Day One Reports Fourth Quarter and Full Year 2024 Financial Results and Corporate Progress

Feb 25, 2025

Achieved Q4 2024 and full year 2024 OJEMDA™ (tovorafenib) net product revenues of $29.0 million and $57.2 million, respectively

Ended 2024 with $531.7 million in cash, cash equivalents and short-term investments

Company to host conference call and webcast today, February 25, 4:30 p.m. ET

BRISBANE, Calif., Feb. 25, 2025 (GLOBE NEWSWIRE) -- Day One Biopharmaceuticals, Inc. (Nasdaq: DAWN) ("Day One" or the "Company"), a biopharmaceutical company dedicated to developing and commercializing targeted therapies for people of all ages with life-threatening diseases, today announced its fourth quarter and full year 2024 financial results and highlighted recent corporate achievements.

"The approval of OJEMDA was the catalyst for our next stage of growth and I am proud that our team was able to offer OJEMDA to so many relapsed or refractory pediatric low-grade glioma (pLGG) patients in our first months of launch," said Jeremy Bender, Ph.D., chief executive officer of Day One. "With OJEMDA as our foundation and a strong balance sheet, we believe we are on a path to long-term, durable growth and to the realization of Day One's mission."

Program Highlights

- OJEMDA net product revenues were $29.0 million and $57.2 million for the fourth quarter and full year ended December 31, 2024, respectively.
  - OJEMDA net product revenues increased 44% from the third to fourth quarter of 2024.
  - In approximately eight months since launch in April 2024, more than 1,600 OJEMDA prescriptions have been written.
- OJEMDA received the Exclusively Pediatric designation by the Centers for Medicare & Medicaid Services in the fourth quarter ended December 31, 2024, reducing its Medicaid and 340B minimum rebate percentage from 23.1% to 17.1%.
- DAY301, our PTK7-targeted ADC, cleared the first dose cohort (a single-patient accelerated titration cohort) in the Phase 1a portion of the Phase 1a/b clinical trial.
- Day One advanced enrollment in the global, pivotal Phase 3 FIREFLY-2 clinical trial, with full enrollment expected in the first half of 2026.

Corporate Highlights

- Chief executive officer Dr. Jeremy Bender presented preliminary 2024 OJEMDA net product revenue and 2025 corporate priorities at the 43rd Annual J.P. Morgan Healthcare Conference. An archived audio webcast of the discussion is available by visiting the Events Presentations section of the Company's website.

Fourth Quarter and Full Year 2024 Financial Highlights

- **Product Revenue, Net:** OJEMDA net product revenues were $29.0 million and $57.2 million for the fourth quarter and full year ended December 31, 2024, respectively.
- **License Revenue:** License revenue from the sale of ex-U.S. commercial rights for tovorafenib were $0.2 million and $73.9 million for the fourth quarter and full year ended December 31, 2024, respectively.
- **R&D Expenses:** Research and development expenses were $61.8 million and $227.7 million for the fourth quarter and full year ended December 31, 2024, respectively, as compared to $37.3 million and $130.5 million for the same periods in 2023. The increase was primarily due to the DAY301 upfront license payment of $55.0 million in the third quarter 2024 and initiation of the DAY301 dose escalation study milestone of $20.0 million in the fourth quarter 2024.
- **SG&A Expenses:** Selling, general and administrative expenses were $29.8 million and $115.5 million for the fourth quarter and full year ended December 31, 2024, respectively, as compared to $22.2 million and $75.6 million for the same periods in 2023. The increase was primarily due to employee compensation costs and professional service expenses to support the launch of OJEMDA.
- **Net Loss:** Net loss totaled $65.7 million and $95.5 million for the fourth quarter and full year ended December 31, 2024, respectively, with non-cash stock-based compensation expense of $11.0 million and $48.3 million for the same periods. Net loss totaled $54.5 million and $188.9 million for the fourth quarter and full year ended December 31, 2023, respectively, with non-cash stock-based compensation expense of $10.8 million and $39.3 million for the same periods.

- **Cash Position:** The Company's cash, cash equivalents and short-term investments totaled $531.7 million on December 31, 2024.

Upcoming Events

- **44th Annual TD Cowen Health Care Conference**
  - Management will participate in a fireside chat on Tuesday, March 4 at 1:10 p.m. ET. A live and archived audio webcast of the discussion will be available by visiting the Events Presentations section of the Company's website.

Conference Call

Day One will host a conference call and webcast today, February 25 at 4:30 p.m. Eastern Time. To access the live conference call by phone, dial 877-704-4453 (domestic) or 201-389-0920 (international), and provide the access code 13745150. Live audio webcast will be accessible from the Day One Media & Investors page. To ensure a timely connection to the webcast, it is recommended that participants register at least 15 minutes prior to the scheduled start time. An archived version of the webcast will be available for replay on the Events & Presentations section of the Day One Investors & Media page for 30 days following the event.

