
**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 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 April 28, 2021, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended March 31, 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 April 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: April 28, 2021

By: /s/ Pavel Raifeld

Pavel Raifeld
Chief Executive Officer



Innoviva Reports First Quarter 2021 Financial Results

- Royalties increased by 8% to \$89.0 million in the first quarter of 2021, compared to the same quarter in 2020.
- Invested an additional \$20.0 million into Armata Pharmaceuticals Inc. (NYSE: ARMP), an anti-infectives leader, in the first quarter of 2021.
- Deborah L. Birx, M.D., appointed to the Company's Board of Directors.

BURLINGAME, Calif., April 28, 2021 – Innoviva, Inc. (NASDAQ: INVA) (“Innoviva” and “the Company”) today reported financial results for the first quarter ended March 31, 2021.

- Gross royalty revenues of \$89.0 million from Glaxo Group Limited (“GSK”) for the first quarter of 2021 included royalties of \$56.4 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®], royalties of \$10.5 million from global net sales of ANORO[®] ELLIPTA[®] and royalties of \$22.1 million from global net sales of TRELEGY[®] ELLIPTA[®].¹
- Increase in fair values of equity and long term investments of \$55.0 million in the first quarter of 2021 was mainly due to higher net valuation of our various investments, including common stock and warrants, as of March 31, 2021.
- Income before income taxes increased by 36% to \$129.4 million, compared to the same quarter in 2020.
- Net cash and cash equivalents, excluding \$3.3 million cash balance attributable to a variable interest entity, totaled \$279.6 million, and receivables from GSK totaled \$89.0 million as of March 31, 2021.

Pavel Raifeld, Chief Executive Officer of Innoviva, Inc., stated: “Our royalty revenues grew 8% year over year, meaningfully positively impacted by non-recurring items in the quarter, including prior-period adjustments and favorable foreign exchange rates.”

“RELVAR[®]/BREO[®] ELLIPTA[®] global net sales increased modestly compared to the first quarter of 2020. U.S. net sales increased by 5% as a decline in volume was more than offset by a favorable prior-period adjustment. Non-U.S. sales decreased by 2% as the ICS/LABA class growth declined and the positive prior-year stockpiling impact was not repeated. ANORO[®] ELLIPTA[®] global net sales increased by 7% in the first quarter of 2021. U.S. net sales increased by 8% due to a favorable prior-period adjustment and beneficial pricing trends, offsetting negative volume dynamics. Non-U.S. ANORO[®] ELLIPTA[®] net sales increased by 5%, supported by a positive currency impact. TRELEGY[®] ELLIPTA[®] global net sales increased by 37% in the first quarter of 2021, driven by strong volume growth and a favorable prior-period adjustment in the U.S. as well as ongoing launches in non-U.S. markets.”

Mr. Raifeld continued, “We are pleased with our portfolio’s performance this quarter in the face of intensifying competition from generic and novel therapies, especially in the ICS/LABA class, and uncertainty related to the ongoing pandemic.”

Mr. Raifeld concluded, “Over the past quarter we continued to strategically deploy capital in promising healthcare companies, successfully resolved our arbitration with Theravance BioPharma and strengthened our Board, positioning Innoviva for further value creation.”

