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 28, 2023**

INNOVIVA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**000-30319**	**94-3265960**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 28, 2023, Innoviva, Inc. (the "Company") issued a press release regarding its results of operations and financial condition for the quarter ended December 31, 2022. 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 28, 2023
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 28, 2023

By: /s/ Pavel Raifeld

Pavel Raifeld
Chief Executive Officer

Exhibit 99.1

Innoviva Reports Fourth Quarter 2022 Financial Results and Highlights Recent Company Progress

- *Royalties of $54.7 million in the fourth quarter of 2022 for RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®*
- *Net product sales of $14.6 million in the fourth quarter of 2022 for GIAPREZA® and XERAVA®*
- *$100 million share repurchase program initiated in the fourth quarter of 2022*
- *Sapna Srivastava, Ph.D., appointed to the Company's Board of Directors*

BURLINGAME, Calif.—(BUSINESS WIRE)— February 28, 2023—Innoviva, Inc. (NASDAQ: INVA) ("Innoviva" or "the Company"), a diversified holding company with a portfolio of royalties and other healthcare assets, today reported financial results for the fourth quarter ended December 31, 2022.

- Gross royalty revenues of $54.7 million from Glaxo Group Limited ("GSK") for the fourth quarter of 2022 included royalties of $44.3 million from global net sales of RELVAR®/BREO® ELLIPTA® and royalties of $10.4 million from global net sales of ANORO® ELLIPTA®.
- Income before income taxes decreased to a loss of $64.7 million, compared to income of $56.5 million in the same quarter of 2021, driven primarily by reduced royalty revenue contribution following Theravance Respiratory Company LLC ("TRC") divestiture partially offset by GIAPREZA® and XERAVA® revenues, incremental operating expenses related to recent acquisitions, and adverse contribution from net changes in fair value of equity and long-term investments.
- Decrease in fair values of equity and long-term investments of $85.4 million in the fourth quarter of 2022 was driven mainly by a $117.3 million unrealized loss related to share price decline for Armata Pharmaceuticals Inc. ("Armata") over the time period, much of which has since been recouped due to favorable year to date share price performance in 2023.
- Net cash provided by operating activities was $201.7 million in 2022, compared to $363.8 million in 2021, driven primarily by reduced revenues following TRC divestiture as well as additional incremental operating expenses, including one-time costs, following recent acquisitions.
- Net cash and cash equivalents totaled $291.0 million, and royalty and product sale receivables totaled $64.1 million as of December 31, 2022.

Pavel Raifeld, Chief Executive Officer of Innoviva, stated: "Our diversified core royalty business remains solid. RELVAR®/BREO® ELLIPTA® global net sales decreased in the fourth quarter of 2022 primarily due to unfavorable prior period adjustments in the U.S., despite stable volume trends. ANORO® ELLIPTA® global net sales decreased slightly compared to the fourth quarter of 2021 mainly due to foreign exchange rate changes."

Mr. Raifeld continued: "We continue to advance our strategy of building a best-in-class hospital and infectious disease business formed through acquisitions of Entasis Therapeutics and La Jolla Pharmaceutical. Notably, GIAPREZA® and XERAVA® had their strongest quarter ever, the FDA accepted our SUL-DUR NDA with Priority Review, and enrollment in our Phase 3 registrational trial of zoliflodacin remains on track, with study completion anticipated in 2023. We believe this platform will afford us multiple opportunities to create and crystalize shareholder value."

"While capital markets volatility has significantly impacted income over the past quarter, primarily manifesting through decline in Armata's share price, most losses have been recouped following recent stock rallies. We remain excited about our prospects and continue to be disciplined with our capital, executing on the $100 million share buyback program and optimizing our operating footprint following recent acquisitions," said Mr. Raifeld.

Recent Highlights

- GSK Net Sales:
    - Fourth quarter 2022 net sales of RELVAR®/BREO® ELLIPTA® by GSK were $295.2 million with $83.0 million in net sales from the U.S. market and $212.2 million from non-U.S. markets.
    - Fourth quarter 2022 net sales of ANORO® ELLIPTA® by GSK were $159.8 million with $82.6 million net sales from the U.S. market and $77.2 million from non-U.S. markets.

- Clinical Updates:
    - On November 30, 2022, the U.S. Food and Drug Administration (FDA) granted priority review for SUL-DUR, an investigational drug for the treatment of infections caused by *Acinetobacter baumannii-calcoaceticus* complex (ABC), including multi-drug resistant and carbapenem-resistant strains.
    - The FDA is currently planning to hold an advisory committee meeting to discuss this New Drug Application. The target PDUFA date (or action date) is May 29, 2023.
    - At the annual meeting of the Infectious Disease Society of America which took place from October 19 to October 23, 2022 in Washington, D.C., Entasis Therapeutics, a wholly owned subsidiary of the Company, had six presentations on SUL-DUR, reinforcing the positive safety and efficacy findings from the Company's pivotal Phase 3 ATTACK trial.
    - Additionally, at the same annual meeting of the Infectious Disease Society of America, La Jolla Pharmaceutical, another wholly owned subsidiary of the Company, had five abstracts on XERAVA® focused primarily on its use in combination therapies.
    - Enrollment in the phase 3 registrational trial for zoliflodacin, a first-in-class oral antibiotic for the treatment of gonorrhea being developed in partnership with GARD-P, remains on track, and study completion is anticipated in 2023.

