
**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 29, 2024**

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 29, 2024, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended December 31, 2023. 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 29, 2024](#)

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 29, 2024

By: /s/ Pavel Raifeld

Pavel Raifeld
Chief Executive Officer



Innoviva Reports Fourth Quarter and Full Year 2023 Financial Results; Highlights Recent Company Progress

Core royalty platform on track; received GSK royalties of \$69.6 million for fourth quarter

Achieved net product revenues of \$19.7 million for the fourth quarter of 2023 representing 35% year on year growth

Strong pipeline progress in 2023: Approval and launch of first pathogen targeted antibacterial XACDURO[®] for treatment of HABP/VABP caused by Acinetobacter infections; positive topline Phase 3 data for oral drug zoliflodacin for treatment of uncomplicated gonorrhea

Repurchased 1.1 million our common stock for \$15.4 million in the fourth quarter of 2023

BURLINGAME, Calif. – February 29, 2024 – Innoviva, Inc. (NASDAQ: INVA) (“Innoviva” or the “Company”), a diversified holding company with a core royalties portfolio, a leading critical care and infectious disease platform known as Innoviva Specialty Therapeutics (“IST”), and a portfolio of strategic investments in healthcare assets, today reported financial results for the fourth quarter and full year ended December 31, 2023 and highlighted select corporate achievements.

Pavel Raifeld, Chief Executive Officer of Innoviva, said: “2023 was a successful and transformational year for Innoviva. We have seen continued strong cash flow from our core royalty portfolio, which we have been investing prudently with a laser focus on driving long-term shareholder value. Last year showcased the success of our approach with the formation and significant pipeline and commercial progress of our therapeutics platform, which is focused on becoming the industry leader in critical care and infectious disease.”

Matthew Ronsheim, Ph.D., President of IST, noted, “Our therapeutics platform achieved tremendous success in its first year: we saw the approval and launch of XACDURO[®], the first pathogen targeted antibacterial approved by the FDA for life threatening *Acinetobacter* infections caused by susceptible isolates; we reported positive Phase III data for zoliflodacin, the potential first novel oral treatment for gonorrhea; and our targeted and lean commercial platform delivered meaningful growth in our core marketed products GIAPREZA[®] and XERAVA[®]. With our best-in-class capabilities and leverageable commercial infrastructure, we are excited about our ability to deliver life-saving drugs to patients in areas of high unmet medical need and about our significant growth prospects in the coming years.”

Mr. Raifeld concluded, “Innoviva’s strong financials reflect a new royalty base (following value-accretive 2022 TRELEGY[®] ELLIPTA[®] royalties monetization), a full year of integrated operations for our therapeutics platform, and significant value creation in our strategic healthcare assets. Innoviva continued to exercise financial discipline and ended the year with over \$275 million in cash and account receivables, while returning capital with share repurchases of over \$75 million and paying down outstanding debt of nearly \$100 million. We believe our diversified growth strategy, a strong leadership team, and our focus on cost discipline position us well to deliver shareholder value.”

Financial Highlights

- **Royalty revenue:** Fourth quarter 2023 gross royalty revenue from Glaxo Group Limited (“GSK”) was \$69.6 million and full year was \$252.7 million, compared to \$54.7 million for the fourth quarter of 2022 and \$253.4 million for the full year 2022.
- **Net Product Sales:** Fourth quarter 2023 net product sales and license revenue were \$19.7 million, which included \$13.1 million from GIAPREZA[®], \$5.2 million from XERAVA[®], and \$1.4 million from XACDURO[®], compared to \$14.6 million for the fourth quarter of 2022. Full year 2023 net product sales and license revenue was \$71.6 million, which included \$41.3 million from GIAPREZA[®], \$17.3 million from XERAVA[®], \$2.0 million from XACDURO[®], and \$11.0 million in milestone payments from our partners.
- **Equity and long-term investments:** Fourth quarter and full year 2023 change in fair values of equity and long-term investments of \$25.5 million and \$88.5 million, respectively, was primarily attributable to Armata Pharmaceuticals (“Armata”) share price appreciation.
- **Net income:** Fourth quarter 2023 net income was \$61.5 million, or \$0.97 basic per share, compared to a net loss of \$68.3 million, or \$(0.98) basic per share, for the fourth quarter 2022, driven primarily by higher revenue and positive impact of change in fair values of equity. Full year 2023 net income was \$179.7 million, or \$2.75 basic per share, compared to net income of \$213.9 million, or \$3.07 basic per share, for the full year 2022.
- **Share repurchase:** During the fourth quarter 2023, Innoviva repurchased 1,121,835 shares of its outstanding common stock for \$15.4 million. During the year 2023, Innoviva repurchased 6,173,565 shares of its outstanding common stock for \$76.5 million. Approximately \$15 million of the authorized program remains outstanding as of year-end.
- **Cash and cash equivalents:** Totaled \$193.5 million. Royalty and net product sales receivables totaled \$84.1 million as of December 31, 2023.

Key 2023 R&D Highlights

- **Zoliflodacin:** potential first-in-class oral antibiotic to treat uncomplicated gonorrhea
 - o In November 2023, in collaboration with The Global Antibiotic Research & Development Partnership (GARDP), Innoviva announced that zoliflodacin, a first-in-class antibiotic, met its primary endpoint in a global pivotal phase 3 clinical trial for the treatment of uncomplicated gonorrhea. The Company expects a New Drug Application to be submitted to the U.S. FDA in the next twelve months.
- **XACDURO[®]** (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use: targeted antibacterial for HABP/VABP caused by *Acinetobacter*
 - o In May 2023, the U.S. Food and Drug Administration (FDA) approved XACDURO[®] for use in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.
 - o Earlier in May, *The Lancet Infectious Diseases* published detailed results from the pivotal Phase 3 ATTACK trial of sulbactam-durlobactam.

