
**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 29, 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 April 29, 2020, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended March 31, 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 April 29, 2020](#)

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 29, 2020

By: /s/ Geoffrey Hulme

Geoffrey Hulme

Interim Principal Executive Officer



Innoviva Reports First Quarter 2020 Financial Results

- Total net revenue increased by 43% to \$78.7 million in the first quarter of 2020, compared to the same quarter in 2019.
- Income before income taxes increased by 96% to \$94.9 million in the first quarter of 2020, compared to the same quarter in 2019.

BURLINGAME, Calif., April 29, 2020 – Innoviva, Inc. (NASDAQ: INVA) (“Innoviva”, or the “Company”) today reported financial results for the first quarter ended March 31, 2020.

- Gross royalty revenues of \$82.1 million from Glaxo Group Limited (“GSK”) for the first quarter of 2020 included royalties of \$56.1 million from global net sales of RELVAR[®] /BREO[®] ELLIPTA[®], royalties of \$9.9 million from global net sales of ANORO[®] ELLIPTA[®] and \$16.1 million from global net sales of TRELEGY[®] ELLIPTA[®].¹
- Total operating expenses for the first quarter of 2020 were \$2.6 million, compared to \$3.0 million in the first quarter of 2019. Stock-based compensation for the first quarter of 2020 was \$0.4 million, compared to \$0.6 million in the first quarter of 2019.
- Changes in fair values of equity investments in the amount of \$21.9 million as of March 31, 2020 reflect the unrealized gains and fair value changes between the total estimated fair value of \$46.9 million of our investment in both common stock and warrants of Armata Pharmaceuticals, Inc. (“Armata”) and the total purchase price of \$25.0 million.
- Net cash and cash equivalents, short-term investments and marketable securities totaled \$384.0 million, and royalties receivable from GSK totaled \$82.1 million, as of March 31, 2020.

“Global net sales of RELVAR[®] /BREO[®] ELLIPTA[®] increased 31% versus the first quarter of 2019. U.S. net sales increased by 47% as increased pricing discounts in the ICS/LABA sector were offset by a one-time significant positive prior period rebate adjustment and continued volume growth. Non-U.S. sales increased 23% versus the first quarter of 2019, driven by sales growth in certain European markets and in Japan. ANORO[®] ELLIPTA[®] global net sales increased 15% in the first quarter of 2020. U.S. net sales increased 8% as volume growth offset price pressure from increased amounts of sales through market segments with higher rebates. Non-U.S. ANORO[®] ELLIPTA[®] net sales grew 24% year over year in the quarter supported by growth in certain European markets. In addition, TRELEGY[®] ELLIPTA[®] global net sales were \$248.2 million,” stated Geoffrey Hulme, Interim Principal Executive Officer.

Hulme continued, “At this point, the impact of the COVID-19 pandemic on the global sales of our three collaboration products is uncertain. Based on our end-market observations, first quarter sales levels may have benefited from unspecified levels of increased patient inventory stocking. Also, the significant RELVAR[®] /BREO[®] ELLIPTA[®] positive prior period rebate adjustment that occurred during the first quarter is not likely to recur in future quarters.”

Hulme concluded, “After the end of the quarter, we were pleased to announce the first closing of a new investment in Entasis Therapeutics, a company focused on the development of novel antibiotics to address multi-drug resistant gram-negative bacteria. Antibiotic-resistant bacterial infections pose an increasing global health risk and are creating a growing need for new treatment options. Innoviva’s investment will help Entasis continue to develop two antibiotics currently in phase three trials. The Armata and Entasis transactions are part of our ongoing efforts to pursue capital allocation options that maximize future shareholder value.”

