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 9, 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 May 9, 2023, Innoviva, Inc. (the "Company") issued a press release regarding its results of operations and financial condition for the quarter ended March 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 May 9, 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: May 9, 2023

By: /s/ Pavel Raifeld

Pavel Raifeld
Chief Executive Officer

Exhibit 99.1

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

Received GSK royalties of $60.3 million, net product revenues of $11.5 million and license revenue of $8.0 million in the first quarter of 2023

Repurchased $40.3 million of common stock and paid off $96.2 million of 2023 convertible notes

BURLINGAME, Calif. – May 9, 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 first quarter ended March 31, 2023, highlighted select corporate achievements and provided an overview of its key business initiatives.

● Gross royalty revenue from Glaxo Group Limited ("GSK") for the first quarter 2023 was $60.3 million, which included royalties of $50.9 million from global net sales of RELVAR®/BREO® ELLIPTA® and royalties of $9.4 million from global net sales of ANORO® ELLIPTA®, compared to $93.5 million for the first quarter of 2022. The decrease was primarily due to the sale of our subsidiary, Theravance Respiratory Company, with its TRELEGY® royalty stream in July 2022.

● Net product sales and license revenue for the first quarter of 2023 was $19.5 million, which included $9.0 million from GIAPREZA® net sales, $2.5 million from XERAVA® net sales and an $8.0 million milestone payment from our partner for the approval of XERAVA® in mainland China.

● Net income was $34.9 million, or $0.51 basic per share, for the first quarter of 2023, compared to net income of $15.8 million, or $0.23 basic per share, for the first quarter of 2022.

● Cash and cash equivalents totaled $144.0 million. Royalty, product sales and milestone receivables totaled $75.8 million as of March 31, 2023.

"The first quarter of 2023 was marked by strong revenues stemming from both our royalty portfolio and our internal product portfolio along with continued execution against key corporate objectives," said Pavel Raifeld, Chief Executive Officer of Innoviva. "Also of note, the U.S. Food and Drug Administration's Antimicrobial Drugs Advisory Committee recently returned a unanimous vote in support of approval for sulbactam-durlobactam in adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia. We believe this is a critical step toward bringing this much needed treatment to patients with these life-threatening infections caused by *Acinetobacter Baumannii-calcoaceticus* complex. We are disciplined with regard to managing costs and focused on realizing synergies from our operating platform. We remain excited about the prospects of our business and continue to pursue shareholder value accretive activities, such as share repurchases."

First Quarter 2023 and Recent Highlights

GSK Net Sales

- First quarter 2023 net sales of RELVAR®/BREO® ELLIPTA® by GSK were $339.2 million with $122.4 million in net sales from the U.S. market and $216.8 million from non-U.S. markets.

- First quarter 2023 net sales of ANORO® ELLIPTA® by GSK were $145.1 million with $62.2 million net sales from the U.S. market and $82.9 million from non-U.S. markets.

Corporate Updates

- Innoviva's recently established subsidiary, Innoviva Specialty Therapeutics, which integrated Entasis Therapeutics Holdings Inc. ("Entasis") and La Jolla Pharmaceutical Company and, in conjunction with its affiliates, markets GIAPREZA® and XERAVA® as well as advances the development and commercialization of sulbactam-durlobactam and zoliflodacin.

- On January 10, 2023, the Company's wholly owned subsidiary, Innoviva Strategic Opportunities LLC, invested $30.0 million in a convertible promissory note of Armata Pharmaceuticals, Inc. to support the clinical development of its multiple innovative bacteriophage assets as well as advanced biologics cGMP manufacturing capabilities.

- On February 2, 2023, the Company's wholly owned subsidiary, Innoviva TRC Holding LLC, invested $5.0 million in a convertible promissory note of Gate Neurosciences Inc. to support the clinical development of its differentiated pipeline of neuropsychiatric therapeutics.

- During the first quarter of 2023, Innoviva repurchased approximately 3.4 million shares of its outstanding common stock for $40.3 million.

- In January 2023, Innoviva paid off the remaining principal balance of $96.2 million of its convertible subordinated notes, due 2023.

