
**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 9, 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:

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 9, 2022, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended September 30, 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

[99.1](#) [Press Release dated November 9, 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: November 9, 2022

By: /s/ Pavel Raifeld

Pavel Raifeld
Chief Executive Officer

Innoviva Reports Third Quarter 2022 Financial Results and Highlights Recent Company Progress

- Royalties at \$65.6 million in the third quarter of 2022, compared to \$65.7 million in the same quarter of 2021, for RELVAR[®]/BREO[®] ELLIPTA[®] and ANORO[®] ELLIPTA[®]
- Announced new \$100.0 million share repurchase program
- Completed the sale of 15% ownership interest in Theravance Respiratory Company (“TRC”) to Royalty Pharma
- Completed acquisition of the remaining approximately 40% equity of Entasis Therapeutics Holdings Inc. (“Entasis”)
- Completed acquisition of La Jolla Pharmaceutical Company (“La Jolla”)

BURLINGAME, Calif.—(BUSINESS WIRE)— November 9, 2022—Innoviva, Inc. (NASDAQ: INVA) (“Innoviva” and “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, 2022.

- Gross royalty revenues of \$65.6 million from Glaxo Group Limited (“GSK”) for the third quarter of 2022 included royalties of \$55.7 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®] and royalties of \$9.9 million from global net sales of ANORO[®] ELLIPTA[®].
- Income before income taxes increased to \$286.4 million, compared to \$123.2 million the same quarter in 2021, primarily due to the gain from the sale of 15% ownership interest in TRC.
- Increase in fair values of equity and long-term investments of \$0.1 million in the third quarter of 2022 was mainly due to the volatility in the capital markets.
- Net cash provided by operating activities was \$192.8 million in the first nine months of 2022, compared to \$265.4 million in the same period of 2021.
- Net cash and cash equivalents totaled \$300.8 million, and royalty and product sale receivables totaled \$72.3 million as of September 30, 2022.

Pavel Raifeld, Chief Executive Officer of Innoviva, Inc., stated: “Our diversified core royalty business continues to perform well and deliver strong revenues despite challenging market conditions. RELVAR[®]/BREO[®] ELLIPTA[®] global net sales grew slightly compared to third quarter 2021 with U.S. net sales growth compensating for foreign currency changes and a slowdown in non-U.S. markets. ANORO[®] ELLIPTA[®] global net sales decreased by 15% compared to third quarter of 2021 mainly due to pricing pressures and foreign currency changes.”

Mr. Raifeld continued: “Over the past quarter, we significantly advanced our strategy with the acquisitions of Entasis and La Jolla, giving us a strong footprint in the hospital and infectious disease space with an attractive growth outlook rooted in a robust portfolio of marketed and pipeline products. Our financials have started to reflect the growing complexity of our business given the newly acquired operating platform which we believe has excellent value creation potential.”

“We remain committed to a disciplined, thoughtful, and thorough approach to capital allocation. The new share repurchase program underscores our confidence in Innoviva’s prospects and value embedded within our business, supported by the strength of our balance sheet and cashflows, as we seek to take advantage of market dislocations. We explore all avenues in our efforts to create shareholder value,” concluded Mr. Raifeld.

