
**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 5, 2020**

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)

**1350 Old Bayshore Highway,
Suite 400**

Burlingame, California 94010

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	INVA	The NASDAQ Global Select Market

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 5, 2020, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended December 31, 2019. 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 February 5, 2020](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: February 5, 2020

INNOVIVA, INC.

By: /s/ Geoffrey Hulme

Geoffrey Hulme

Interim Principal Executive Officer



Innoviva Reports Fourth Quarter 2019 Financial Results

- Total net revenue decreased by 4.9% to \$76.0 million in the fourth quarter of 2019, compared to the same quarter in 2018.
- Income before income taxes decreased by 3.9% to \$70.3 million in the fourth quarter of 2019, compared to the same quarter in 2018.

BURLINGAME, Calif., February 5, 2020 – Innoviva, Inc. (NASDAQ: INVA) (the Company) today reported financial results for the fourth quarter ended December 31, 2019.

- Gross royalty revenues of \$79.4 million from Glaxo Group Limited (“GSK”) for the fourth quarter of 2019 included royalties of \$53.1 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®], royalties of \$11.9 million from global net sales of ANORO[®] ELLIPTA[®] and \$14.4 million from global net sales of TRELEGY[®] ELLIPTA[®].¹
- Total operating expenses for the fourth quarter of 2019 were \$2.3 million, compared with \$2.6 million in the fourth quarter of 2018. Stock-based compensation for the fourth quarter of 2019 and 2018 was \$0.5 million.
- Net cash and cash equivalents, short-term investments and marketable securities totaled \$350.8 million, and royalties receivable from GSK totaled \$79.4 million, as of December 31, 2019.

“Global net sales of RELVAR[®]/BREO[®] ELLIPTA[®] decreased 18% versus the fourth quarter of 2018. U.S. net sales declined 42% as increased pricing discounts in the ICS/LABA sector offset volume growth. Non-U.S. sales increased 11% versus the fourth quarter of 2018, driven by market share gains in certain European markets and continued growth in Japan. Non-U.S. sales growth was negatively impacted by foreign currency translation; in constant exchange rates (CER), RELVAR[®]/BREO[®] ELLIPTA[®] non-US net sales grew 16%.”

“ANORO[®] ELLIPTA[®] global net sales declined 2% in the fourth quarter of 2019. U.S. net sales declined 7%, as increased amounts of sales through market segments with higher rebates and reduced channel inventories offset volume growth. Non-U.S. ANORO[®] ELLIPTA[®] net sales grew 9% year over year in the quarter. Non-U.S. sales growth was negatively impacted by foreign currency translation; in constant exchange rates (CER), ANORO[®] ELLIPTA[®] non-US net sales grew 13%.”

In addition, TRELEGY[®] ELLIPTA[®] global net sales were \$221.4 million,” stated Geoffrey Hulme, Interim Principal Executive Officer.

Hulme continued, “Despite new generic entrants in the U.S. ICS/LABA class at the beginning of 2019, and the resulting negative impact on BREO[®] ELLIPTA[®]’s pricing, Innoviva’s full-year income from operations rose versus 2018, its cash resources increased meaningfully, and its debt levels continued to decline. The company enters 2020 in an advantageous financial and operating position.”

Hulme concluded, “Subsequent to the end of the fourth quarter, and as part of our ongoing efforts to maximize shareholder value, we were excited to announce our pending investment in Armata Pharmaceuticals, a leader in the emerging bacteriophage therapeutic area. The increasing global health risk posed by antibiotic-resistant bacterial infections has created a growing need for alternative, differentiated options. Innoviva’s pending investment will help Armata advance its bacteriophage platform into the clinic. This transaction is consistent with the commitment of the board and management to prudently and opportunistically deploy capital in order to create shareholder value.”

