
**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 30, 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)

**1350 Old Bayshore Highway,
Suite 400
Burlingame, CA 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 30, 2019, Innoviva, Inc. (the “Company”) issued a press release regarding its results of operations and financial condition for the quarter ended September 30, 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 October 30, 2019](#)
104 [Cover Page Interactive Data File \(embedded within the Inline XBRL document\)](#)

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: October 30, 2019

By: /s/ Geoffrey Hulme

Geoffrey Hulme

Interim Principal Executive Officer



Innoviva Reports Third Quarter 2019 Financial Results

- Total net revenue increased by 7% to \$65.8 million in the third quarter of 2019, compared to the same quarter in 2018.
- Income before income taxes increased by 15% to \$57.6 million in the third quarter of 2019, compared to the same quarter in 2018.

BRISBANE, Calif., October 30, 2019 – Innoviva, Inc. (NASDAQ: INVA) (the Company) today reported financial results for the third quarter ended September 30, 2019.

- Gross royalty revenues of \$69.2 million from Glaxo Group Limited (“GSK”) for the third quarter of 2019 included royalties of \$46.4 million from global net sales of RELVAR[®]/BREO[®] ELLIPTA[®], royalties of \$11.6 million from global net sales of ANORO[®] ELLIPTA[®] and \$11.2 million from global net sales of TRELEGY[®] ELLIPTA[®].¹
- Total operating expenses for the third quarter of 2019 were \$5.0 million, compared with \$4.0 million in the third quarter of 2018. The amount for the third quarter of 2019 included \$2.8 million legal and related fees for the arbitration initiated by Thervanace Biopharma, Inc. against the Company and Theravance Respiratory Company, LLC (“TRC”). Per the final decision of the arbitrator in September 2019, these expenses will be reimbursed by TRC. TRC’s expenses are consolidated in the Company’s consolidated statements of income. The amount for the third quarter of 2019 also included \$0.6 million in expenses associated with the termination of our Brisbane office lease. Stock-based compensation for the third quarter of 2019 was \$0.5 million, compared to (\$0.9) million for the third quarter of 2018 due to a reversal of \$1.9 million expense in connection with the separation of senior management members.
- Net cash and cash equivalents, short-term investments and marketable securities totaled \$297.2 million, and royalties receivable from GSK totaled \$69.2 million, as of September 30, 2019.

“Global net sales of RELVAR[®]/BREO[®] ELLIPTA[®] decreased 10% versus the third quarter of 2018. U.S. net sales declined 32% as increased pricing discounts in the ICS/LABA sector offset volume growth. Non-U.S. sales growth increased 14% versus the third quarter of 2018, driven by continued market share gains in certain European markets and growth in Japan. Non-U.S. sales growth was negatively impacted by foreign currency translation; in constant exchange rates (CER), RELVAR[®]/BREO[®] ELLIPTA[®] non-US net sales grew 21%.”

“ANORO[®] ELLIPTA[®] global net sales grew 18% in the third quarter of 2019. U.S. net sales grew 17%, compared to the same quarter of 2018, as increased volume growth offset higher levels of sales through market segments with higher rebates. Non-U.S. ANORO[®] ELLIPTA[®] net sales grew 20% year over year in the quarter. The rate of growth increased from the second quarter of 2019 even after a negative impact from foreign currency translation. On a CER basis, ANORO[®] ELLIPTA[®] non-U.S. net sales grew 27%. In addition, TRELEGY[®] ELLIPTA[®] global net sales were \$172.8 million,” stated Geoffrey Hulme, Interim Principal Executive Officer.

Hulme continued, “In the quarter, although U.S. RELVAR[®]/BREO[®] ELLIPTA[®] net sales were again impacted in part by weaker pricing that has occurred following the launch of generic versions of Advair, non-U.S. net sales for RELVAR[®]/BREO[®] ELLIPTA[®] grew strongly year over year and comprised 60% of global net sales of RELVAR[®]/BREO[®] ELLIPTA[®]. US net sales of ANORO[®] ELLIPTA[®] returned to growth and non-US net sales grew strongly.”

“During the third quarter, our core operating expenses were similar to the levels in the second quarter. As part of our ongoing focus on operating expenses, we secured a termination of our Brisbane office lease. Our office relocation to Burlingame will result in a meaningful reduction in our lease liability and annual rent expense. The ratio of operating cash flow to net royalty revenues was strong in the quarter. The board and management continue to study potential strategic actions to maximize future shareholder value.”

