Innoviva Reports Second Quarter 2024 Financial Results; Highlights Recent Company Progress

July 31, 2024

Core royalty platform continued strong performance, receiving GSK royalties of $67.2 million

Innoviva Specialty Therapeutics' (IST) marketed portfolio grew 38% year-over-year, achieving net product sales of $21.7 million

Important treatment guidelines and guidance updates recognized our key products: XACDURO® by 2024 Infectious Diseases Society of America (IDSA); XERAVA® by 2024 Surgical Infection Society

XACDURO® approved in China

BURLINGAME, Calif.--(BUSINESS WIRE)--Jul. 31, 2024-- Innoviva, Inc. (NASDAQ: INVA) ("Innoviva" or the "Company"), a diversified holding company with a core royalties portfolio, a leading critical care and infectious disease platform known as Innoviva Specialty Therapeutics ("IST"), and a portfolio of strategic investments in healthcare assets, today reported financial results for the second quarter ended June 30, 2024, and highlighted select corporate achievements.

"Our robust second quarter continues to demonstrate the successful transformation of Innoviva. We have strong performance across multiple fronts, driven by our core GSK royalties portfolio and accelerating growth from our commercial products, GIAPREZA®, XACDURO® and XERAVA®," said Pavel Raifeld, Chief Executive Officer of Innoviva. "We remain committed to enhancing shareholder value through thoughtful capital allocation and operational excellence. We also are excited about our portfolio of strategic healthcare assets, where we continue to see potential for significant value creation."

Mr. Raifeld added, "In addition to driving strong operational delivery from our critical care and infectious disease platform IST, we continue to expand its global footprint and enhance recognition. Our partner in China, Zai Lab, successfully obtained regulatory approval for XACDURO®, bringing us closer to making XACDURO® available to all patients globally. In the U.S, important treatment guidelines and guidance updates recognized our key products, underscoring their life-saving potential. XACDURO® was named the preferred agent for treatment of Carbapenem-resistant *Acinetobacter baumannii* infections in the 2024 Infectious Diseases Society of America (IDSA) treatment guidance. XERAVA® is recommended by the 2024 Surgical Infection Society (SIS) treatment guidelines for empiric therapy in the management of complicated intra-abdominal infection."

Financial Highlights

- **Royalty revenue:** Second quarter 2024 gross royalty revenue from Glaxo Group Limited ("GSK") was $67.2 million, compared to $65.7 million for the second quarter 2023.
- **Net Product Sales:** Second quarter 2024 net product sales were $21.7 million, which included $13.1 million from GIAPREZA®, $6.2 million from XERAVA®, and $2.4 million from XACDURO®, a 38% increase compared to $15.7 million for the second quarter 2023.
- **License Revenue:** Second quarter 2024 license revenue of $14.5 million included an $8 million milestone payment from our partner for the regulatory approval of XACDURO® in China and $6.5 million in non-recurring cost-sharing reimbursements from our partner for product development.
- **Equity and long-term investments:** Second quarter 2024 net unfavorable change in fair values of equity and long-term investments of $90.7 million was primarily attributable to lower share price of Armata Pharmaceuticals ("Armata"), despite continued operational progress.
- **Net income:** The change in fair values of our investments negatively impacted second quarter 2024 earnings, resulting in a net loss of $34.7 million, or ($0.55) basic per share, compared to a net income of $1.3 million, or $0.02 basic per share, for the second quarter of 2023.
- **Share repurchases:** During the second quarter 2024, Innoviva completed its $100 million share repurchase program by repurchasing 0.4 million shares, for a total amount of approximately $5.3 million.
- **Cash and cash equivalents:** Totaled $217.0 million. Royalty and net product sales receivables totaled $94.0 million as of June 30, 2024.

Key Business and R&D Highlights

- **XACDURO®** (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use: targeted antibacterial for the treatment of patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii calcoaceticus complex*.
  - In May 2024, XACDURO® was approved in China by the National Medical Products Administration (NMPA) for use in Chinese patients 18 years of age and older.
  - In July 2024, XACDURO® was named as the preferred agent for the treatment of Carbapenem-resistant *Acinetobacter baumannii* infections, in combination with a carbapenem, in the updated 2024 IDSA treatment guidance.

- The World Health Organization considers *Acinetobacter* a top-priority pathogen worldwide that needs novel antibiotics[1].

- **XERAVA®** (eravacycline), for injection is indicated for the treatment of complicated intra-abdominal infections (cIAI) caused by susceptible microorganisms in patients 18 years or older.
  - In July 2024, XERAVA® was named as a recommended agent for empiric therapy in the updated 2024 SIS treatment guidelines for the management of complicated intra-abdominal infections. SIS also recommended XERAVA® be reserved for high-risk patients.
- **Zoliflodacin:** a potential first-in-class, single dose, oral antibiotic in development for the treatment of patients with uncomplicated gonorrhea is currently being developed in partnership with The Global Antibiotic Research & Development Partnership (GARDP).
  - Zoliflodacin has successfully completed Phase 3 clinical trials and the results were reported at ESCMID Global 2024. The Company expects to submit an NDA to the U.S. FDA in early 2025.

