

**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): **October 27, 2021**

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 October 27, 2021, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended September 30, 2021. 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 October 27, 2021](#)

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: October 27, 2021

By: /s/ Pavel Raifeld

Pavel Raifeld
Chief Executive Officer

Innoviva Reports Third Quarter 2021 Financial Results

- Royalties increased by 10% to \$101.3 million in the third quarter of 2021, compared to the same quarter in 2020.

BURLINGAME, Calif., October 27, 2021 – Innoviva, Inc. (NASDAQ: INVA) (“Innoviva” and “the Company”) today reported financial results for the third quarter ended September 30, 2021.

- Gross royalty revenues of \$101.3 million from Glaxo Group Limited (“GSK”) for the third quarter of 2021 included royalties of \$54.1 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®], royalties of \$11.6 million from global net sales of ANORO[®] ELLIPTA[®] and royalties of \$35.6 million from global net sales of TRELEGY[®] ELLIPTA[®].¹
- Increase in fair values of strategic equity and long term investments of \$33.6 million in the third quarter of 2021 was mainly due to higher net valuation as of September 30, 2021.
- Income from operations increased by 12% to \$94.6 million, compared to the same quarter in 2020.
- Basic and diluted net income per share attributable to Innoviva stockholders increased 3.7 and 3.5 times to \$1.04 and \$0.90 from \$0.28 and \$0.26, respectively, compared to the same quarter in 2020,
- Net cash and cash equivalents totaled \$135.1 million, and receivables from GSK totaled \$101.3 million as of September 30, 2021.

Pavel Raifeld, Chief Executive Officer of Innoviva, Inc., stated, “Our royalty revenues grew 10% year over year, displaying strong positive momentum in a volatile environment.”

“RELVAR[®]/BREO[®] ELLIPTA[®] global net sales decreased 15% compared to the third quarter of 2020 mainly because the significant favorable prior period adjustment in the U.S. in 2020 was not repeated. Non-U.S. sales increased 4% with strong growth in Japan and the EU despite generic competition and class-wide pressures. ANORO[®] ELLIPTA[®] global net sales decreased by 2% in the third quarter of 2021 due to pandemic-driven LABA/LAMA class weakness. U.S. net sales decreased with slower new patient growth. Non-U.S. ANORO[®] ELLIPTA[®] net sales increased 8% because of meaningful growth in select markets despite class challenges. TRELEGY[®] ELLIPTA[®] global net sales increased 77% in the third quarter of 2021, driven by excellent U.S. growth for the triple therapy class and favorable prior period adjustment. Non-US TRELEGY[®] ELLIPTA[®] sales also grew as Trelegy continues to launch in new markets.”

Mr. Raifeld concluded, “We are pleased with the growth and resilience in our core royalty business. In addition, we are excited by strong progress across our asset portfolio, including recent pivotal clinical data read out at Entasis Therapeutics. Our financial performance remains robust, with basic net income per share exceeding \$1 for the quarter, a nearly four-fold increase over the third quarter of 2020, supported by the recently completed equity repurchase, as we continue to focus on shareholder value creation through thoughtful capital deployment and operational excellence.”

Recent Highlights

GSK Net Sales:

- Third quarter 2021 net sales of RELVAR®/BREO® ELLIPTA® by GSK were \$360.6 million, down 15% from \$426.0 million in the same quarter of 2020, with \$146.0 million in net sales from the U.S. market and \$214.6 million from non-U.S. markets.
- Third quarter 2021 net sales of ANORO® ELLIPTA® by GSK were \$179.1 million, down 2% from \$182.8 million in the same quarter of 2020, with \$102.0 million net sales from the U.S. market and \$77.1 million from non-U.S. markets.
- Third quarter 2021 net sales of TRELEGY® ELLIPTA® by GSK were \$445.6 million, up 77% from \$251.9 million in the same quarter of 2020, with \$314.8 million in net sales from the U.S. market and \$130.8 million in net sales from non-U.S. markets.

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, 2020 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,	
	2021	2020	2021	2020
Revenue:				
Royalty revenue from a related party, net ⁽¹⁾	\$ 97,862	\$ 88,694	\$ 284,186	\$ 236,318
Revenue from collaborative arrangements with a related party	-	-	-	10,000
Total net revenue	<u>97,862</u>	<u>88,694</u>	<u>284,186</u>	<u>246,318</u>
Operating expenses:				
Research and development	449	1,010	536	1,569
General and administrative	2,860	3,254	13,074	8,413
Total operating expenses	<u>3,309</u>	<u>4,264</u>	<u>13,610</u>	<u>9,982</u>
Income from operations	94,553	84,430	270,576	236,336
Other income (expense), net	(652)	(13)	(2,036)	85
Interest income	453	41	503	1,501
Interest expense	(4,790)	(4,603)	(14,229)	(13,680)
Changes in fair values of equity and long-term investments, net	33,613	(29,368)	133,973	39,245
Income before income taxes	123,177	50,487	388,787	263,487
Income tax expense, net	20,531	8,866	65,600	44,689
Net income	102,646	41,621	323,187	218,798
Net income attributable to noncontrolling interest	30,208	13,403	67,678	48,299
Net income attributable to Innoviva stockholders	<u>\$ 72,438</u>	<u>\$ 28,218</u>	<u>\$ 255,509</u>	<u>\$ 170,499</u>
Basic net income per share attributable to Innoviva stockholders	\$ 1.04	\$ 0.28	\$ 2.96	\$ 1.68
Diluted net income per share attributable to Innoviva stockholders	\$ 0.90	\$ 0.26	\$ 2.63	\$ 1.53
Shares used to compute basic net income per share	69,458	101,358	86,298	101,306
Shares used to compute diluted net income per share	81,699	113,572	98,536	113,543

(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,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Royalties from a related party	\$ 101,318	\$ 92,150	\$ 294,554	\$ 246,686
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>\$ 97,862</u>	<u>\$ 88,694</u>	<u>\$ 284,186</u>	<u>\$ 236,318</u>

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

	September 30, 2021 <u>(unaudited)</u>	December 31, 2020 <u>(1)</u>
Assets		
Cash, cash equivalents and marketable securities	\$ 135,115	\$ 246,487
Other current assets	101,813	95,571
Property and equipment, net	15	28
Equity and long-term investments	507,116	438,258
Capitalized fees paid to a related party, net	114,885	125,253
Deferred tax assets, net	28,159	93,759
Other assets	136	214
Total assets	<u>\$ 887,239</u>	<u>\$ 999,570</u>
Liabilities and stockholders' equity		
Other current liabilities	\$ 1,457	\$ 1,958
Accrued interest payable	1,668	4,152
Convertible subordinated notes, net	240,215	239,783
Convertible senior notes, net	152,080	145,734
Other long-term liabilities	14	106
Innoviva stockholders' equity	402,811	539,912
Noncontrolling interest	88,994	67,925
Total liabilities and stockholders' equity	<u>\$ 887,239</u>	<u>\$ 999,570</u>

(1) The selected consolidated balance sheet amounts at December 31, 2020 are derived from audited financial statements.

INNOVIVA, INC.
Cash Flows Summary
(in thousands)

	<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>
	<u>(unaudited)</u>	
Net cash provided by operating activities	\$ 265,432	\$ 227,833
Net cash provided by investing activities	63,627	544
Net cash used in financing activities	(440,431)	(27,280)

Investor & Media Contacts:

Sloane & Company
James Goldfarb
212-486-9500
jgoldfarb@sloanep.com

###
