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): **May 8, 2024**

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 Stock Market LLC

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 May 8, 2024, Innoviva, Inc. (the "Company") issued a press release regarding its results of operations and financial condition for the quarter ended March 31, 2024. 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 May 8, 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: May 8, 2024

By: /s/ Pavel Raifeld
Pavel Raifeld
Chief Executive Officer

Exhibit 99.1

Innoviva Reports First Quarter 2024 Financial Results; Highlights Recent Company Progress

Core royalty platform on track; receiving GSK royalties of $61.9 million

Achieved net product revenues of $19.1 million, representing 66% year-over-year growth driven by launch of XACDURO® and growth of key core product GIAPREZA®

Strong pipeline progress: positive Phase 3 zoliflodacin clinical trial results in uncomplicated gonorrhea highlighted at ESCMID Global 2024; on track to submit NDA in early 2025

Derek Small appointed to the Company's Board of Directors

BURLINGAME, Calif. – May 8, 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 first quarter ended March 31, 2024, and highlighted select corporate achievements.

"Our first quarter financial results continue to demonstrate the successful transformation for Innoviva. We had a strong performance driven by resilient cash flows from our core GSK royalties portfolio and robust revenue growth across our commercial products marketed by IST, a leader in critical care medicine and infectious disease," said Pavel Raifeld, Chief Executive Officer of Innoviva. "We also remain laser focused on utilizing our strong financials to drive shareholder value by continuing to exercise cost discipline, investing prudently in our strategic healthcare assets, and completing our share buyback plan."

Matt Ronsheim, Ph.D., President of IST, noted: "Our IST platform is a powerful engine for growth anchored by a robust portfolio of differentiated life saving therapies. We are pleased with our first quarter performance, led by the strong launch of our novel therapeutic XACDURO®. Our core products GIAPREZA® and XERAVA® continue to grow, propelled by increasing awareness of our strong data underscoring the value of our products. We are also excited about our lead pipeline product, zoliflodacin, a potential first in class well tolerated oral drug for uncomplicated gonorrhea, whose Phase 3 data was highlighted in an oral presentation by our non-profit partner GARDP at ESCMID Global 2024, the largest global infectious disease congress. We remain on track to submit our New Drug Application for zoliflodacin in early 2025."

Financial Highlights

- **Royalty revenue:** First quarter 2024 gross royalty revenue from Glaxo Group Limited ("GSK") was $61.9 million, compared to $60.3 million for the first quarter of 2023.
- **Net Product Sales:** First quarter 2024 net product sales and license revenue were $19.1 million, which included $12.1 million from GIAPREZA®, $4.8 million from XERAVA®, and $2.2 million from XACDURO®, a 66% increase compared to $11.5 million for the first quarter of 2023.
- **Equity and long-term investments**: First quarter 2024 net change in fair values of equity and long-term investments of $22.0 million was primarily attributable to Armata Pharmaceuticals ("Armata") share price appreciation.

- **Net income**: First quarter 2024 net income was $36.5 million, or $0.58 basic per share, compared to a net income of $34.9 million, or $0.51 basic per share, for the first quarter of 2023.

- **Share repurchases:** During the first quarter 2024, Innoviva repurchased 0.6 million shares of its outstanding common stock for $9.7 million. Subsequent to March 31, 2024, and through April 25, 2024, we completed the program by repurchasing 0.4 million shares for a total amount of approximately $5.3 million.

- **Cash and cash equivalents**: Totaled $178.4 million. Royalty and net product sales receivables totaled $76.0 million as of March 31, 2024.

Key Business and R&D Highlights

- **XACDURO®** (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use: targeted antibacterial for patients with HABP/VABP caused by *Acinetobacter*

    - Following the launch in September 2023, commercial efforts continue to deliver strong performance with growing number of health systems integrating XACDURO® into their protocols.

- **Zoliflodacin**: a potential first-in-class, single dose, oral antibiotic in development for the treatment of patients with uncomplicated gonorrhea

    - Positive Phase 3 zoliflodacin clinical trial results highlighted in an oral presentation given by the Company's non-profit partner, The Global Antibiotic Research & Development Partnership (GARDP), at the European Society of Clinical Microbiology and Infectious Disease Global Congress (ESCMID Global 2024).

