
**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 9, 2022**

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 9, 2022, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended December 30, 2021. 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 9, 2022](#)

104 Cover Page Interactive File (the cover page tags are 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.

INNOVIVA, INC.

Date: February 9, 2022

By: /s/ Pavel Raifeld

Pavel Raifeld
Chief Executive Officer

Innoviva Reports Fourth Quarter 2021 Financial Results

- Royalties increased by 18% to \$111.1 million in the fourth quarter of 2021, compared to the same quarter in 2020; royalties increased by 19% to \$405.7 million in full year 2021, compared to the prior year.
- Announced strategic investment of \$45.0 million into Armata Pharmaceuticals, Inc. (NYSE: ARMP), an anti-infectives leader, in February 2022 following a \$4.0 million investment in the fourth quarter of 2021.

BURLINGAME, Calif., February 9, 2022 – Innoviva, Inc. (NASDAQ: INVA) (“Innoviva” and “the Company”) today reported financial results for the fourth quarter and the year ended December 31, 2021.

- Gross royalty revenues of \$111.1 million from Glaxo Group Limited (“GSK”) for the fourth quarter of 2021 included royalties of \$57.7 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®], royalties of \$10.8 million from global net sales of ANORO[®] ELLIPTA[®] and royalties of \$42.6 million from global net sales of TRELEGY[®] ELLIPTA[®].¹ Gross royalty revenues were \$405.7 million in full year 2021.
- Income from operations increased by 23% to \$104.5 million, compared to the same quarter in 2020, because of higher royalty revenues and lower operating expenses. Income from operations increased by 17% to \$375.1 million in full year 2021, compared to the prior year.
- Decrease in fair values of strategic equity and long-term investments of \$42.9 million in the fourth quarter of 2021 was mainly due to the volatility in the capital markets. However, for full year 2021, the fair value of such strategic equity and long-term investments increased by \$91.0 million.
- Net cash and cash equivalents totaled \$201.5 million, and receivables from GSK totaled \$110.7 million, as of December 31, 2021.

Pavel Raifeld, Chief Executive Officer of Innoviva, Inc., stated “Our royalty revenues in the fourth quarter grew 18% year over year, displaying strong positive momentum in a volatile environment.”

“RELVAR[®]/BREO[®] ELLIPTA[®] global net sales increased 3% compared to the fourth quarter of 2020 supported by increased patient adherence and favorable prior period adjustments in the U.S. market. Non-U.S. sales decreased slightly due to class-wide pandemic pressures affecting new patient growth. ANORO[®] ELLIPTA[®] global net sales decreased by 17% compared to fourth quarter of 2020 mainly due to by pandemic-driven LABA/LAMA class weakness in the U.S. Non-U.S. ANORO[®] ELLIPTA[®] net sales also decreased slightly due to lower than expected class growth driven predominantly by the ongoing pandemic. TRELEGY[®] ELLIPTA[®] global net sales increased 53% compared to fourth quarter of 2020, driven by strong U.S. growth for the triple therapy class and favorable prior period adjustments. Non-US TRELEGY[®] ELLIPTA[®] sales also grew meaningfully supported by class growth and continued launches in new markets.”

Mr. Raifeld concluded, “Our core royalty business has performed very well last year under challenging conditions, attesting to its multiple growth drivers and significant diversification. We are equally pleased with the progress across our strategic investments and the repurchase of GSK’s equity stake, collectively accounting for over \$450 million deployed in 2021 and contributing to our diluted net income per share growth of over 40% to \$2.87. Our excellent operating cash flow generation, exceeding \$350 million in 2021, and strong cash position enable thoughtful, flexible business development, and we are excited about many opportunities we see in the current environment to advance our strategy. We are well positioned for and remain laser focused on continued strong execution to ensure sustained shareholder value creation.”

Recent Highlights

- GSK Net Sales:
 - o Fourth quarter 2021 net sales of RELVAR®/BREO® ELLIPTA® by GSK were \$384.4 million, up 3% from \$372.8 million in the fourth quarter of 2020, with \$158.2 million in net sales from the U.S. market and \$226.2 million from non-U.S. markets.
 - o Fourth quarter 2021 net sales of ANORO® ELLIPTA® by GSK were \$166.7 million, down 17% from \$200.9 million in the fourth quarter of 2020, with \$85.3 million net sales from the U.S. market and \$81.4 million from non-U.S. markets.
 - o Fourth quarter 2021 net sales of TRELEGY® ELLIPTA® by GSK were \$480.2 million, up 53% from \$313.6 million in the fourth quarter of 2020, with \$337.1 million in net sales from the U.S. market and \$143.1 million in net sales from non-U.S. markets.
- Strategic Investments:
 - o During the fourth quarter of 2021, the Company invested \$4.0 million to acquire 1.2 million shares of Armata Pharmaceuticals, Inc. (“Armata”) common stock at \$3.30 per share, which resulted in total ownership of approximately 60% of Armata’s outstanding stock (without giving effect to our warrants).
 - o In February 2022, the Company entered into an agreement with Armata, pursuant to which it will invest, subject to certain closing conditions, additional \$45.0 million in 9 million shares of Armata common stock and warrants to purchase up to 4.5 million shares of Armata common stock with an exercise price of \$5.00 per share in two tranches. At the closing of the first tranche, Innoviva acquired approximately 3.6 million shares of Armata common stock and 1.8 million warrants for an aggregate purchase price of \$18.1 million. Upon closing of the second tranche, Innoviva expects to own approximately 70% of Armata’s outstanding stock.