About OJEMDA™
OJEMDA (tovorafenib) is a Type II RAF kinase inhibitor of mutant BRAF V600, wild-type BRAF, and wild-type CRAF kinases.

OJEMDA is indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Tovorafenib was granted Breakthrough Therapy and Rare Pediatric Disease designations by the FDA for the treatment of patients with pLGG harboring an activating RAF alteration, and it was evaluated by the FDA under priority review. Tovorafenib has also received Orphan Drug designation from the FDA for the treatment of malignant glioma and from the European Commission for the treatment of glioma.

For more information, please visit www.ojemda.com.

About Day One Biopharmaceuticals
Day One Biopharmaceuticals believes when it comes to pediatric cancer, we can do better. The Company was founded to address a critical unmet need: the dire lack of therapeutic development in pediatric cancer. Inspired by "The Day One Talk" that physicians have with patients and their families about an initial cancer diagnosis and treatment plan, Day One aims to re-envision cancer drug development and redefine what's possible for all people living with cancer—regardless of age—starting from Day One.

Day One partners with leading clinical oncologists, families, and scientists to identify, acquire, and develop important targeted cancer treatments. The Company's pipeline includes tovorafenib (OJEMDA™), DAY301 and a VRK1 inhibitor program.

Day One is based in Brisbane, California. For more information, please visit www.dayonebio.com or find the Company on LinkedIn or X.

Day One uses its Investor Relations website (ir.dayonebio.com), its X handle (x.com/DayOneBio), and LinkedIn Home Page (linkedin.com/company/dayonebio) as a means of disseminating or providing notification of, among other things, news or announcements regarding its business or financial performance, investor events, press releases, and earnings releases, and as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD.

Cautionary Note Regarding Forward-Looking Statements
This press release contains "forward-looking" statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: Day One's plans to develop and commercialize cancer therapies, expectations from current and planned clinical trials, the execution of the Phase 2 and Phase 3 clinical trial for tovorafenib as designed, expectations with respect to the timing of Day One's Phase 1a/b clinical trial of DAY301, any expectations about safety, efficacy, timing and ability to complete clinical trials, release data results and to obtain regulatory approvals for tovorafenib and other candidates in development, and the ability of tovorafenib to treat pLGG or related indications.

Statements including words such as "believe," "plan," "continue," "expect," "will," "develop," "signal," "potential," or "ongoing" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements.

Forward-looking statements are subject to risks and uncertainties that may cause Day One's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties in this press release and other risks set forth in our filings with the Securities and Exchange Commission, including Day One's ability to develop, obtain and retain regulatory approval for or commercialize any product candidate, Day One's ability to protect intellectual property, the potential impact of global business or macroeconomic conditions, including as a result of inflation, interest rate volatility, significant political, trade or regulatory developments, geopolitical conflicts and the sufficiency of Day One's cash, cash equivalents and

investments to fund its operations. These forward-looking statements speak only as of the date hereof and Day One specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

Day One Biopharmaceuticals, Inc.
Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Year Ended December 31,		
	2024	**2023**	**2022**
Revenue:			
Product revenue, net	$ 57,217	$ —	$ —
License revenue	73,944	—	—
Total revenues	131,161	—	—
Cost and operating expenses:			
Cost of product revenue	5,279	—	—
Research and development	227,702	130,521	85,618
Selling, general and administrative	115,450	75,543	61,291
Total cost and operating expenses	348,431	206,064	146,909
Loss from operations	(217,270)	(206,064)	(146,909)
Non-operating income:			
Gain from sale of priority review voucher	108,000	—	—
Investment income, net	19,701	17,187	4,746
Other income (expense), net	1,217	(40)	(18)
Total non-operating income, net	128,918	17,147	4,728
Loss before income taxes	(88,352)	(188,917)	(142,181)
Income tax expense	(7,144)	—	—
Net loss	(95,496)	(188,917)	(142,181)
Net loss per share - basic	$ (1.02)	$ (2.37)	$ (2.17)
Net loss per share - diluted	$ (1.02)	$ (2.37)	$ (2.17)
Weighted-average number of common shares used in net loss per share - basic	93,234,195	79,773,004	65,466,773
Weighted-average number of common shares used in net loss per share - diluted	93,234,195	79,773,004	65,466,773

Day One Biopharmaceuticals, Inc.
Selected Condensed Balance Sheet Data
(in thousands)
(unaudited)

	December 31, 2024	**December 31, 2023**
Cash, cash equivalents and short-term investments	$ 531,720	$ 366,347
Total assets	582,788	376,048
Total liabilities	80,037	29,508
Accumulated deficit	(554,081)	(458,585)
Total stockholders' equity	502,751	346,540

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