

**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): **April 27, 2022**

INNOVIVA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation)

000-30319

(Commission File Number)

94-3265960

(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 April 27, 2022, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended March 31, 2022. 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.

Exhibit # Description

99.1	Press Release dated April 27, 2022.
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: April 27, 2022

By: /s/ Pavel Raifeld

Pavel Raifeld
Chief Executive Officer



Innoviva Reports First Quarter 2022 Financial Results

- Royalties increased by 5% to \$93.5 million in the first quarter of 2022, compared to the same quarter in 2021.
- Issued \$261.0 million convertible senior notes due 2028 and repurchased a portion of the convertible subordinated notes due 2023.
- Invested \$45.0 million into Armata Pharmaceuticals Inc. (NYSE: ARMP) (“Armata”), an anti-infectives leader.
- Made a non-binding offer to acquire and provided \$15.0 million convertible debt financing to Entasis Therapeutics Holdings Inc. (NASDAQ: ETTX) (“Entasis”), an anti-infectives leader.

BURLINGAME, Calif., April 27, 2022 – Innoviva, Inc. (NASDAQ: INVA) (“Innoviva” and “the Company”) today reported financial results for the first quarter ended March 31, 2022.

- Gross royalty revenues of \$93.5 million from Glaxo Group Limited (“GSK”) for the first quarter of 2022 included royalties of \$55.8 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®], royalties of \$8.4 million from global net sales of ANORO[®] ELLIPTA[®] and royalties of \$29.3 million from global net sales of TRELEGY[®] ELLIPTA[®].¹
- Income from operations decreased by 2% to \$77.7 million, compared to the same quarter in 2021, primarily due to the accounting consolidation of Entasis’ financials, including operating expenses, starting on February 17, 2022.
- Decrease in fair values of equity and long-term investments of \$9.4 million in the first quarter of 2022 was mainly due to the volatility in the capital markets.
- Net cash and cash equivalents totaled \$183.3 million, excluding \$33.5 million of Entasis’ cash balance, and receivables from GSK totaled \$93.5 million as of March 31, 2022.

Pavel Raifeld, Chief Executive Officer of Innoviva, Inc., stated: “Our royalty revenues in the first quarter grew 5% year over year, displaying strong positive momentum in a volatile, pandemic-influenced environment.”

“RELVAR[®]/BREO[®] ELLIPTA[®] global net sales decreased slightly compared to first quarter 2021 with 4% U.S. net sales growth compensating for a slowdown in non-U.S. markets. U.S. sales were supported by favorable prior period adjustments. ANORO[®] ELLIPTA[®] global net sales decreased by 20% compared to first quarter of 2021 mainly due to pandemic driven LABA/LAMA class weakness and idiosyncratic pricing pressures in the U.S. market. Non-U.S. ANORO[®] ELLIPTA[®] net sales grew 3%, driven by increased patient dynamism in key EU markets. TRELEGY[®] ELLIPTA[®] global net sales increased 33% compared to first quarter 2021, driven primarily by strong U.S. growth for the triple therapy class. Non-US TRELEGY[®] ELLIPTA[®] net sales grew 31% supported by robust class performance and continued traction in new markets.”

Mr. Raifeld concluded, “Our diversified core royalty business has performed well, despite the lingering impact of the pandemic. We continued to optimize our capital structure, raising over \$250 million in 2028 convertible notes last quarter and repurchasing a significant portion of our outstanding 2023 convertible notes. We remain excited about the progress of, and continue to commit capital to, our strategic investments. While this quarter’s accounting consolidation of Entasis and debt refinancing have reduced our reported income, we view underlying activities giving rise to such accounting impacts as significant positives. Market volatility can meaningfully affect our reported earnings, and we are pleased with the resilience displayed by our key assets despite the market-wide downturn over the past quarter. In fact, it has created many new opportunities for accretive capital deployment, and we believe that our strong operating cash flow generation and disciplined, agile business development approach position us well to take advantage of the current environment and drive long-term value creation.”

Recent Highlights

- GSK Net Sales:
 - First quarter 2022 net sales of RELVAR[®]/BREO[®] ELLIPTA[®] by GSK were \$371.8 million, down 1% from \$375.9 million in the same quarter of 2021, with \$160.4 million in net sales from the U.S. market and \$211.4 million from non-U.S. markets.
 - First quarter 2022 net sales of ANORO[®] ELLIPTA[®] by GSK were \$129.9 million, down 20% from \$161.5 million in the same quarter of 2021, with \$54.5 million net sales from the U.S. market and \$75.4 million from non-U.S. markets.
 - First quarter 2022 net sales of TRELEGY[®] ELLIPTA[®] by GSK were \$450.9 million, up 33% from \$339.8 million in the same quarter of 2021, with \$317.4 million in net sales from the U.S. market and \$133.5 million in net sales from non-U.S. markets.
 - Capital Allocation:
 - During the first quarter of 2022, the Company’s wholly owned subsidiary, Innoviva Strategic Opportunities LLC, invested \$45.0 million to acquire 9.0 million shares of Armata common stock and warrants to purchase 4.5 million additional shares of common stock exercisable at \$5.00 per share, which resulted in Innoviva collectively owning approximately 69% of Armata’s outstanding stock without giving effect to our warrants.
 - During the first quarter of 2022, the Company’s wholly owned subsidiary, Innoviva Strategic Opportunities LLC, purchased a \$15.0 million note from Entasis that is convertible, subject to certain conditions, into Entasis’ common shares at \$1.48 per share and an equal number of warrants with \$1.48 per share strike price. The Company also made a non-binding offer to acquire all outstanding equity securities of Entasis that it does not own at \$2.00 per share.
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- o During the first quarter of 2022, the Company issued 2.125% convertible notes due 2028 with principal value of \$261.0 million and used a portion of the proceeds to repurchase \$144.8 million (or approximately 60% of outstanding) notes due 2023, resulting in \$20.7 million accounting loss on debt extinguishment.