    - The data showed that in the micro-intent-to-treat population (n=744), zoliflodacin achieved a microbiological cure rate of 90.9%, a 5.3% difference compared to ceftriaxone and azithromycin, the current global standard of care, which achieved a 96.2% cure rate (95% CI: 1.4%, 8.7%). Microbiological cure rates at extragenital sites were comparable between treatment arms (secondary endpoints). Zoliflodacin was generally well tolerated and emergent adverse events were comparable between treatment arms (46.2% vs 46.4%). No deaths or other serious adverse events were reported.

    - The Company expects a New Drug Application to be submitted to the U.S. FDA in early 2025.

Strategic Healthcare Assets

- Our portfolio of strategic assets under the Company's various subsidiaries was valued at $628.4 million as of March 31, 2024, compared to $561.0 million as of December 31, 2023. In the first quarter 2024, Innoviva invested an additional $35.0 million in one of our assets, Armata, to help advance its lead therapeutic phage candidates. In addition, Innoviva invested an additional $5.8 million, with accrued interest, in Gate Neurosciences to support its strategy of developing next generation targeted CNS therapies, and an additional $2.7 million into ImaginAb Inc. to support its radiopharmaceutical platform.

Corporate Updates

- In April 2024, Derek Small, an accomplished biopharmaceutical entrepreneur and executive, joined the Company's Board of Directors.
- Management will participate in the upcoming Bank of America Securities Health Care Conference, taking place on May 15, 2024, in Las Vegas. A live webcast of the Company's corporate presentation is scheduled for 9:20 a.m. PT and can be accessed here. An archived replay will be available following the event.

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® 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®, 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, 2023 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 and Comprehensive Income
(in thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Revenue:		
Royalty revenue, net (1)	$ 58,415	$ 56,858
Net product sales	19,084	11,514
License Revenue	—	8,000
Total revenue	77,499	76,372
Expenses:		
Cost of products sold (inclusive of amortization of inventory fair value adjustments)	10,971	8,749
Cost of license revenue	—	1,600
Selling, general and administrative	30,405	19,735
Research and development	3,878	12,588
Amortization of acquired intangible assets	6,440	3,805
Changes in fair values of equity method investments, net	(35,342)	(15,817)
Changes in fair values of equity and long-term investments, net	13,335	2,164
Interest and dividend income	(4,399)	(3,365)
Interest expense	5,851	4,427
Other expense, net	1,236	1,346
Total expenses	32,375	35,232
Income before income taxes	45,124	41,140
Income tax expense	8,592	6,275
Net income and comprehensive income	$ 36,532	$ 34,865
Net income per share		
Basic	$ 0.58	$ 0.51
Diluted	$ 0.46	$ 0.42
Shares used to compute net income per share		
Basic	63,185	67,786
Diluted	84,531	89,788

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

	Three Months Ended March 31,	
	2024	2023
	(unaudited)	
Royalties	$ 61,871	$ 60,314
Amortization of capitalized fees	(3,456)	(3,456)
Royalty revenue, net	$ 58,415	$ 56,858

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

	March 31, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 178,357	$ 193,513
Royalty and product sale receivables	76,010	84,075
Inventory, net	37,437	40,737
Prepaid expense and other current assets	19,538	25,894
Property and equipment, net	324	483
Equity and long-term investments	628,437	560,978
Capitalized fees	80,328	83,784
Right-of-use assets	2,269	2,536
Goodwill	17,905	17,905
Intangible assets	223,895	230,335
Other assets	3,112	3,267
Total assets	$ 1,267,612	$ 1,243,507
Liabilities and stockholders' equity		
Other current liabilities	$ 28,059	$ 33,435
Accrued interest payable	833	3,422
Deferred revenues	987	1,277
Convertible senior notes, due 2025, net	191,476	191,295
Convertible senior notes, due 2028, net	255,283	254,939
Other long term liabilities	71,686	71,870
Deferred tax liabilities	3,807	563
Income tax payable - long term	11,800	11,751
Innoviva stockholders' equity	703,681	674,955
Total liabilities and stockholders' equity	$ 1,267,612	$ 1,243,507

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

	Three Months Ended March 31,	
	2024	2023
Net cash provided by operating activities	$ 37,047	$ 25,684
Net cash used in investing activities	(43,038)	(35,722)
Net cash used in financing activities	(9,165)	(136,962)
Net change	$ (15,156)	$ (147,000)
Cash and cash equivalents at beginning of period	193,513	291,049
Cash and cash equivalents at end of period	$ 178,357	$ 144,049