Update on Strategic Healthcare Assets

- Our portfolio of strategic assets under the Company's various subsidiaries was valued at \$561.0 million as of December 31, 2023. In fourth quarter 2023, Innoviva invested an additional \$5.0 million in one of our assets, Gate Neurosciences, to support its strategy of developing next generation targeted CNS therapies.

About Innoviva

Innoviva is a diversified holding company with a core royalties portfolio, a leading critical care and infectious disease platform known as Innoviva Specialty Therapeutics ("IST"), and a portfolio of strategic investments in healthcare assets. Innoviva's royalty portfolio includes respiratory assets partnered with Glaxo Group Limited ("GSK") Innoviva is entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. Innoviva's other innovative healthcare assets include infectious disease and critical care assets stemming from acquisitions of Entasis Therapeutics, including XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use approved for the treatment of adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of *Acinetobacter baumannii-calcoaceticus* complex and the investigational zoliflodacin currently being developed for the treatment of uncomplicated gonorrhea, and La Jolla Pharmaceutical Company, 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®, BREO® and TRELEGY® 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[®], XERAVA[®] and XACDURO[®] 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, 2022 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenue:				
Royalty revenue, net (1)	\$ 66,165	\$ 51,216	\$ 238,846	\$ 311,645
Net product sales	19,675	14,587	60,617	19,694
License Revenue	-	-	11,000	-
Total revenue	85,840	65,803	310,463	331,339
Expenses:				
Cost of products sold (inclusive of amortization of inventory fair value adjustments)	13,130	10,113	41,040	13,793
Cost of license revenue	-	-	1,600	-
Selling, general and administrative	26,319	17,454	98,232	63,538
Research and development	2,356	9,985	33,922	41,432
Amortization of acquired intangible assets	6,510	4,070	21,784	5,581
Gain on TRC sale	-	-	-	(266,696)
Loss on debt extinguishment	-	-	-	20,662
Changes in fair values of equity method investments, net	(9,506)	117,274	(77,392)	161,749
Changes in fair values of equity and long-term investments, net	(16,016)	(31,868)	(11,129)	(8,462)
Interest and dividend income	(4,786)	(3,188)	(15,818)	(6,369)
Interest expense	5,952	4,028	19,157	15,789
Other expense (income), net	680	2,623	4,969	3,373
Total expenses	24,639	130,491	116,365	44,390
Income before income taxes	61,201	(64,688)	194,098	286,949
Income tax expense	(330)	3,626	14,376	66,687
Net income	61,531	(68,314)	179,722	220,262
Net income attributable to noncontrolling interest	-	-	-	6,341
Net income attributable to Innoviva stockholders	\$ 61,531	\$ (68,314)	\$ 179,722	\$ 213,921
Basic net income per share attributable to Innoviva stockholders	\$ 0.97	\$ (0.98)	\$ 2.75	\$ 3.07
Diluted net income per share attributable to Innoviva stockholders	\$ 0.76	\$ (0.98)	\$ 2.20	\$ 2.37
Shares used to compute basic net income per share	63,710	69,656	65,435	69,644
Shares used to compute diluted net income per share	84,995	69,656	86,876	95,248

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
	(unaudited)		(unaudited)	
Royalties	\$ 69,620	\$ 54,671	\$ 252,669	\$ 325,468
Amortization of capitalized fees	(3,455)	(3,455)	(13,823)	(13,823)
Royalty revenue, net	\$ 66,165	\$ 51,216	\$ 238,846	\$ 311,645

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

	December 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	\$ 193,513	\$ 291,049
Royalty and product sale receivables	84,075	64,073
Inventory, net	40,737	55,897
Prepaid expense and other current assets	25,894	32,492
Property and equipment, net	483	170
Equity and long-term investments	560,978	403,013
Capitalized fees	83,784	97,607
Right-of-use assets	2,536	3,265
Goodwill	17,905	26,713
Intangible assets	230,335	252,919
Other assets	3,267	4,299
Total assets	\$ 1,243,507	\$ 1,231,497
Liabilities and stockholders' equity		
Other current liabilities	\$ 33,435	\$ 32,322
Accrued interest payable	3,422	4,359
Deferred revenues	1,277	2,094
Convertible subordinated notes, due 2023, net	-	96,193
Convertible senior notes, due 2025, net	191,295	190,583
Convertible senior notes, due 2028, net	254,939	253,597
Other long term liabilities	71,870	70,918
Deferred tax liabilities	563	5,771
Income tax payable - long term	11,751	9,872
Innoviva stockholders' equity	674,955	565,788
Total liabilities and stockholders' equity	\$ 1,243,507	\$ 1,231,497

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

	Year Ended December 31,	
	2023	2022
Net cash provided by operating activities	\$ 141,064	\$ 201,726
Net cash used in investing activities	(66,761)	(56,634)
Net cash used in financing activities	(171,839)	(55,568)
Net change	\$ (97,536)	\$ 89,524
Cash and cash equivalents at beginning of period	291,049	201,525
Cash and cash equivalents at end of period	<u>\$ 193,513</u>	<u>\$ 291,049</u>