	8,111
General and administrative - cash severance expenses	-	-	5,704	-
General and administrative - related party	-	-	2,700	-
Total operating expenses	2,638	3,111	22,753	33,613
Income from operations	77,220	66,409	238,251	183,604
Other income (expense), net	(16)	70	(5,702)	(7,038)
Interest income	519	393	1,660	1,311
Interest expense	(4,581)	(8,354)	(23,954)	(43,601)

Income before income taxes	73,142	58,518	210,255	134,276
Income tax benefit (expense), net	196,073	(4)	196,073	(4)
Net income	269,215	58,514	406,328	134,272
Net income attributable to noncontrolling interest	5,455	129	11,272	129
Net income attributable to Innoviva stockholders	$ 263,760	$ 58,385	$ 395,056	$ 134,143
Basic net income per share attributable to Innoviva stockholders	$ 2.61	$ 0.55	$ 3.92	$ 1.25
Diluted net income per share attributable to Innoviva stockholders	$ 2.34	$ 0.50	$ 3.53	$ 1.17
Shares used to compute basic net income per share	100,979	106,156	100,849	106,945
Shares used to compute diluted net income per share	113,299	119,189	113,408	119,866

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018 (unaudited)	2017	2018 (unaudited)	2017
Royalties from a related party	$ 83,313	$ 70,539	$ 274,827	$ 227,941
Amortization of capitalized fees paid to a related party	(3,455)	(3,455)	(13,823)	(13,823)
Royalty revenue	79,858	67,084	261,004	214,118
Strategic alliance - MABA program license	-	2,436	-	3,099
Total net revenue	$ 79,858	$ 69,520	$ 261,004	$ 217,217

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

	December 31, 2018 (unaudited)	December 31, 2017 (1)
Assets		
Cash, cash equivalents and marketable securities	$ 114,908	$ 129,075
Other current assets	84,135	71,294
Property and equipment, net	160	209
Capitalized fees paid to a related party, net	152,899	166,722
Deferred tax assets	196,054	-
Other assets	37	37
Total assets	$ 548,193	$ 367,337
Liabilities and stockholders' equity (deficit)		
Other current liabilities	$ 1,436	$ 3,822
Accrued interest payable	4,264	5,920
Convertible subordinated notes, net	238,664	238,123
Convertible senior notes, net	130,734	124,158
Senior secured term loans, net	13,457	237,081
Other long-term liabilities	586	940
Innoviva stockholders' equity (deficit)	153,583	(242,859)
Noncontrolling interest	5,469	152
Total liabilities and stockholders' equity (deficit)	$ 548,193	$ 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)

	Year Ended December 31,	
	2018	2017
	(unaudited)	
Net cash provided by operating activities	$ 223,531	$ 141,749
Net cash provided by (used in) investing activities	3,519	(23,236)
Net cash used in financing activities	(237,969)	(163,193)

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