
**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 28, 2020**

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 28, 2020, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended September 30, 2020. 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 28, 2020](#)

104 Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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.

Date: October 28, 2020

INNOVIVA, INC.

By: /s/ Pavel Raifeld

Pavel Raifeld

Chief Executive Officer



Innoviva Reports Third Quarter 2020 Financial Results

- Royalties increased by 33% to \$92.2 million in the third quarter of 2020, compared to the same quarter in 2019.
- Invested an additional \$12.5 million into the common stock and warrants of Entasis Therapeutics Holding Inc. (NASDAQ: ETTX), a leader in anti-infectives development.

BURLINGAME, Calif., October 28, 2020 – Innoviva, Inc. (NASDAQ: INVA) (the “Company”) today reported financial results for the third quarter ended September 30, 2020.

- Gross royalty revenues of \$92.2 million from Glaxo Group Limited (“GSK”) for the third quarter of 2020 included royalties of \$63.9 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®], royalties of \$11.9 million from global net sales of ANORO[®] ELLIPTA[®] and royalties of \$16.4 million from global net sales of TRELEGY[®] ELLIPTA[®].¹
- Decrease in fair values of equity investments of \$29.4 million was mainly due to the lower stock prices of Armata Pharmaceuticals Inc. and Entasis Therapeutics Holdings, Inc. as of September 30, 2020.
- Income before income taxes decreased by 12% to \$50.5 million, compared to the same quarter in 2019.
- Net cash and cash equivalents, short-term investments and marketable securities, excluding \$4.3 million cash balance attributable to a variable interest entity, totaled \$474.9 million, and receivables from GSK totaled \$92.2 million, as of September 30, 2020.

Pavel Raifeld, Chief Executive Officer of Innoviva, Inc., stated: “RELVAR[®]/BREO[®] ELLIPTA[®] global net sales increased by 38% compared to the third quarter of 2019. U.S. net sales increased by 79% due to a significant prior period adjustment from favorable pricing and continued volume growth. Non-U.S. sales increased by 10%, driven by sales growth in certain European markets, Japan and Canada.

ANORO[®] ELLIPTA[®] global net sales increased by 3% in the third quarter of 2020 compared to the same quarter of 2019. U.S. net sales decreased by 4% due to competitive pricing pressure despite strong volume trends. Non-U.S. ANORO[®] ELLIPTA[®] net sales increased 16%, supported by growth in certain European markets. In addition, TRELEGY[®] ELLIPTA[®] global net sales were \$251.9 million, compared to \$172.8 million during the comparable period a year ago.

“As the market environment has continued to normalize, we are pleased with the performance of our products due to excellent underlying demand,” said Pavel Raifeld.

Mr. Raifeld concluded, “Today’s results demonstrate the resilience of our revenues even in the face of massive global disruptions driven by COVID-19 and point to our products’ long-term sustainability, while the FDA’s recent approval of the asthma indication for Trelegy reinforces strong growth potential. Combined with our resources, focus on thoughtful capital allocation, and strict cost discipline, this positions us well for shareholder value creation.”

Recent Highlights

- GSK Net Sales:
 - Third quarter 2020 net sales of RELVAR[®]/BREO[®] ELLIPTA[®] by GSK were \$426.0 million, up 38% from \$309.5 million in the third quarter of 2019, with \$219.2 million in net sales from the U.S. market and \$206.8 million from non-U.S. markets.
 - Third quarter 2020 net sales of ANORO[®] ELLIPTA[®] by GSK were \$182.8 million, up 3% from \$177.7 million in the third quarter of 2019, with \$111.5 million net sales from the U.S. market and \$71.3 million from non-U.S. markets.
 - Third quarter 2020 net sales of TRELEGY[®] ELLIPTA[®] by GSK were \$251.9 million, up 46% from \$172.8 million in the third quarter of 2019, with \$165.3 million in net sales from the U.S. market and \$86.6 million in net sales from non-U.S. markets.
- Capital Allocation:
 - During the third quarter of 2020, the Company invested additional \$12.5 million in 4.7 million shares of common stock of Entasis Therapeutics, Inc., a company focused on development of novel anti-bacterial therapies for multi-drug resistant Gram-negative bacteria, which pose well acknowledged public health risk and a rapidly growing medical need, and warrants to purchase up to an additional 4.7 million shares of the common stock at \$2.675 per unit. With this additional investment, Innoviva owned approximately 52.6% of Entasis' outstanding common stock as of September 30, 2020.