About Innoviva

Innoviva is a diversified holding company with a core royalties portfolio, a leading critical care and infectious disease platform known as Innoviva Specialty Therapeutics ("IST"), and a portfolio of strategic investments in healthcare assets. Innoviva's royalty portfolio includes respiratory assets partnered with Glaxo Group Limited ("GSK"). Innoviva is entitled to receive royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®. Innoviva's other innovative healthcare assets include infectious disease and critical care assets stemming from acquisitions of Entasis Therapeutics, including XACDURO® (sulbactam for injection; durlobactam for injection), co-packaged for intravenous use approved for the treatment of adults with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible strains of Acinetobacter baumannii-calcoaceticus complex and the investigational zoliflodacin currently being developed for the treatment of uncomplicated gonorrhea, and La Jolla Pharmaceutical Company, including GIAPREZA® (angiotensin II), approved to increase blood pressure in adults with septic or other distributive shock and XERAVA® (eravacycline) for the treatment of complicated intra-abdominal infections in adults.

ANORO®, RELVAR® and BREO® are trademarks of the GSK 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®, GIAPREZA®, XERAVA® and XACDURO® 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); 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"); the timing, manner and amount of capital deployment, including potential capital returns to stockholders; and risks related to the Company's growth strategy. 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, 2023 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.

References

(1) Tala, B., Jad, A., Claude, A., Jihad, I., Chantal, L., Rakan, N.,& Eid, A. (2017). Risk Factors, Clinical Presentation, and Outcome of Acinetobacter baumannii Bacteremia. Front. Cell. Infect. Microbiol., 04 May 2017, Sec. Molecular Bacterial Pathogenesis Volume 7 – 2017: https://doi.org/10.3389/fcimb.2017.00156

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023

Revenue:				
Royalty revenue, net (1)	$ 63,742	$ 62,265	$ 122,157	$ 119,123
Net product sales	21,651	15,727	40,735	27,241
License revenue	14,505	3,000	14,505	11,000
Total revenue	99,898	80,992	177,397	157,364
Expenses:				
Cost of products sold (inclusive of amortization of inventory fair value adjustments)	8,472	8,979	19,443	17,728
Cost of license revenue	-	-	-	1,600
Selling, general and administrative	27,740	23,542	58,145	43,277
Research and development	2,560	14,989	6,438	27,577
Amortization of acquired intangible assets	6,440	4,958	12,880	8,763
Changes in fair values of equity method investments, net	60,108	19,911	24,766	4,094
Changes in fair values of equity and long-term investments, net	30,556	83	43,891	2,247
Interest and dividend income	(3,474)	(3,553)	(7,873)	(6,918)
Interest expense	5,802	4,382	11,653	8,809
Other expense, net	973	1,896	2,209	3,242
Total expenses, net	139,177	75,187	171,552	110,419
Income (loss) before income taxes	(39,279)	5,805	5,845	46,945
Income tax expense (benefit), net	(4,594)	4,525	3,998	10,800
Net income (loss) and comprehensive income (loss)	$ (34,685)	$ 1,280	$ 1,847	$ 36,145
Net income (loss) per share				
Basic	$ (0.55)	$ 0.02	$ 0.03	$ 0.54
Diluted	$ (0.55)	$ 0.02	$ 0.03	$ 0.46
Shares used to compute net income (loss) per share				
Basic	62,526	65,341	62,856	66,557
Diluted	62,526	65,489	63,064	88,175

(1) Total net revenue is comprised of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(unaudited)		(unaudited)	
Royalties	$ 67,198	$ 65,721	$ 129,069	$ 126,035
Amortization of capitalized fees	(3,456)	(3,456)	(6,912)	(6,912)
Royalty revenue, net	$ 63,742	$ 62,265	$ 122,157	$ 119,123

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

	June 30, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 217,003	$ 193,513
Royalty and product sale receivables	93,980	84,075
Inventory	36,664	40,737
Prepaid expense and other current assets	10,630	25,894
Property and equipment, net	427	483
Equity and long-term investments	536,435	560,978
Capitalized fees paid, net	76,872	83,784
Right-of-use assets	3,118	2,536
Goodwill	17,905	17,905
Intangible assets	217,455	230,335

Deferred tax asset, net	11,446	-
Other assets	2,982	3,267
Total assets	$ 1,224,917	$ 1,243,507
Liabilities and stockholders' equity		
Other current liabilities	$ 23,929	$ 33,435
Accrued interest payable	3,422	3,422
Deferred revenue	855	1,277
Convertible senior notes, due 2025, net	191,659	191,295
Convertible senior notes, due 2028, net	255,623	254,939
Other long-term liabilities	72,065	71,870
Deferred tax liabilities, net	-	563
Income tax payable, long-term	11,849	11,751
Innoviva stockholders' equity	665,515	674,955
Total liabilities and stockholders' equity	$ 1,224,917	$ 1,243,507

INNOVIVA, INC.
Cash Flows Summary
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2024	2023
Net cash provided by operating activities	$ 80,765	$ 63,866
Net cash used in investing activities	(43,038)	(35,722)
Net cash used in financing activities	(14,237)	(146,168)
Net change	$ 23,490	$ (118,024)
Cash and cash equivalents at beginning of period	193,513	291,049
Cash and cash equivalents at end of period	$ 217,003	$ 173,025

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