Recent Highlights

- GSK Net Sales:
 - First quarter 2021 net sales of RELVAR[®]/BREO[®] ELLIPTA[®] by GSK were \$375.9 million, up slightly from \$374.3 million in the same quarter of 2020, with \$154.6 million in net sales from the U.S. market and \$221.3 million from non-U.S. markets.
 - First quarter 2021 net sales of ANORO[®] ELLIPTA[®] by GSK were \$161.5 million, up 7% from \$151.6 million in the same quarter of 2020, with \$88.4 million net sales from the U.S. market and \$73.1 million from non-U.S. markets.
 - First quarter 2021 net sales of TRELEGY[®] ELLIPTA[®] by GSK were \$339.8 million, up 37% from \$248.2 million in the same quarter of 2020, with \$237.5 million in net sales from the U.S. market and \$102.3 million in net sales from non-U.S. markets.
- Capital Allocation:
 - During the first quarter of 2021, the Company’s wholly owned subsidiary, Innoviva Strategic Opportunities LLC, invested \$20.0 million to acquire 6.2 million shares of Armata common stock and an equal number of warrants exercisable at \$3.25 per share, which resulted in Innoviva collectively owning approximately 60% of Armata’s outstanding stock (without giving effect to our warrants).
- New Director:
 - On March 9, 2021, the Company appointed Deborah L. Birx, M.D., to its Board of Directors, where she serves as an independent director. Dr. Birx is a world renowned medical expert and leader who most recently served as the response coordinator of the White House Coronavirus Task Force. Dr. Birx’s career highlights also include having served as Ambassador-at-Large, when she assumed the role of the Coordinator of the United States Government Activities to Combat HIV/AIDS and U.S. Special Representative for Global Health Diplomacy. Dr. Birx also served as the U.S. Global AIDS Coordinator where she oversaw the President’s Emergency Plan for AIDS Relief (PEPFAR) at the Centers for Disease Control and Prevention and as the Director of the U.S. Military HIV Research Program (USMHRP) at the Walter Reed Army Institute of Research.

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 Balance Sheets
(in thousands)

	March 31, 2021 <u>(unaudited)</u>	December 31, 2020 <u>(1)</u>
Assets		
Cash, cash equivalents and marketable securities	\$ 282,890	\$ 246,487
Other current assets	90,043	95,571
Property and equipment, net	24	28
Equity and long-term investments	519,325	438,258
Capitalized fees paid to a related party, net	121,797	125,253
Deferred tax assets, net	74,023	93,759
Other assets	188	214
Total assets	<u>\$ 1,088,290</u>	<u>\$ 999,570</u>
Liabilities and stockholders' equity		
Other current liabilities	\$ 2,136	\$ 1,958
Accrued interest payable	1,668	4,152
Convertible subordinated notes, net	239,925	239,783
Convertible senior notes, net	147,803	145,734
Other long-term liabilities	77	106
Innoviva stockholders' equity	634,461	539,912
Noncontrolling interest	62,220	67,925
Total liabilities and stockholders' equity	<u>\$ 1,088,290</u>	<u>\$ 999,570</u>

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

INNOVIVA, INC.
Condensed Consolidated Statements of Income
(in thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Revenue:		
Royalty revenue from a related party, net ⁽¹⁾	\$ 85,518	\$ 78,678
Operating expenses:		
Research and development	49	-
General and administrative	5,986	2,563
Total operating expenses	<u>6,035</u>	<u>2,563</u>
Income from operations	79,483	76,115
Other income (expense), net	(433)	68
Interest income	30	1,302
Interest expense	(4,694)	(4,516)
Changes in fair values of equity and long-term investments, net	55,045	21,915
Income before income taxes	<u>129,431</u>	<u>94,884</u>
Income tax expense, net	19,736	15,932
Net income	<u>109,695</u>	<u>78,952</u>
Net income attributable to noncontrolling interest	15,572	13,515
Net income attributable to Innoviva stockholders	<u>\$ 94,123</u>	<u>\$ 65,437</u>
Basic net income per share attributable to Innoviva stockholders	\$ 0.93	\$ 0.65
Diluted net income per share attributable to Innoviva stockholders	\$ 0.84	\$ 0.59
Shares used to compute basic net income per share	101,365	101,235
Shares used to compute diluted net income per share	113,624	113,509

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

	Three Months Ended March 31,	
	2021	2020
	(unaudited)	
Royalties from a related party	\$ 88,974	\$ 82,134
Amortization of capitalized fees paid to a related party	(3,456)	(3,456)
Royalty revenue from a related party, net	<u>\$ 85,518</u>	<u>\$ 78,678</u>

INNOVIVA, INC.
Cash Flows Summary
(in thousands)

	Three Months Ended March 31,	
	2021	2020
	(unaudited)	
Net cash provided by operating activities	\$ 84,107	\$ 73,481
Net cash provided by (used in) investing activities	(26,394)	16,044
Net cash used in financing activities	(21,310)	(15,640)

Investor & Media Contacts:

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