¹ For TRELEGY® ELLIPTA®, the amount represents 100% of royalty payments made by GSK to Theravance Respiratory Company, LLC (“TRC”). Innoviva owns 15% of the economic interest in TRC.

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; the impact of the novel coronavirus (“COVID-19”). 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, 2020 and Quarterly Reports on Form 10-Q, which are 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,	
	2021	2020	2021	2020
Revenue:				
Royalty revenue from a related party, net ⁽¹⁾	\$ 107,680	\$ 90,476	\$ 391,866	\$ 326,794
Revenue from collaborative arrangements with a related party	-	-	-	10,000
Total net revenue	<u>107,680</u>	<u>90,476</u>	<u>391,866</u>	<u>336,794</u>
Operating expenses:				
Research and development	40	219	576	1,788
General and administrative	3,113	5,470	16,187	13,883
Total operating expenses	<u>3,153</u>	<u>5,689</u>	<u>16,763</u>	<u>15,671</u>
Income from operations	104,527	84,787	375,103	321,123
Interest and dividend income	454	23	1,839	1,524
Other income (expense), net	(708)	(433)	(3,626)	(348)
Interest expense	(4,841)	(4,651)	(19,070)	(18,331)
Changes in fair values of equity and long-term investments, net	(42,943)	11,032	91,030	50,277
Income before income taxes	56,489	90,758	445,276	354,245
Income tax expense, net	10,839	15,742	76,439	60,431
Net income	45,650	75,016	368,837	293,814
Net income attributable to noncontrolling interest	35,305	21,113	102,983	69,412
Net income attributable to Innoviva stockholders	<u>\$ 10,345</u>	<u>\$ 53,903</u>	<u>\$ 265,854</u>	<u>\$ 224,402</u>
Basic net income per share attributable to Innoviva stockholders	\$ 0.15	\$ 0.53	\$ 3.24	\$ 2.21
Diluted net income per share attributable to Innoviva stockholders	\$ 0.14	\$ 0.48	\$ 2.87	\$ 2.02
Shares used to compute basic net income per share	69,492	101,361	82,062	101,320
Shares used to compute diluted net income per share	81,770	113,590	94,311	113,554

(1) Total net revenue from a related party is comprised of the following (in thousands):

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
			(unaudited)	
Royalties from a related party	\$ 111,135	\$ 93,931	\$ 405,689	\$ 340,617
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>\$ 107,680</u>	<u>\$ 90,476</u>	<u>\$ 391,866</u>	<u>\$ 326,794</u>

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

	December 31, 2021	December 31, 2020
		(1)
Assets		
Cash and cash equivalents	\$ 201,525	\$ 246,487
Other current assets	112,148	95,571
Property and equipment, net	12	28
Equity and long-term investments	483,845	438,258
Capitalized fees paid to a related party, net	111,430	125,253
Deferred tax assets, net	17,327	93,759
Other assets	108	214
Total assets	\$ 926,395	\$ 999,570
Liabilities and stockholders' equity		
Other current liabilities	\$ 1,655	\$ 1,958
Accrued interest payable	4,152	4,152
Convertible subordinated notes, net	240,364	239,783
Convertible senior notes, net	154,289	145,734
Other long-term liabilities	-	106
Innoviva stockholders' equity	414,743	539,912
Noncontrolling interest	111,192	67,925
Total liabilities and stockholders' equity	\$ 926,395	\$ 999,570

(1) The selected consolidated balance sheet amounts at December 31, 2020 are derived from audited financial statements.

INNOVIVA, INC.
Cash Flows Summary
(in thousands)

	Year Ended December 31,	
	2021	2020
		(unaudited)
Net cash provided by operating activities	\$ 363,813	\$ 313,113
Net cash provided by (used in) investing activities	43,722	(314,937)
Net cash used in financing activities	(452,497)	(29,785)

Investor & Media Contacts:

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