Recent Highlights

- GSK Net Sales:
 - Fourth quarter 2019 net sales of RELVAR[®]/BREO[®] ELLIPTA[®] by GSK were \$354.4 million, down 18% from \$431.7 million in the fourth quarter of 2018, with \$137.2 million in net sales from the U.S. market and \$217.2 million from non-U.S. markets.
 - Fourth quarter 2019 net sales of ANORO[®] ELLIPTA[®] by GSK were \$182.7 million, down 2% from \$186.2 million in the fourth quarter of 2018, with \$116.8 million net sales from the U.S. market and \$65.9 million from non-U.S. markets.
 - Fourth quarter 2019 net sales of TRELEGY[®] ELLIPTA[®] by GSK were \$221.4 million, up significantly from \$99.0 million in the fourth quarter of 2018, with \$162.4 million in net sales from the U.S. market and \$59.0 million in net sales from non-U.S. markets.
- Capital Allocation:
 - In December 2019, the Company paid off the remaining principal balance of its senior secured term loans.
 - On January 27, 2020, the Company entered into a securities purchase agreement with Armata Pharmaceuticals, Inc. (NYSE American: ARMP), pursuant to which it will purchase, upon satisfaction of certain closing conditions, approximately \$25 million of Armata common stock and warrant securities.

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 a company with a portfolio of royalties that include 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[®].

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, 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, 2018, which is on file with the Securities and Exchange Commission (“SEC”) and available on the SEC’s website at www.sec.gov. 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 Income
(in thousands, except per share data)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenue:				
Royalty revenue from a related party, net ⁽¹⁾	\$ 75,971	\$ 79,858	\$ 261,016	\$ 261,004
Operating expenses:				
General and administrative	2,332	2,638	14,656	14,349
General and administrative - cash severance expenses	-	-	-	5,704
General and administrative - related party	-	-	-	2,700
Total operating expenses	<u>2,332</u>	<u>2,638</u>	<u>14,656</u>	<u>22,753</u>
Income from operations	73,639	77,220	246,360	238,251
Other expense, net	(223)	(16)	(345)	(5,702)
Interest income	1,538	519	5,540	1,660
Interest expense	(4,689)	(4,581)	(18,660)	(23,954)
Income before income taxes	70,265	73,142	232,895	210,255
Income tax benefit (expense), net	(12,403)	196,073	(41,902)	196,073
Net income	57,862	269,215	190,993	406,328
Net income attributable to noncontrolling interest	11,913	5,455	33,705	11,272
Net income attributable to Innoviva stockholders	<u>\$ 45,949</u>	<u>\$ 263,760</u>	<u>\$ 157,288</u>	<u>\$ 395,056</u>
Basic net income per share attributable to Innoviva stockholders	\$ 0.45	\$ 2.61	\$ 1.55	\$ 3.92
Diluted net income per share attributable to Innoviva stockholders	\$ 0.42	\$ 2.34	\$ 1.43	\$ 3.53
Shares used to compute basic net income per share	101,199	100,979	101,150	100,849
Shares used to compute diluted net income per share	113,453	113,299	113,409	113,408

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
Royalties from a related party	\$ 79,426	\$ 83,313	\$ 274,839	\$ 274,827
Amortization of capitalized fees paid to a related party	(3,455)	(3,455)	(13,823)	(13,823)
Royalty revenue from a related party, net	<u>\$ 75,971</u>	<u>\$ 79,858</u>	<u>\$ 261,016</u>	<u>\$ 261,004</u>

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

	December 31, 2019 (unaudited)	December 31, 2018 (1)
Assets		
Cash, cash equivalents and marketable securities	\$ 350,845	\$ 114,908
Other current assets	80,389	84,135
Property and equipment, net	33	160
Capitalized fees paid to a related party, net	139,076	152,899
Deferred tax assets	154,171	196,054
Other assets	312	37
Total assets	\$ 724,826	\$ 548,193
Liabilities and stockholders' equity		
Other current liabilities	\$ 1,219	\$ 1,436
Accrued interest payable	4,152	4,264
Convertible subordinated notes, net	239,217	238,664
Convertible senior notes, net	137,903	130,734
Senior secured term loans, net	-	13,457
Other long-term liabilities	219	586
Innoviva stockholders' equity	313,495	153,583
Noncontrolling interest	28,621	5,469
Total liabilities and stockholders' equity	\$ 724,826	\$ 548,193

(1) The selected consolidated balance sheet amounts at December 31, 2018 are derived from audited financial statements.

INNOVIVA, INC.
Cash Flows Summary
(in thousands)

	Year Ended December 31,	
	2019	2018
	(unaudited)	
Net cash provided by operating activities	\$ 257,458	\$ 223,531
Net cash provided by (used in) investing activities	(18,003)	3,519
Net cash used in financing activities	(23,776)	(237,969)

Investor & Media Contacts:

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