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): **August 2, 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 August 2, 2023, Innoviva, Inc. (the "Company") issued a press release regarding its results of operations and financial condition for the quarter ended June 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 August 2, 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: August 2, 2023

By: /s/ Pavel Raifeld

Pavel Raifeld
Chief Executive Officer

Exhibit 99.1

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

Received GSK royalties of $65.7 million, net product revenues of $15.7 million and license revenue of $3.0 million in the second quarter of 2023

Received FDA approval for XACDURO® for treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of Acinetobacter

Repurchased $9.2 million of common stock

BURLINGAME, Calif. – August 2, 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 second quarter ended June 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 second quarter 2023 was $65.7 million, which included royalties of $54.4 million from global net sales of RELVAR®/BREO® ELLIPTA® and royalties of $11.3 million from global net sales of ANORO® ELLIPTA® compared to $111.7 million for the second quarter of 2022, which included royalties of $59.3 million from global net sales of RELVAR®/BREO® ELLIPTA® and $9.6 million from global net sales of ANORO® ELLIPTA®, respectively. The decrease was primarily due to the sale of our subsidiary, Theravance Respiratory Company, and its TRELEGY® ELLIPTA® royalty stream in July 2022.

· Net product sales and license revenue for the second quarter of 2023 was $18.7 million, which included $11.2 million from GIAPREZA® net sales, $4.5 million from XERAVA® net sales and an $3.0 million milestone payment from our partner for FDA approval of XACDURO®.

· Net income was $1.3 million, or $0.02 basic per share, for the second quarter of 2023, compared to net income of $0.9 million, or $0.01 basic per share, for the second quarter of 2022.

· Cash and cash equivalents totaled $173.0 million. Royalty, product sales and milestone receivables totaled $81.0 million as of June 30, 2023.

"The second quarter of 2023 was marked by strong revenues stemming from our robust royalty portfolio and historically highest sales from our internal product portfolio," said Pavel Raifeld, Chief Executive Officer of Innoviva. "We ended the quarter on a strong note with the approval of XACDURO® (sulbactam for injection; durlobactam for injection) for treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia. This is the first pathogen-targeted therapy to be approved for these life-threatening infections caused by *Acinetobacter Baumannii-calcoaceticus* complex, and we plan to bring this product to patients later this year. We remained disciplined on costs and saw meaningful operational progress among our investees, market volatility notwithstanding. We are excited about the prospects of our business and continue to pursue shareholder value accretive activities, such as share repurchases."

Second Quarter 2023 and Recent Highlights

GSK Net Sales

- Second quarter 2023 net sales of RELVAR®/BREO® ELLIPTA® by GSK were $363.0 million with $149.8 million in net sales from the U.S. market and $213.2 million from non-U.S. markets.

- Second quarter 2023 net sales of ANORO® ELLIPTA® by GSK were $173.3 million with $85.5 million net sales from the U.S. market and $87.8 million from non-U.S. markets.

Corporate Updates

- During the second quarter of 2023, Innoviva repurchased 775,504 shares of its outstanding common stock for $9.2 million.

- On July 11, 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 build-out of its state-of-the art cGMP manufacturing facility.

- On July 11, 2023, Innoviva director, Deborah Birx, resigned from Innoviva Board and joined Armata as Chief Executive Officer.

Clinical Updates

- On May 23, 2023, Innoviva's wholly owned subsidiary, Innoviva Specialty Therapeutics, received FDA's approval of 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*). The company is preparing to launch XACDURO® later this year.

- Recruitment is now complete in the registrational Phase 3 Zoliflodacin study. Oral Zoliflodacin is a novel oral antibiotic in development for the treatment of uncomplicated gonorrhea infection. Top-line results for this ongoing Phase 3 trial are expected in late 2023.

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Royalty revenue, net (1)	$ 62,265	$ 108,220	$ 119,123	$ 198,279
Net product sales	15,727	-	27,241	-
License revenue	3,000	-	11,000	-
Total revenue	80,992	108,220	157,364	198,279
Expenses:				
Cost of products sold (inclusive of amortization of inventory fair value adjustments, excluding depreciation and amortization of intangible assets)	8,979	-	17,728	-
Cost of license revenue	-	-	1,600	-
Selling, general and administrative	23,542	11,782	43,277	18,274
Research and development	14,989	13,884	27,577	19,722
Amortization of acquired intangible assets	4,958	-	8,763	-
Loss on debt extinguishment	-	-	-	20,662
Changes in fair values of equity method investments, net	19,911	42,823	4,094	54,773
Changes in fair values of equity and long-term investments, net	83	15,777	2,247	13,238
Interest and dividend income	(3,553)	(724)	(6,918)	(1,046)
Interest expense	4,382	3,655	8,809	6,665
Other expense, net	1,896	528	3,242	778
Total expenses	75,187	87,725	110,419	133,066
Income before income taxes	5,805	20,495	46,945	65,213
Income tax expense	4,525	(876)	10,800	5,984
Net income	1,280	21,371	36,145	59,229
Net income attributable to noncontrolling interest	-	20,432	-	42,517
Net income attributable to Innoviva stockholders	$ 1,280	$ 939	$ 36,145	$ 16,712
Basic net income per share attributable to Innoviva stockholders	$ 0.02	$ 0.01	$ 0.54	$ 0.24
Diluted net income per share attributable to Innoviva stockholders	$ 0.02	$ 0.05	$ 0.46	$ 0.24
Shares used to compute basic net income per share	65,341	69,643	66,557	69,594
Shares used to compute diluted net income per share	65,489	95,653	88,175	94,692

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	June 30,	2023	2022
	(unaudited)		(unaudited)	
Royalties	$ 65,721	$ 111,676	$ 126,035	$ 205,191
Amortization of capitalized fees	(3,456)	(3,456)	(6,912)	(6,912)
Royalty revenue, net	$ 62,265	$ 108,220	$ 119,123	$ 198,279

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

	June 30, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 173,025	$ 291,049
Royalty and product sale receivables	80,996	64,073
Inventory, net	46,846	55,897
Prepaid expense and other current assets	22,671	32,492
Property and equipment, net	161	170
Equity and long-term investments	433,001	403,013
Capitalized fees	90,695	97,607
Right-of-use assets	2,719	3,265
Goodwill	14,882	26,713
Intangible assets	243,356	252,919
Deferred tax assets	6,327	-
Other assets	3,562	4,299
Total assets	$ 1,118,241	$ 1,231,497
Liabilities and stockholders' equity		
Other current liabilities	$ 32,722	$ 32,322
Accrued interest payable	3,422	4,359
Deferred revenue	3,254	2,094
Convertible subordinated notes, due 2023, net	-	96,193
Convertible senior notes, due 2025, net	190,937	190,583
Convertible senior notes, due 2028, net	254,264	253,597
Other long term liabilities	68,584	70,918
Deferred tax liabilities	-	5,771
Income tax payable - long term	9,971	9,872
Innoviva stockholders' equity	555,087	565,788
Total liabilities and stockholders' equity	$ 1,118,241	$ 1,231,497

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

	Six Months Ended June 30,	
	2023	2022
Net cash provided by operating activities	$ 63,866	$ 177,137
Net cash used in investing activities	(35,722)	(145,678)
Net cash (used in) provided by financing activities	(146,168)	50,596
Net change	$ (118,024)	$ 82,055
Cash and cash equivalents at beginning of period	291,049	201,525
Cash, cash equivalents and restricted cash at end of period	$ 173,025	$ 283,580

Investors and Media Contact:
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