

**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): **July 28, 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 July 28, 2021, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended June 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 July 28, 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: July 28, 2021

By: /s/ Pavel Raifeld
Pavel Raifeld
Chief Executive Officer



Innoviva Reports Second Quarter 2021 Financial Results

- Royalties increased by 44% to \$104.3 million in the second quarter of 2021, compared to the same quarter in 2020.
- Repurchased GSK's full 32% equity stake in Innoviva for \$392 million purchase price.
- Strategically invested an additional \$20 million into Entasis Therapeutics Holdings Inc. (NASDAQ:ETTX), a leader in anti-infectives development.

BURLINGAME, Calif., July 28, 2021 – Innoviva, Inc. (NASDAQ: INVA) (“Innoviva” and “the Company”) today reported financial results for the second quarter ended June 30, 2021.

- Gross royalty revenues of \$104.3 million from Glaxo Group Limited (“GSK”) for the second quarter of 2021 included royalties of \$65.9 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®], royalties of \$12.0 million from global net sales of ANORO[®] ELLIPTA[®] and royalties of \$26.4 million from global net sales of TRELEGY[®] ELLIPTA[®].¹
- Increase in fair values of strategic equity and long-term investments of \$45.3 million in the second quarter of 2021 was mainly due to higher net valuation, as of June 30, 2021.
- Income before income taxes increased by 15% to \$136.2 million, compared to the same quarter in 2020.
- Net cash and cash equivalents, excluding \$3.2 million cash balance attributable to a variable interest entity, totaled \$40.1 million, and receivables from GSK totaled \$104.3 million as of June 30, 2021.

Pavel Raifeld, Chief Executive Officer of Innoviva, Inc., stated: “Our royalty revenues grew 44% year over year, demonstrating continued strength and resilience in the face of the pandemic.”

“RELVAR[®]/BREO[®] ELLIPTA[®] global net sales increased meaningfully compared to the second quarter of 2020. U.S. net sales increased significantly, driven in part by a favorable adjustment. Non-U.S. sales increased by 13% as the ICS/LABA class growth decline was more than offset by beneficial adherence trends among existing patients. ANORO[®] ELLIPTA[®] global net sales increased by 7% in the second quarter of 2021. U.S. net sales decreased by 3% due to negative volume dynamics. Non-U.S. ANORO[®] ELLIPTA[®] net sales increased by 25% as the environment normalized. TRELEGY[®] ELLIPTA[®] global net sales increased by 69% in the second quarter of 2021, driven by strong volume growth and a favorable adjustment in the U.S. as well as strong launches in non-U.S. markets.”

Mr. Raifeld concluded, “Over the past quarter, we continued to execute on our strategy of creating shareholder value through operational excellence and strategic investments, deploying in excess of \$400 million. We are pleased with the superior performance across all key aspects of our business, and we believe GSK equity stake repurchase to be a strategically and economically attractive transaction that ushered a new chapter in our story and strongly positioned us for continued success.”

Recent Highlights

- GSK Net Sales:
 - Second quarter 2021 net sales of RELVAR[®]/BREO[®] ELLIPTA[®] by GSK were \$439.5 million, up 45% from \$303.8 million in the same quarter of 2020, with \$212.3 million in net sales from the U.S. market and \$227.2 million from non-U.S. markets.
 - Second quarter 2021 net sales of ANORO[®] ELLIPTA[®] by GSK were \$184.0 million, up 7% from \$172.3 million in the same quarter of 2020, with \$106.0 million net sales from the U.S. market and \$78.0 million from non-U.S. markets.
 - Second quarter 2021 net sales of TRELEGY[®] ELLIPTA[®] by GSK were \$405.9 million, up 69% from \$240.5 million in the same quarter of 2020, with \$285.5 million in net sales from the U.S. market and \$120.4 million in net sales from non-U.S. markets.
- Capital Allocation:
 - In May 2021, the Company repurchased 32,005,260 shares of its common stock from GSK at \$12.25 per share for a total amount (including related transaction fees) of \$394.1 million. The repurchased shares represented all of GSK’s equity stake in the Company, which was approximately 32% of the Company’s shares.
 - During the second quarter of 2021, the Company’s wholly owned subsidiary, Innoviva Strategic Opportunities LLC, invested \$20.0 million to acquire 10 million shares of Entasis’ common stock and warrants to purchase up to an additional 10 million shares of common stock at \$2.00 per share. With this additional investment, Innoviva collectively owned approximately 60.6% of Entasis’ common stock as of June 30, 2021 in addition to the warrants.

