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 1, 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 November 1, 2023, Innoviva, Inc. (the "Company") issued a press release regarding its results of operations and financial condition for the quarter ended September 30, 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 November 1, 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: November 1, 2023

By: /s/ Pavel Raifeld

Pavel Raifeld
Chief Executive Officer

Exhibit 99.1

Innoviva Reports Third Quarter 2023 Financial Results and Highlights Recent Company Progress

Received GSK royalties of $57.0 million and net product revenues of $13.7 million in the third quarter of 2023

Launched first-in-class therapy XACDURO® for treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of Acinetobacter

Announced positive topline Phase 3 zoliflodacin data for treatment of gonorrhea in November 2023

Repurchased $11.0 million of common stock

BURLINGAME, Calif. – November 1, 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 third quarter ended September 30, 2023, highlighted select corporate achievements and provided an overview of its key business initiatives.

· Gross royalty revenue from Glaxo Group Limited ("GSK") for the third quarter 2023 was $57.0 million, which included royalties of $45.6 million from global net sales of RELVAR®/BREO® ELLIPTA® and royalties of $11.4 million from global net sales of ANORO® ELLIPTA® compared to $65.6 million for the third quarter of 2022, which included royalties of $55.7 million from global net sales of RELVAR®/BREO® ELLIPTA® and $9.9 million from global net sales of ANORO® ELLIPTA®, respectively.

· Net product sales and license revenue for the third quarter of 2023 was $13.7 million, which included $8.0 million from GIAPREZA® net sales, $5.1 million from XERAVA® net sales and $0.6 million from XACDURO® net sales.

· Net income was $82.0 million, or $1.26 basic per share, for the third quarter of 2023, compared to net income of $265.5 million, or $3.81 basic per share, for the third quarter of 2022; the decrease was primarily driven by non-repeated gain on sales of our subsidiary, Theravance Respiratory Company, and its TRELEGY® ELLIPTA® royalty stream in July 2022.

· Cash and cash equivalents totaled $180.0 million. Royalty, product sales and milestone receivables totaled $67.8 million as of September 30, 2023.

"The third quarter of 2023 was marked by significant revenues stemming from our royalty portfolio and solid performance by our internal product portfolio," said Pavel Raifeld, Chief Executive Officer of Innoviva. "A few weeks ago, we launched XACDURO® in the United States and are encouraged by the market receptivity. Moreover, we announced positive topline data from the Phase 3 trial of our lead pipeline asset, zoliflodacin, and are excited about its potential to affect the treatment paradigm for gonorrhea patients, especially in the presence of antimicrobial resistance concerns. These milestones reinforce the strength and promise of our infectious disease and critical care business."

Mr. Raifeld concluded, “We continued to exercise cost discipline and saw meaningful operational progress among our investees. In addition, we benefited from significant increases in the equity fair values of our investments. We are confident in the prospects of our business and plan to continue to pursue shareholder-friendly policies, such as share repurchases.”

Third Quarter 2023 and Recent Highlights

GSK Net Sales

- Third quarter 2023 net sales of RELVAR®/BREO® ELLIPTA® by GSK were $303.9 million with $109.5 million in net sales from the U.S. market and $194.4 million from non-U.S. markets.

- Third quarter 2023 net sales of ANORO® ELLIPTA® by GSK were $175.8 million with $89.2 million net sales from the U.S. market and $86.6 million from non-U.S. markets.

Corporate Updates

- During the third quarter of 2023, Innoviva repurchased 856,750 shares of its outstanding common stock for $11.0 million.

- On July 10, 2023, Innoviva’s wholly owned subsidiary, Innoviva Strategic Opportunities, entered into a credit and security agreement with Armata Pharmaceuticals, Inc. (NYSE: ARMP) (“Armata”) and invested $25.0 million to advance Armata’s pipeline of therapeutic phage candidates and support the buildout of its state-of-the art cGMP manufacturing facility.

- On August 21, 2023, Innoviva appointed Stephen Basso as Chief Financial Officer.

Clinical Updates

- In September 2023, Innoviva’s wholly owned subsidiary, Innoviva Specialty Therapeutics, launched XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous 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 (*Acinetobacter*). XACDURO® is the first and only pathogen-targeted antibiotic and a significant advancement in the way healthcare professionals treat *Acinetobacter*.

