
**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): **May 1, 2019**

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)

2000 Sierra Point Parkway

Suite 500

Brisbane, California 94005

(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))

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 May 1, 2019, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended March 31, 2019. 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 May 1, 2019](#)

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: May 1, 2019

By: /s/ Geoffrey Hulme

Geoffrey Hulme

Interim Principal Executive Officer



Innoviva Reports First Quarter 2019 Financial Results

- Total net revenue increased by 5% to \$55.2 million in the first quarter of 2019, compared to the same quarter in 2018.
- Income before income taxes increased by 60% to \$48.5 million in the first quarter of 2019, compared to the same quarter in 2018.

BRISBANE, Calif., May 1, 2019 — Innoviva, Inc. (NASDAQ: INVA) (the Company) today reported financial results for the first quarter ended March 31, 2019.

- Gross royalty revenues of \$58.6 million from Glaxo Group Limited (“GSK”) for the first quarter of 2019 included royalties of \$42.7 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®], royalties of \$8.6 million from global net sales of ANORO[®] ELLIPTA[®] and \$7.3 million from global net sales of TRELEGY[®] ELLIPTA[®].¹
- Total operating expenses for the first quarter of 2019 were \$3.0 million compared with \$11.7 million (including \$2.7 million payment to a related party pursuant to a settlement agreement, and \$3.2 million in cash severance payments) in the first quarter of 2018. Stock-based compensation for the first quarter of 2019 was \$0.6 million compared to \$2.2 million for the first quarter of 2018.
- Net cash and cash equivalents, short-term investments and marketable securities totaled \$192.2 million, and royalties receivable from GSK totaled \$58.6 million, as of March 31, 2019.

“Global net sales of RELVAR[®]/BREO[®] ELLIPTA[®] decreased 7% versus the first quarter of 2018. U.S. net sales declined 27% as increased pricing discounts and payer rebate adjustments related to prior periods offset volume growth. Non-U.S. net sales continued their growth and increased 8%, driven by market share gains in certain European markets and growth in Japan despite foreign currency exchange headwinds negatively impacting results. In constant exchange rates (CER), RELVAR[®]/BREO[®] ELLIPTA[®] non-US net sales grew 15%. ANORO[®] ELLIPTA[®] global net sales decreased 2% versus the first quarter of 2018. U.S. net sales fell 9% as increased pricing pressure, payer rebate adjustments related to prior periods, and higher levels of sales through market segments with higher rebates offset volume growth in the LAMA/LABA class. Non-US ANORO[®] ELLIPTA[®] net sales continued their growth rising 11% despite a negative impact from foreign currency translation during the quarter. On a CER basis, ANORO[®] ELLIPTA[®] non-US net sales grew 18%. In addition, TRELEGY[®] ELLIPTA[®] global net sales were \$112.7 million,” stated Geoffrey Hulme, interim Principal Executive Officer.

Hulme continued, “During the first quarter, our operating expenses remained well-controlled and the strong conversion of royalty revenues to operating cash flows continued. The management and board are examining options regarding management of capital and strategic actions in order to maximize future shareholder value.”

Recent Highlights

- GSK Net Sales:
 - First quarter 2019 net sales of RELVAR®/BREO® ELLIPTA® by GSK were \$284.9 million, down 7% from \$307.7 million in the first quarter of 2018, with \$100.1 million in net sales from the U.S. market and \$184.8 million from non-U.S. markets.
 - First quarter 2019 net sales of ANORO® ELLIPTA® by GSK were \$131.8 million, down 2% from \$134.2 million in the first quarter of 2018, with \$75.7 million net sales from the U.S. market and \$56.1 million from non-U.S. markets.
 - First quarter 2019 net sales of TRELEGY® ELLIPTA® by GSK were \$112.7 million, up significantly from \$14.6 million in the first quarter of 2018, with \$85.1 million in net sales from the U.S. market and \$27.6 million in net sales from non-U.S. markets.
- Product Updates:
 - The Pharmaceuticals and Medical Devices Agency of Japan approved TRELEGY® ELLIPTA® (fluticasone furoate/umeclidinium/vilanterol 'FF/UMEC/VI') for the treatment of chronic obstructive pulmonary disease (COPD). TRELEGY® ELLIPTA® is the first triple therapy in a single inhaler approved in Japan.

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 focused on royalty management. Innoviva’s portfolio includes the 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. 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, 2018, 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 Operations
(in thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Revenue:		
Royalty revenue from a related party, net ⁽¹⁾	\$ 55,183	\$ 52,380
Operating expenses:		
General and administrative	3,015	5,811
General and administrative - cash severance expenses	—	3,174
General and administrative - related party	—	2,700
Total operating expenses	<u>3,015</u>	<u>11,685</u>
Income from operations	52,168	40,695
Other income (expense), net	1	(3,099)
Interest income	975	391
Interest expense	(4,617)	(7,657)
Income before income taxes	<u>48,527</u>	<u>30,330</u>
Income tax expense, net	8,508	—
Net income	<u>40,019</u>	<u>30,330</u>
Net income attributable to noncontrolling interest	6,229	749
Net income attributable to Innoviva stockholders	<u>\$ 33,790</u>	<u>\$ 29,581</u>
Basic net income per share attributable to Innoviva stockholders	\$ 0.33	\$ 0.29
Diluted net income per share attributable to Innoviva stockholders	\$ 0.31	\$ 0.27
Shares used to compute basic net income per share	101,059	100,604
Shares used to compute diluted net income per share	113,376	113,566

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

	Three Months Ended March 31,	
	2019	2018
	(unaudited)	
Royalties from a related party	\$ 58,639	\$ 55,836
Amortization of capitalized fees paid to a related party	(3,456)	(3,456)
Royalty revenue from a related party, net	<u>\$ 55,183</u>	<u>\$ 52,380</u>

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

	March 31, 2019	December 31, 2018
	(unaudited)	(1)
Assets		
Cash, cash equivalents and marketable securities	\$ 192,178	\$ 114,908
Other current assets	59,341	84,135
Property and equipment, net	148	160
Operating lease right-of-use asset	1,421	—
Capitalized fees paid to a related party, net	149,443	152,899
Deferred tax assets	187,546	196,054
Other assets	37	37
Total assets	<u>\$ 590,114</u>	<u>\$ 548,193</u>
Liabilities and stockholders' equity		
Other current liabilities	\$ 2,035	\$ 1,436
Accrued interest payable	1,775	4,264
Convertible subordinated notes, net	238,799	238,664
Convertible senior notes, net	132,468	130,734
Senior secured term loans, net	13,477	13,457
Other long-term liabilities	1,617	586
Innoviva stockholders' equity	188,245	153,583
Noncontrolling interest	11,698	5,469
Total liabilities and stockholders' equity	<u>\$ 590,114</u>	<u>\$ 548,193</u>

(1) The selected consolidated balance sheet amounts at December 31, 2018 are derived from audited financial statements.

INNOVIVA, INC.
Cash Flows Summary
(in thousands)

	Three Months Ended	
	March 31,	
	2019	2018
	(unaudited)	
Net cash provided by operating activities	\$ 76,655	\$ 49,914
Net cash provided by (used in) investing activities	(74,167)	26,513
Net cash provided by (used in) financing activities	246	(122,625)

Investor & Media Contacts:

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