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Royalty revenue from a related party, net ⁽¹⁾	\$ 100,806	\$ 68,946	\$ 186,324	\$ 147,624
Revenue from collaborative arrangements with a related party	-	10,000	-	10,000
Total net revenue	<u>100,806</u>	<u>78,946</u>	<u>186,324</u>	<u>157,624</u>
Operating expenses:				
Research and development	38	559	87	559
General and administrative	4,228	2,596	10,214	5,159
Total operating expenses	<u>4,266</u>	<u>3,155</u>	<u>10,301</u>	<u>5,718</u>
Income from operations	96,540	75,791	176,023	151,906
Other income (expense), net	(951)	30	(1,384)	98
Interest income	20	158	50	1,460
Interest expense	(4,745)	(4,561)	(9,439)	(9,077)
Changes in fair values of equity and long-term investments, net	45,315	46,698	100,360	68,613
Income before income taxes	136,179	118,116	265,610	213,000
Income tax expense, net	25,333	19,891	45,069	35,823
Net income	110,846	98,225	220,541	177,177
Net income attributable to noncontrolling interest	21,898	21,381	37,470	34,896
Net income attributable to Innoviva stockholders	<u>\$ 88,948</u>	<u>\$ 76,844</u>	<u>\$ 183,071</u>	<u>\$ 142,281</u>
Basic net income per share attributable to Innoviva stockholders	\$ 1.01	\$ 0.76	\$ 1.93	\$ 1.40
Diluted net income per share attributable to Innoviva stockholders	\$ 0.90	\$ 0.69	\$ 1.73	\$ 1.27
Shares used to compute basic net income per share	88,423	101,324	94,858	101,280
Shares used to compute diluted net income per share	100,639	113,545	107,096	113,527

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Royalties from a related party	\$ 104,262	\$ 72,402	\$ 193,236	\$ 154,536
Amortization of capitalized fees paid to a related party	(3,456)	(3,456)	(6,912)	(6,912)
Royalty revenue from a related party, net	<u>\$ 100,806</u>	<u>\$ 68,946</u>	<u>\$ 186,324</u>	<u>\$ 147,624</u>

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

	June 30, 2021 <u>(unaudited)</u>	December 31, 2020 <u>(1)</u>
Assets		
Cash, cash equivalents and marketable securities	\$ 43,265	\$ 246,487
Other current assets	104,996	95,571
Property and equipment, net	19	28
Equity and long-term investments	473,677	438,258
Capitalized fees paid to a related party, net	118,341	125,253
Deferred tax assets, net	48,690	93,759
Other assets	162	214
Total assets	<u>\$ 789,150</u>	<u>\$ 999,570</u>
Liabilities and stockholders' equity		
Other current liabilities	\$ 1,219	\$ 1,958
Accrued interest payable	4,152	4,152
Convertible subordinated notes, net	240,072	239,783
Convertible senior notes, net	149,917	145,734
Other long-term liabilities	45	106
Innoviva stockholders' equity	329,780	539,912
Noncontrolling interest	<u>63,965</u>	<u>67,925</u>
Total liabilities and stockholders' equity	<u>\$ 789,150</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)

	Six Months Ended June 30,	
	2021	2020
	(unaudited)	
Net cash provided by operating activities	\$ 168,721	\$ 153,275
Net cash provided by investing activities	63,627	9,044
Net cash used in financing activities	(435,570)	(27,268)

Investor & Media Contacts:

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