Recent Highlights

- GSK Net Sales:
 - Third quarter 2019 net sales of RELVAR[®]/BREO[®] ELLIPTA[®] by GSK were \$309.5 million, down 10% from \$344.9 million in the third quarter of 2018, with \$122.3 million in net sales from the U.S. market and \$187.2 million from non-U.S. markets.
 - Third quarter 2019 net sales of ANORO[®] ELLIPTA[®] by GSK were \$177.7 million, up 18% from \$150.8 million in the third quarter of 2018, with \$116.4 million net sales from the U.S. market and \$61.3 million from non-U.S. markets.
 - Third quarter 2019 net sales of TRELEGY[®] ELLIPTA[®] by GSK were \$172.8 million, up significantly from \$55.7 million in the third quarter of 2018, with \$129.6 million in net sales from the U.S. market and \$43.2 million in net sales from non-U.S. markets.

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 Income
(in thousands, except per share data)
(Unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|------------------|------------------------------------|-------------------|
| | 2019 | 2018 | 2019 | 2018 |
| Revenue: | | | | |
| Royalty revenue from a related party, net ⁽¹⁾ | \$ 65,755 | \$ 61,680 | \$ 185,045 | \$ 181,146 |
| Operating expenses: | | | | |
| General and administrative | 4,962 | 1,489 | 12,324 | 11,711 |
| General and administrative - cash severance expenses | - | 2,530 | - | 5,704 |
| General and administrative - related party | - | - | - | 2,700 |
| Total operating expenses | <u>4,962</u> | <u>4,019</u> | <u>12,324</u> | <u>20,115</u> |
| Income from operations | 60,793 | 57,661 | 172,721 | 161,031 |
| Other expense, net | (115) | (2,626) | (122) | (5,686) |
| Interest income | 1,624 | 370 | 4,002 | 1,141 |
| Interest expense | (4,693) | (5,238) | (13,971) | (19,373) |
| Income before income taxes | 57,609 | 50,167 | 162,630 | 137,113 |
| Income tax expense, net | 10,558 | - | 29,499 | - |
| Net income | 47,051 | 50,167 | 133,131 | 137,113 |
| Net income attributable to noncontrolling interest | 7,242 | 3,078 | 21,792 | 5,817 |
| Net income attributable to Innoviva stockholders | <u>\$ 39,809</u> | <u>\$ 47,089</u> | <u>\$ 111,339</u> | <u>\$ 131,296</u> |
| Basic net income per share attributable to Innoviva stockholders | \$ 0.39 | \$ 0.47 | \$ 1.10 | \$ 1.30 |
| Diluted net income per share attributable to Innoviva stockholders | \$ 0.36 | \$ 0.43 | \$ 1.01 | \$ 1.19 |
| Shares used to compute basic net income per share | 101,191 | 100,936 | 101,134 | 100,806 |
| Shares used to compute diluted net income per share | 113,415 | 113,363 | 113,394 | 113,444 |

(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, | |
|--|-------------------------------------|------------------|------------------------------------|-------------------|
| | 2019 | 2018 | 2019 | 2018 |
| | (unaudited) | | (unaudited) | |
| Royalties from a related party | \$ 69,211 | \$ 65,136 | \$ 195,413 | \$ 191,514 |
| 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>\$ 65,755</u> | <u>\$ 61,680</u> | <u>\$ 185,045</u> | <u>\$ 181,146</u> |

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

| | September 30, 2019 (unaudited) | December 31, 2018 (1) |
|---|--------------------------------------|-----------------------------|
| Assets | | |
| Cash, cash equivalents and marketable securities | \$ 297,201 | \$ 114,908 |
| Other current assets | 69,594 | 84,135 |
| Property and equipment, net | 24 | 160 |
| Capitalized fees paid to a related party, net | 142,531 | 152,899 |
| Deferred tax assets | 166,555 | 196,054 |
| Other assets | 48 | 37 |
| Total assets | \$ 675,953 | \$ 548,193 |
| Liabilities and stockholders' equity | | |
| Other current liabilities | \$ 1,556 | \$ 1,436 |
| Accrued interest payable | 1,773 | 4,264 |
| Convertible subordinated notes, net | 239,075 | 238,664 |
| Convertible senior notes, net | 136,052 | 130,734 |
| Senior secured term loans, net | 13,517 | 13,457 |
| Other long-term liabilities | 217 | 586 |
| Innoviva stockholders' equity | 267,055 | 153,583 |
| Noncontrolling interest | 16,708 | 5,469 |
| Total liabilities and stockholders' equity | \$ 675,953 | \$ 548,193 |

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

INNOVIVA, INC.
Cash Flows Summary
(in thousands)

| | Nine Months Ended September 30, | |
|---|---------------------------------|------------|
| | 2019 | 2018 |
| | (unaudited) | |
| Net cash provided by operating activities | \$ 190,553 | \$ 161,754 |
| Net cash provided by (used in) investing activities | (69,997) | 49,113 |
| Net cash used in financing activities | (10,027) | (235,588) |

Investor & Media Contacts:

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