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): **November 6, 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 November 6, 2024, Innoviva, Inc. (the "Company") issued a press release regarding its results of operations and financial condition for the quarter ended September 30, 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 November 6, 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: November 6, 2024

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

Exhibit 99.1

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

Core royalty platform continued strong performance, receiving GSK royalties of $60.5 million with 6% year-over-year growth

Innoviva Specialty Therapeutics' (IST) marketed portfolio achieved U.S. net product sales of $19.7 million, reflecting 68% year-over-year growth

BURLINGAME, Calif. – November 6, 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 third quarter ended September 30, 2024, and highlighted select corporate achievements.

"For the third quarter of 2024, we continue to deliver strong revenue growth, with solid performance from our core GSK royalty assets, and accelerating sales from our IST commercial products, GIAPREZA®, XACDURO® and XERAVA®. Since the formation of IST, now in its second year of operation, we have shown consistent sales expansion in our commercial products, primarily driven by increasing product demand, validating our investment in hospital-based therapeutics," said Pavel Raifeld, Chief Executive Officer of Innoviva. "Of special note, XACDURO® was nominated for the Best Biotechnology Product by The Galien Foundation USA in recognition of its pioneering science and positive impact on patients. We are proud of this recognition which highlights the commitment and innovation we are bringing to this space, where there is significant unmet medical need and an immense demand for new drugs. We also continue to further advance our pipeline and are on track to submit a New Drug Application ("NDA") for zoliflodacin, potentially first in class, single dose oral drug for the treatment of uncomplicated gonorrhea, to the U.S. FDA in early 2025."

Mr. Raifeld continued, "Over the past quarter, we also saw meaningful operational progress across our strategic healthcare assets. We remain focused on prudent capital allocation in our quest to maximize shareholder value and see multiple opportunities for continued value creation."

Financial Highlights

- **Royalty revenue:** Third quarter 2024 gross royalty revenue from Glaxo Group Limited ("GSK") was $60.5 million, compared to $57.0 million for the third quarter 2023.
- **Net Product Sales:** Third quarter 2024 net product sales were $27.8 million, which included U.S. net product sales of $19.7 million and ex-U.S. product sales of $8.1 million. U.S. net product sales consisted of $13.1 million from GIAPREZA®, $2.3 million from XERAVA®, and $4.3 million from XACDURO®, a 68% increase compared to $11.8 million for the third quarter 2023.
- **License Revenue:** Third quarter 2024 license revenue of $4.6 million included product development cost-sharing reimbursements from our partner.

- **Equity and long-term investments:** Third quarter 2024 unfavorable net change in fair value of equity and long-term investments of $35.2 million was primarily due to lower share price of Armata Pharmaceuticals ("Armata").

- **Net income**: Net income of $1.2 million, or $0.02 basic per share, for the third quarter of 2024, compared to a net income of $82.0 million, or $1.26 basic per share, for the third quarter of 2023.

- **Cash and cash equivalents**: Totaled $260.6 million. Royalty and product sales receivables totaled $91.1 million as of September 30, 2024.

Key Business and R&D Highlights

- **XACDURO®** (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use, a targeted antibacterial treatment for patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

    - XACDURO® was recently nominated for the 2024 Prix Galien USA Award for Best Biotechnology Product, which recognizes excellence in scientific innovation that improves the state of human health.

- **Zoliflodacin**: a potential first-in-class, single dose, oral antibiotic is currently being developed in partnership with The Global Antibiotic Research & Development Partnership ("GARDP") for the treatment of patients with uncomplicated gonorrhea.

    - In September 2024, we presented additional findings on our investigational agent zoliflodacin at the 2024 Sexually Transmitted Infections Prevention Conference in Atlanta. The first oral presentation demonstrated that zoliflodacin had potent *in vitro* activity against 200 clinical isolates, consistent with previous U.S. surveillance data. The second presentation demonstrated that microbiological cure rates for specific subgroups were comparable to the primary endpoint analysis. Safety in these subgroups was also comparable.