Clinical Updates

- On April 17, 2023, the FDA's Antimicrobial Drugs Advisory Committee (AMDAC) unanimously voted 12-0 in support of approval of sulbactam-durlobactam based on a favorable benefit-risk assessment for the treatment of adults with hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by susceptible strains of *Acinetobacter baumannii-calcoaceticus* complex (*Acinetobacter*). The sulbactam-durlobactam New Drug Application (NDA), filed by Entasis, was accepted and granted Priority Review by the FDA in November 2022, with a Prescription Drug User Fee Act (PDUFA) target action date of May 29, 2023.

- Phase 3 Zoliflodacin study on track to complete enrollment in second half of 2023. Zoliflodacin is a novel, first-in-class oral antibiotic in development for the treatment of uncomplicated gonorrhea.

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 healthcare assets include infectious disease and hospital assets stemming from acquisitions of Entasis Therapeutics, including its lead asset sulbactam-durlobactam, and La Jolla Pharmaceutical 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® and XERAVA® 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 March 31,	
	2023	2022
Revenue:		
Royalty revenue, net (1)	$ 56,858	$ 90,059
Net product sales	11,514	-
License revenue	8,000	-
Total revenue	76,372	90,059
Expenses:		
Cost of products sold (inclusive of amortization of inventory fair value adjustments, excluding depreciation and amortization of intangible assets)	8,749	-
Cost of license revenue	1,600	-
Selling, general and administrative	19,735	6,492
Research and development	12,588	5,838
Amortization of acquired intangible assets	3,805	-
Loss on debt extinguishment	-	20,662
Changes in fair values of equity method investments, net	(15,817)	11,950
Changes in fair values of equity and long-term investments, net	2,164	(2,539)
Interest and dividend income	(3,365)	(322)
Interest expense	4,427	3,010
Other expense, net	1,346	250
Total expenses	35,232	45,341
Income before income taxes	41,140	44,718
Income tax expense	6,275	6,860
Net income	34,865	37,858
Net income attributable to noncontrolling interest	-	22,085
Net income attributable to Innoviva stockholders	$ 34,865	$ 15,773
Basic net income per share attributable to Innoviva stockholders	$ 0.51	$ 0.23
Diluted net income per share attributable to Innoviva stockholders	$ 0.42	$ 0.20
Shares used to compute basic net income per share	67,786	69,544
Shares used to compute diluted net income per share	89,788	93,730

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

	Three Months Ended March 31,	
	2023	2022
	(unaudited)	
Royalties	$ 60,314	$ 93,515
Amortization of capitalized fees	(3,456)	(3,456)
Royalty revenue, net	$ 56,858	$ 90,059

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

	March 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 144,049	$ 291,049
Royalty and product sale receivables	75,804	64,073
Inventory, net	49,653	55,897
Prepaid expense and other current assets	26,940	32,492
Property and equipment, net	180	170
Equity and long-term investments	455,865	403,013
Capitalized fees	94,151	97,607
Right-of-use assets	2,973	3,265
Goodwill	27,946	26,713
Intangible assets	248,314	252,919
Other assets	3,893	4,299
Total assets	$ 1,129,768	$ 1,231,497
Liabilities and stockholders' equity		
Other current liabilities	$ 35,210	$ 32,322
Accrued interest payable	833	4,359
Deferred revenue	2,094	2,094
Convertible subordinated notes, due 2023, net	-	96,193
Convertible senior notes, due 2025, net	190,759	190,583
Convertible senior notes, due 2028, net	253,933	253,597
Other long term liabilities	70,133	70,918
Deferred tax liabilities	5,392	5,771
Income tax payable - long term	9,921	9,872
Innoviva stockholders' equity	561,493	565,788
Total liabilities and stockholders' equity	$ 1,129,768	$ 1,231,497

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

	Three Months Ended March 31,	
	2023	2022
Net cash provided by operating activities	$ 25,684	$ 98,102
Net cash used in investing activities	(35,722)	(143,156)
Net cash (used in) provided by financing activities	(136,962)	60,331
Net change	$ (147,000)	$ 15,277
Cash and cash equivalents at beginning of period	291,049	201,525
Cash, cash equivalents and restricted cash at end of period	$ 144,049	$ 216,802

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