- In November 2023, in collaboration with The Global Antibiotic Research & Development Partnership (GARDP), we 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, a prevalent disease affecting over 80 million patients a year globally with rapidly rising antimicrobial resistance concerns. Study investigators found that oral zoliflodacin demonstrated statistical non-inferiority of microbiological cure at the urogenital site when compared to treatment with intramuscular injection of ceftriaxone and oral azithromycin, a current global standard of care regimen. In the study, zoliflodacin demonstrated a favorable safety profile and was generally well tolerated, with the majority of adverse events being mild-to-moderate. There were no discontinuations reported due to adverse events, serious adverse events, or deaths.

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 innovative healthcare assets include infectious disease and hospital 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 (*Acinetobacter*) 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, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
Royalty revenue, net (1)	$ 53,558	$ 62,150	$ 172,681	$ 260,429
Net product sales	13,701	5,107	40,942	5,107
License revenue	-	-	11,000	-
Total revenue	67,259	67,257	224,623	265,536
Expenses:				
Cost of products sold (inclusive of amortization of inventory fair value adjustments, excluding depreciation and amortization of intangible assets)	10,182	3,680	27,910	3,680
Cost of license revenue	-	-	1,600	-
Selling, general and administrative	28,636	27,810	71,913	46,084
Research and development	3,989	11,725	31,566	31,447
Amortization of acquired intangible assets	6,511	1,511	15,274	1,511
Gain on sale of Theravance Respiratory Company, LLC (“TRC”)	-	(266,696)	-	(266,696)
Loss on debt extinguishment	-	-	-	20,662
Changes in fair values of equity method investments, net	(71,980)	(10,298)	(67,886)	44,475
Changes in fair values of equity and long-term investments, net	2,640	10,168	4,887	23,406
Interest and dividend income	(4,114)	(2,135)	(11,032)	(3,181)
Interest expense	4,396	5,096	13,205	11,761
Other expense, net	1,047	(28)	4,289	750
Total expenses	(18,693)	(219,167)	91,726	(86,101)
Income before income taxes	85,952	286,424	132,897	351,637
Income tax expense	3,906	57,077	14,706	63,061
Net income	82,046	229,347	118,191	288,576
Net income attributable to noncontrolling interest	-	(36,176)	-	6,341
Net income attributable to Innoviva stockholders	$ 82,046	$ 265,523	$ 118,191	$ 282,235
Basic net income per share attributable to Innoviva stockholders	$ 1.26	$ 3.81	$ 1.79	$ 4.05
Diluted net income per share attributable to Innoviva stockholders	$ 0.98	$ 2.80	$ 1.45	$ 3.07
Shares used to compute basic net income per share	64,953	69,731	66,016	69,640
Shares used to compute diluted net income per share	86,164	95,830	87,504	95,072

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(unaudited)		(unaudited)	
Royalties	$ 57,014	$ 65,606	$ 183,049	$ 270,797
Amortization of capitalized fees	(3,456)	(3,456)	(10,368)	(10,368)
Royalty revenue, net	$ 53,558	$ 62,150	$ 172,681	$ 260,429

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

	September 30, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 179,997	$ 291,049
Royalty and product sale receivables	67,765	64,073
Inventory, net	40,515	55,897
Prepaid expense and other current assets	16,722	32,492
Property and equipment, net	361	170
Equity and long-term investments	529,531	403,013
Capitalized fees	87,239	97,607
Right-of-use assets	2,828	3,265
Goodwill	17,905	26,713
Intangible assets	236,845	252,919
Deferred tax assets	4,952	-
Other assets	3,444	4,299
Total assets	$ 1,188,104	$ 1,231,497
Liabilities and stockholders' equity		
Other current liabilities	$ 33,802	$ 32,322
Accrued interest payable	833	4,359
Deferred revenue	1,548	2,094
Convertible subordinated notes, due 2023, net	-	96,193
Convertible senior notes, due 2025, net	191,115	190,583
Convertible senior notes, due 2028, net	254,603	253,597
Other long term liabilities	68,690	70,918
Deferred tax liabilities	-	5,771
Income tax payable - long term	10,020	9,872
Innoviva stockholders' equity	627,493	565,788
Total liabilities and stockholders' equity	$ 1,188,104	$ 1,231,497

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

	Nine Months Ended September 30,	
	2023	2022
Net cash provided by operating activities	$ 107,808	$ 192,827
Net cash used in investing activities	(61,610)	(47,956)
Net cash used in financing activities	(157,250)	(45,567)
Net change	$ (111,052)	$ 99,304
Cash and cash equivalents at beginning of period	291,049	201,525
Cash, cash equivalents and restricted cash at end of period	$ 179,997	$ 300,829

Investors and Media Contact:
Argot Partners
(212) 600-1902
innoviva@argotpartners.com