¹ For TRELEGY[®] ELLIPTA[®], Innoviva is entitled to 15% of royalty payments made by GSK that are assigned to TRC, LLC.

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, 2019 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,	
	2020	2019	2020	2019
Revenue:				
Royalty revenue from a related party, net ⁽¹⁾	\$ 88,694	\$ 65,755	\$ 236,318	\$ 185,045
Revenue from collaborative arrangements with a related party	-	-	10,000	-
Total net revenue	<u>88,694</u>	<u>65,755</u>	<u>246,318</u>	<u>185,045</u>
Operating expenses:				
Research and development	1,010	-	1,569	-
General and administrative	3,254	4,962	8,413	12,324
Total operating expenses	<u>4,264</u>	<u>4,962</u>	<u>9,982</u>	<u>12,324</u>
Income from operations	84,430	60,793	236,336	172,721
Other income (expense), net	(13)	(115)	85	(122)
Interest income	41	1,624	1,501	4,002
Interest expense	(4,603)	(4,693)	(13,680)	(13,971)
Changes in fair values of equity investments	(29,368)	-	39,245	-
Income before income taxes	50,487	57,609	263,487	162,630
Income tax expense, net	8,866	10,558	44,689	29,499
Net income	41,621	47,051	218,798	133,131
Net income attributable to noncontrolling interest	13,403	7,242	48,299	21,792
Net income attributable to Innoviva stockholders	<u>\$ 28,218</u>	<u>\$ 39,809</u>	<u>\$ 170,499</u>	<u>\$ 111,339</u>
Basic net income per share attributable to Innoviva stockholders	\$ 0.28	\$ 0.39	\$ 1.68	\$ 1.10
Diluted net income per share attributable to Innoviva stockholders	\$ 0.26	\$ 0.36	\$ 1.53	\$ 1.01
Shares used to compute basic net income per share	101,358	101,191	101,306	101,134
Shares used to compute diluted net income per share	113,572	113,415	113,543	113,394

(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,	
	2020	2019	2020	2019
	(unaudited)		(unaudited)	
Royalties from a related party	\$ 92,150	\$ 69,211	\$ 246,686	\$ 195,413
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>\$ 88,694</u>	<u>\$ 65,755</u>	<u>\$ 236,318</u>	<u>\$ 185,045</u>

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

	September 30, 2020 <u>(unaudited)</u>	December 31, 2019 <u>(1)</u>
Assets		
Cash, cash equivalents and marketable securities	\$ 479,193	\$ 350,845
Other current assets	92,848	80,389
Property and equipment, net	33	33
Equity investments	111,745	-
Capitalized fees paid to a related party, net	128,708	139,076
Deferred tax assets, net	109,490	154,171
Other assets	239	312
Total assets	\$ 922,256	\$ 724,826
Liabilities and stockholders' equity		
Other current liabilities	\$ 2,230	\$ 1,219
Accrued interest payable	1,668	4,152
Convertible subordinated notes, net	239,638	239,217
Convertible senior notes, net	143,712	137,903
Other long-term liabilities	136	219
Innoviva stockholders' equity	485,556	313,495
Noncontrolling interest	49,316	28,621
Total liabilities and stockholders' equity	\$ 922,256	\$ 724,826

(1) The selected consolidated balance sheet amounts at December 31, 2019 are derived from audited financial statements.

INNOVIVA, INC.
Cash Flows Summary
(in thousands)

	Nine Months Ended September 30,	
	2020	2019
	<u>(unaudited)</u>	
Net cash provided by operating activities	\$ 227,833	\$ 190,553
Net cash provided by (used in) investing activities	544	(69,997)
Net cash used in financing activities	(27,280)	(10,027)

Investor & Media Contacts:

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