- Corporate Updates:
    - Innoviva's Board of Directors authorized a share repurchase program in the fourth quarter of 2022 under which the Company may repurchase up to $100.0 million of its outstanding shares of common stock.
    - In January 2023, Sapna Srivastava, Ph.D., a highly experienced executive within the biopharmaceutical and banking industries, joined the Company's Board of Directors.
    - In January 2023, we closed a $30 million convertible debt facility with Armata, supporting the clinical development of its multiple innovative bacteriophage assets as well as advanced biologics cGMP manufacturing capabilities.
    - In January 2023, we invested an additional $5 million in Gate Neurosciences, Inc. to support the clinical development of their differentiated pipeline of neuropsychiatric therapeutics.
    - In January 2023, we paid off our convertible notes due 2023 in the amount of $96.2 million.

About Innoviva

Innoviva is a diversified holding company with a portfolio of royalties and other healthcare assets. Innoviva's royalty portfolio includes respiratory assets partnered with Glaxo Group Limited ("GSK"), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, "FF/VI") and ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, "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's other healthcare assets include infectious disease and hospital assets stemming from acquisitions of Entasis Therapeutics, including its lead asset sulbactam-durlobactam, and La Jolla Pharmaceutical, including GIAPREZA® (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock and XERAVA® (eravacycline) for the treatment of complicated intra-abdominal infections in adults.

ANORO®, RELVAR® and BREO® are trademarks of the GSK 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®, GIAPREZA® and XERAVA® 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); 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"); the timing, manner and amount of capital deployment, including potential capital returns to stockholders; and risks related to the Company's growth strategy. 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, 2021 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. Additional risk factors are presented on Form 8-K filed on August 23, 2022. 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,	
	2022	2021	2022	2021
Revenue:				
Royalty revenue, net (1)	$ 51,216	$ 107,680	$ 311,645	$ 391,866
Net product sales	14,587	-	19,694	-
Total revenue	65,803	107,680	331,339	391,866
Expenses:				
Cost of products sold (inclusive of amortization of inventory fair value adjustments)	10,113	-	13,793	-
Selling, general and administrative	17,390	3,113	63,538	16,187
Research and development	10,049	40	41,432	576
Amortization of acquired intangible assets	4,070	-	5,581	-
Gain on TRC sale	-	-	(266,696)	
Loss on debt extinguishment	-	-	20,662	
Changes in fair values of equity method investments, net	117,275	9,025	161,749	(84,392)
Changes in fair values of equity and long-term investments, net	(31,868)	33,917	(8,462)	(6,638)
Interest and dividend income	(3,188)	(454)	(6,369)	(1,839)
Interest expense	4,028	4,841	15,789	19,070
Other expense (income), net	2,622	708	3,373	3,626
Total expenses	130,491	51,190	44,390	(53,410)
Income before income taxes	(64,688)	56,490	286,949	445,276
Income tax expense	3,626	10,839	66,687	76,439
Net income	(68,314)	45,651	220,262	368,837
Net income attributable to noncontrolling interest	-	35,305	6,341	102,983
Net income attributable to Innoviva stockholders	$ (68,314)	$ 10,346	$ 213,921	$ 265,854
Basic net income per share attributable to Innoviva stockholders	$ (0.98)	$ 0.15	$ 3.07	$ 3.24
Diluted net income per share attributable to Innoviva stockholders	$ (0.98)	$ 0.14	$ 2.37	$ 2.87
Shares used to compute basic net income per share	69,656	69,492	69,644	82,062
Shares used to compute diluted net income per share	69,656	81,770	95,249	94,310

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
	(unaudited)		(unaudited)	
Royalties	$ 54,671	$ 111,135	$ 325,468	$ 405,689
Amortization of capitalized fees	(3,455)	(3,455)	(13,823)	(13,823)
Royalty revenue, net	$ 51,216	$ 107,680	$ 311,645	$ 391,866

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

	December 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 291,049	$ 201,525
Royalty and product sale receivables	64,073	110,711
Inventory, net	55,897	-
Prepaid expense and other current assets	32,492	1,437
Property and equipment, net	170	12
Equity and long-term investments	403,013	483,845
Capitalized fees	97,607	111,430
Right-of-use assets	3,265	97
Goodwill	26,713	-
Intangible assets	252,919	-
Deferred tax assets, net	-	17,327
Other assets	4,299	11
Total assets	$ 1,231,497	$ 926,395
Liabilities and stockholders' equity		
Other current liabilities	$ 32,322	$ 1,655
Accrued interest payable	4,359	4,152
Deferred revenues	2,094	-
Convertible subordinated notes, due 2023, net	96,193	240,364
Convertible senior notes, due 2025, net	190,583	154,289
Convertible senior notes, due 2028, net	253,597	-
Other long term liabilities	70,918	-
Deferred tax liabilities	5,771	
Income tax payable - long term	9,872	-
Innoviva stockholders' equity	565,788	414,743
Noncontrolling interest	-	111,192
Total liabilities and stockholders' equity	$ 1,231,497	$ 926,395

INNOVIVA, INC.
Cash Flows Summary
(in thousands)
(unaudited)

	Year Ended December 31,	
	2022	2021
Net cash provided by operating activities	$ 201,726	$ 363,813
Net cash provided by (used in) investing activities	(56,634)	43,722
Net cash used in financing activities	(55,568)	(452,497)
Net change	$ 89,524	$ (44,962)
Cash and cash equivalents at beginning of period	201,525	246,487
Cash, cash equivalents and restricted cash at end of period	$ 291,049	$ 201,525

Innoviva Contacts:
Argot Partners
(212) 600-1902
innoviva@argotpartners.com