Recent Highlights

- GSK Net Sales:
 - Third quarter 2022 net sales of RELVAR[®]/BREO[®] ELLIPTA[®] by GSK were \$371.1 million, up 3% from \$360.6 million in the same quarter of 2021, with \$184.5 million in net sales from the U.S. market and \$186.6 million from non-U.S. markets.
 - Third quarter 2022 net sales of ANORO[®] ELLIPTA[®] by GSK were \$153.0 million, down 15% from \$179.1 million in the same quarter of 2021, with \$77.6 million net sales from the U.S. market and \$75.4 million from non-U.S. markets.
 - Corporate Updates:
 - Innoviva's Board of Directors has authorized a new share repurchase program under which the Company may repurchase up to \$100.0 million of its outstanding shares of common stock. The timing and amount of any share repurchases under the share repurchase program will be determined by Innoviva's management in its discretion based on ongoing assessments of the capital needs of the business, the market price of Innoviva's common stock, prevailing stock prices, general market conditions and other considerations. Share repurchases under the program may be made through a variety of methods, which may include open market purchases, privately negotiated transactions, in block trades, accelerated share repurchase transactions, exchange transactions, or any combination thereof or by other means in accordance with federal securities laws. This program has no termination date, may be suspended or discontinued at any time at the Company's discretion, and does not obligate the Company to acquire any amount of common stock.
 - On July 20, 2022, we completed the sale of our 15% ownership interest in TRC to Royalty Pharma for \$282 million, including payment for our portion of TRC's cash balance of \$4.4 million, and a potential \$50.0 million sales-based milestone payment, and received full ownership of equity and other investments that TRC owned prior to the transaction.
 - On July 11, 2022, we completed the purchase of all the issued and outstanding equity securities of Entasis not already owned by Innoviva for \$42.4 million. Entasis brings to Innoviva an infectious disease focused R&D platform anchored by its lead asset sulbactam-durlobactam (SUL-DUR).
 - On August 22, 2022, we completed the acquisition of La Jolla for a net cash price of \$150.5 million. La Jolla brings to Innoviva an established product portfolio, 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.
 - Clinical Updates:
 - At the annual meeting of the Infectious Disease Society of America which took place from October 19 to October 23, 2022 in Washington, D.C., our wholly owned subsidiary, Entasis, had six presentations on SUL-DUR data reinforcing the positive safety and efficacy findings from the Company's pivotal Phase 3 ATTACK trial, while another wholly owned subsidiary, La Jolla, had five abstracts on XERAVA[®] which focused primarily on its use in combination therapies.
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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, 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. Additional risk factors are presented on Form 8-K filed on August 23, 2022. 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,	
	2022	2021	2022	2021
Revenue:				
Royalty revenue, net (1)	\$ 62,150	\$ 97,862	\$ 260,429	\$ 284,186
Net product sales	5,107	-	5,107	-
Total revenue	<u>67,257</u>	<u>97,862</u>	<u>265,536</u>	<u>284,186</u>
Expenses:				
Cost of products sold (inclusive of amortization of inventory fair value adjustments)	3,680	-	3,680	-
Selling, general and administrative	27,810	2,860	46,084	13,074
Research and development	11,725	449	31,447	536
Amortization of acquired intangible assets	1,511	-	1,511	-
Gain on TRC sale	(266,696)	-	(266,696)	-
Loss on debt extinguishment	-	-	20,662	-
Changes in fair values of equity and long-term investments, net	(130)	(33,613)	67,881	(133,973)
Interest and dividend income	(2,135)	(453)	(3,181)	(503)
Interest expense	5,096	4,790	11,761	14,229
Other expense (income), net	(28)	652	750	2,036
Total expenses	<u>(219,167)</u>	<u>(25,315)</u>	<u>(86,101)</u>	<u>(104,601)</u>
Income before income taxes	286,424	123,177	351,637	388,787
Income tax expense (benefit), net	57,077	20,531	63,061	65,600
Net income	229,347	102,646	288,576	323,187
Net income attributable to noncontrolling interest	(36,176)	30,208	6,341	67,678
Net income attributable to Innoviva stockholders	<u>\$ 265,523</u>	<u>\$ 72,438</u>	<u>\$ 282,235</u>	<u>\$ 255,509</u>
Basic net income per share attributable to Innoviva stockholders	\$ 3.81	\$ 1.04	\$ 4.05	\$ 2.96
Diluted net income per share attributable to Innoviva stockholders	\$ 2.80	\$ 0.90	\$ 3.07	\$ 2.63
Shares used to compute basic net income per share	69,731	69,458	69,640	86,298
Shares used to compute diluted net income per share	95,830	81,699	95,072	98,536

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(unaudited)		(unaudited)	
Royalties from a related party	\$ 65,606	\$ 101,318	\$ 270,797	\$ 294,554
Amortization of capitalized fees paid to a related party	(3,456)	(3,456)	(10,368)	(10,368)
Royalty revenue from a related party, net	<u>\$ 62,150</u>	<u>\$ 97,862</u>	<u>\$ 260,429</u>	<u>\$ 284,186</u>

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

	September 30, 2022	December 31, 2021
Assets		
Cash and cash equivalents	\$ 300,789	\$ 201,525
Short-term marketable securities	282	-
Royalty and product sale receivables	72,349	110,711
Inventory, net	70,807	-
Prepaid expense and other current assets	10,364	1,437
Property and equipment, net	165	12
Equity and long-term investments	489,111	483,845
Capitalized fees	101,062	111,430
Right-of-use assets	3,679	97
Goodwill	15,995	-
Intangible assets	258,489	-
Deferred tax assets, net	-	17,327
Other assets	4,620	11
Total assets	\$ 1,327,712	\$ 926,395
Liabilities and stockholders' equity		
Other current liabilities	\$ 25,398	\$ 1,655
Accrued interest payable	5,702	4,152
Deferred revenues	2,849	-
Income tax payable	33,804	-
Convertible subordinated notes, due 2023, net	96,131	240,364
Convertible senior notes, due 2025, net	190,408	154,289
Convertible senior notes, due 2028, net	253,271	-
Other long term liabilities	78,781	-
Innoviva stockholders' equity	641,368	414,743
Noncontrolling interest	-	111,192
Total liabilities and stockholders' equity	\$ 1,327,712	\$ 926,395



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

	Nine Months Ended September 30,	
	2022	2021
Net cash provided by operating activities	\$ 192,827	\$ 265,432
Net cash provided by (used in) investing activities	(47,956)	63,627
Net cash used in financing activities	(45,567)	(440,431)
Net change	99,304	(111,372)
Cash and cash equivalents at beginning of period	201,525	246,487
Cash, cash equivalents and restricted cash at end of period	<u>\$ 300,829</u>	<u>\$ 135,115</u>

Innoviva Contacts:

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