Recent Highlights

- GSK Net Sales:
 - First quarter 2020 net sales of RELVAR[®] /BREO[®] ELLIPTA[®] by GSK were \$374.3 million, up 31% from \$284.9 million in the first quarter of 2019, with \$147.5 million in net sales from the U.S. market and \$226.8 million from non-U.S. markets.
 - First quarter 2020 net sales of ANORO[®] ELLIPTA[®] by GSK were \$151.6 million, up 15% from \$131.8 million in the first quarter of 2019, with \$81.8 million net sales from the U.S. market and \$69.8 million from non-U.S. markets.
 - First quarter 2020 net sales of TRELEGY[®] ELLIPTA[®] by GSK were \$248.2 million, up significantly from \$112.7 million in the first quarter of 2019, with \$172.4 million in net sales from the U.S. market and \$75.8 million in net sales from non-U.S. markets.
- Capital Allocation:
 - On April 12, 2020, Innoviva entered into a securities purchase agreement with Entasis Therapeutics, Inc. (NASDAQ: ETTX), pursuant to which it will purchase, upon satisfaction of certain closing conditions, approximately \$35.0 million of Entasis common stock and warrant securities.
 - During the first quarter of 2020, the Company invested \$25.0 million in 8,710,800 shares of Armata’s common stock and warrants to purchase up to an additional 8,710,800 shares of the common stock at \$2.87 per share. As of this initial investment, Innoviva owns approximately 47% of Armata’s common stock as of March 31, 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 impact of the COVID -19 pandemic; 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. 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, which is 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 March 31,	
	2020	2019
Revenue:		
Royalty revenue from a related party, net (1)	\$ 78,678	\$ 55,183
Operating expenses:		
General and administrative	2,563	3,015
Total operating expenses	2,563	3,015
Income from operations	76,115	52,168
Other income, net	68	1
Interest income	1,302	975
Interest expense	(4,516)	(4,617)
Changes in fair values of equity investments	21,915	-
Income before income taxes	94,884	48,527
Income tax expense, net	15,932	8,508
Net income	78,952	40,019
Net income attributable to noncontrolling interest	13,515	6,229
Net income attributable to Innoviva stockholders	\$ 65,437	\$ 33,790
Basic net income per share attributable to Innoviva stockholders	\$ 0.65	\$ 0.33
Diluted net income per share attributable to Innoviva stockholders	\$ 0.59	\$ 0.31
Shares used to compute basic net income per share	101,235	101,059
Shares used to compute diluted net income per share	113,509	113,376

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

	Three Months Ended	
	March 31,	
	2020	2019
	(unaudited)	
Royalties from a related party	\$ 82,134	\$ 58,639
Amortization of capitalized fees paid to a related party	(3,456)	(3,456)
Royalty revenue from a related party, net	<u>\$ 78,678</u>	<u>\$ 55,183</u>

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

	March 31,	December 31,
	2020	2019
	(unaudited)	(1)
Assets		
Cash, cash equivalents and marketable securities	\$ 383,951	\$ 350,845
Other current assets	82,956	80,389
Property and equipment, net	42	33
Equity investments	46,915	-
Capitalized fees paid to a related party, net	135,620	139,076
Deferred tax assets, net	138,239	154,171
Other assets	288	312
Total assets	<u>\$ 788,011</u>	<u>\$ 724,826</u>
Liabilities and stockholders' equity		
Other current liabilities	\$ 1,130	\$ 1,219
Accrued interest payable	1,668	4,152
Convertible subordinated notes, net	239,355	239,217
Convertible senior notes, net	139,797	137,903
Other long-term liabilities	192	219
Innoviva stockholders' equity	379,543	313,495
Noncontrolling interest	26,326	28,621
Total liabilities and stockholders' equity	<u>\$ 788,011</u>	<u>\$ 724,826</u>

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

INNOVIVA, INC.
Cash Flows Summary
(in thousands)

	Three Months Ended March 31,	
	2020	2019
	(unaudited)	
Net cash provided by operating activities	\$ 73,481	\$ 76,655
Net cash provided by (used in) investing activities	16,044	(74,167)
Net cash provided by (used in) financing activities	(15,640)	246

Investor & Media Contacts:

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