In conjunction with the \$15.0 million investment into Entasis on February 17, 2022, the Company determined that it became the primary beneficiary of Entasis in accordance with U.S. GAAP and started to consolidate Entasis financials into the Company financials. The change in accounting treatment does not materially affect Innoviva's underlying financials or business operations.

¹ For TRELEGY[®] ELLIPTA[®], the amount represents 100% of royalty payments made by GSK to Theravance Respiratory Company, LLC ("TRC"). Innoviva owns 15% of the economic interest in TRC.

About Innoviva

Innoviva, Inc. (referred to as "Innoviva", the "Company", or "we" and other similar pronouns), is a company with a portfolio of royalties that include respiratory assets partnered with Glaxo Group Limited ("GSK"), including RELVAR[®]/BREO[®] ELLIPTA[®] (fluticasone furoate/ vilanterol, "FF/VI"), ANORO[®] ELLIPTA[®] (umeclidinium bromide/ vilanterol, "UMEC/VI") and TRELEGY[®] ELLIPTA[®] (the combination FF/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 is also entitled to 15% of royalty payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC ("TRC"), relating to TRELEGY[®] ELLIPTA[®] and any other product or combination of products that may be discovered and developed in the future under the LABA Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the "GSK Agreements"), which have been assigned to TRC other than RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®].

ANORO[®], RELVAR[®], BREO[®], TRELEGY[®] and ELLIPTA[®] are trademarks of the GlaxoSmithKline 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[®] and TRELEGY[®] ELLIPTA[®] 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 beyond the existing respiratory portfolio); 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"). 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, 2021 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,	
	2022	2021
Revenue:	\$ 90,059	\$ 85,518
Operating expenses:		
Research and development	5,838	49
General and administrative	6,492	5,986
Total operating expenses	<u>12,330</u>	<u>6,035</u>
Income from operations	77,729	79,483
Interest and dividend income	322	30
Other expense, net	(250)	(433)
Interest expense	(3,010)	(4,694)
Loss on debt extinguishment	(20,662)	-
Changes in fair values of equity and long-term investments	(9,411)	55,045
Income before income taxes	44,718	129,431
Income tax expense, net	6,860	19,736
Net income	37,858	109,695
Net income attributable to noncontrolling interest	22,085	15,572
Net income attributable to Innoviva stockholders	<u>\$ 15,773</u>	<u>\$ 94,123</u>
Basic net income per share attributable to Innoviva stockholders	\$ 0.23	\$ 0.93
Diluted net income per share attributable to Innoviva stockholders	\$ 0.20	\$ 0.84
Shares used to compute basic net income per share	69,544	101,365
Shares used to compute diluted net income per share	93,730	113,624

(1) Total net revenue from a related party is comprised of the following (in thousands):

	Three Months Ended	
	March 31,	
	2022	2021
	(unaudited)	
Royalties from a related party	\$ 93,515	\$ 88,974
Amortization of capitalized fees paid to a related party	(3,456)	(3,456)
Royalty revenue from a related party, net	<u>\$ 90,059</u>	<u>\$ 85,518</u>

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

	March 31, 2022 <u>(unaudited)</u>	December 31, 2021 <u>(1)</u>
Assets		
Cash and cash equivalents	\$ 216,802	\$ 201,525
Other current assets	101,021	112,148
Property and equipment, net	191	12
Equity and long-term investments	544,437	483,845
Capitalized fees paid to a related party, net	107,974	111,430
Right of use assets	3,794	97
Goodwill	1,844	-
Intangible assets	108,700	-
Deferred tax assets, net	22,398	17,327
Other assets	313	11
Total assets	<u>\$ 1,107,474</u>	<u>\$ 926,395</u>
Liabilities and stockholders' equity		
Other current liabilities	\$ 11,814	\$ 1,655
Accrued interest payable	1,397	4,152
Convertible subordinated notes, due 2023, net	96,016	240,364
Convertible senior notes, due 2025, net	190,063	154,289
Convertible senior notes, due 2028, net	252,668	-
Lease liabilities, long-term	3,299	-
Innoviva stockholders' equity	386,642	414,743
Noncontrolling interest	165,575	111,192
Total liabilities and stockholders' equity	<u>\$ 1,107,474</u>	<u>\$ 926,395</u>

(1) The selected consolidated balance sheet amounts at December 31, 2021 are derived from audited financial statements.

INNOVIVA, INC.
Cash Flows Summary
(in thousands)

	Three Months Ended March 31,	
	2022	2021
	(unaudited)	
Net cash provided by operating activities	\$ 98,102	\$ 84,107
Net cash used in investing activities	(143,156)	(26,394)
Net cash provided by (used in) financing activities	60,331	(21,310)

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