    - In October 2024, we had five presentations at IDWeek 2024, which took place in Los Angeles. One oral presentation on zoliflodacin included a review of the unique public-private partnership that led the clinical development of zoliflodacin. The second presentation highlighted the activity of sulbactam-durlobactam and standard-of-care antibiotics against *Acinetobacter baumannii-calcoaceticus* complex for hospitalized patients in the U.S. Three posters were presented including two on zoliflodacin: *In vitro* activity against baseline isolates in U.S. participants from the phase 3 trial and a pharmacometrics analysis supporting dose selection. Surveillance data of eravacycline against clinical pathogens, collected worldwide from multiple infections sites during 2018-2022 was also presented.

    - We continue to advance zoliflodacin following its successful Phase 3 clinical trial results and expect to submit an NDA to the U.S. FDA in early 2025.

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Royalty revenue, net (1)	$ 57,056	$ 53,558	$ 179,213	$ 172,681
Net product sales	27,822	13,701	68,557	40,942
License revenue	4,630	-	19,135	11,000
Total revenue	89,508	67,259	266,905	224,623
Expenses:				
Cost of products sold (inclusive of amortization of inventory fair value adjustments)	9,990	10,182	29,433	27,910
Cost of license revenue	-	-	-	1,600
Selling, general and administrative	26,219	28,636	84,364	71,913
Research and development	3,551	3,989	9,989	31,566
Amortization of acquired intangible assets	6,511	6,511	19,391	15,274
Changes in fair values of equity method investments, net	18,231	(71,980)	42,997	(67,886)
Changes in fair values of equity and long-term investments, net	16,936	2,640	60,827	4,887
Interest and dividend income	(5,500)	(4,114)	(13,373)	(11,032)
Interest expense	5,807	4,396	17,460	13,205
Other expense, net	914	1,047	3,123	4,289
Total expenses, net	82,659	(18,693)	254,211	91 ,726
Income before income taxes	6,849	85,952	12,694	132,897
Income tax expense, net	5,636	3,906	9634	14,706
Net income and comprehensive income	$ 1,213	$ 82,046	$ 3,060	$ 118,191
Net income per share				
Basic	$ 0.02	$ 1.26	$ 0.05	$ 1.79
Diluted	$ 0.02	$ 0.98	$ 0.05	$ 1.45
Shares used to compute net income per share				
Basic	62,569	64,953	62,759	66,016
Diluted	62,951	86,164	63,020	87,504

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(unaudited)		(unaudited)	
Royalties	$ 60,512	$ 57,014	$ 189,581	$ 183,049
Amortization of capitalized fees	(3,456)	(3,456)	(10,368)	(10,368)
Royalty revenue, net	$ 57,056	$ 53,558	$ 179,213	$ 172,681

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

	September 30, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 260,630	$ 193,513
Royalty and product sale receivables	91,058	84,075
Inventory	34,236	40,737
Prepaid expense and other current assets	14,697	25,894
Property and equipment, net	544	483
Equity and long-term investments	507,718	560,978
Capitalized fees paid, net	73,416	83,784
Right-of-use assets	2,789	2,536
Goodwill	17,905	17,905
Intangible assets	210,944	230,335
Deferred tax asset, net	14,875	-
Other assets	2,800	3,267
Total assets	$ 1,231,612	$ 1,243,507
Liabilities and stockholders' equity		
Other current liabilities	$ 30,357	$ 33,435
Accrued interest payable	833	3,422
Deferred revenue	717	1,277
Convertible senior notes, due 2025, net	191,843	191,295
Convertible senior notes, due 2028, net	255,972	254,939
Other long-term liabilities	71,449	71,870
Deferred tax liabilities, net	-	563
Income tax payable, long-term	11,899	11,751
Innoviva stockholders' equity	668,542	674,955
Total liabilities and stockholders' equity	$ 1,231,612	$ 1,243,507

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

	Nine Months Ended September 30,	
	2024	2023
Net cash provided by operating activities	$ 129,451	$ 107,808
Net cash used in investing activities	(48,308)	(61,610)
Net cash used in financing activities	(14,026)	(157,250)
Net change	67,117	(111 ,052)
Cash and cash equivalents at beginning of period	193,513	291,049
Cash and cash equivalents at end of period	$ 260,630	$ 179,997