Day One Reports Second Quarter 2025 Financial Results and Corporate Progress

Aug 5, 2025

OJEMDA™ (tovorafenib) net product revenue of $33.6 million in Q2 2025, a 10% quarter-over-quarter increase

OJEMDA full-year 2025 net product revenue expected to be $140 to $150 million

Ended the second quarter with $453.1 million in cash, cash equivalents and short-term investments

Company to host conference call and webcast today, August 5, 4:30 p.m. ET

BRISBANE, Calif., Aug. 05, 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 second quarter 2025 financial results and highlighted recent corporate achievements.

"We have strong momentum going into the second half of 2025. We continue to focus on our three core priorities: accelerating revenue growth with OJEMDA, advancing our pipeline, and pursuing value-driving portfolio expansion anchored in financial discipline," said Jeremy Bender, Ph.D., chief executive officer of Day One. "With strong execution across the organization and a solid financial foundation, we're building a company that aims to deliver meaningful value to patients and to shareholders."

OJEMDA Commercial Performance

- OJEMDA net product revenue was $33.6 million in the second quarter of 2025, an increase of 310% from the second quarter of 2024.
- U.S. OJEMDA net product revenue increased 10% from the first quarter of 2025.
- OJEMDA prescriptions exceeded 1,000 in the second quarter of 2025, representing a 15% increase compared to the first quarter of 2025 and a 346% increase compared to the second quarter of 2024.
- Achieved $113.1 million in OJEMDA net product revenue for the most recent 12-month period ended June 30, 2025.
- The Company is providing 2025 net product revenue guidance of $140 to $150 million.

Program Highlights

- DAY301, the Company's PTK7-targeted ADC, is actively enrolling patients in the Phase 1a portion of the Phase 1a/b clinical trial; the trial is progressing as planned.
- Day One expects to present 3-year follow-up data from the FIREFLY-1 clinical trial in the fourth quarter of 2025.
- Day One published additional data characterizing growth velocity recovery and effective rash management at the 2025 American Society of Clinical Oncology Annual Meeting.
    - Abstract 10029: Growth recovery in patients with BRAF-altered pediatric low-grade gliomas (pLGGs) after discontinuation of tovorafenib
    - Abstract 10037: Post hoc analysis of rashes reported in patients with BRAF-altered relapsed/refractory pediatric low-grade glioma treated with the type II RAF inhibitor tovorafenib in FIREFLY-1
- Patient enrollment in the pivotal Phase 3 FIREFLY-2 clinical trial is on track to achieve completion of trial enrollment in the first half of 2026.
- Day One terminated its research collaboration and license agreement with Sprint Bioscience AB following careful consideration of the current development status for the VRK1 program and the Company's overall strategic objectives.

Corporate Highlights

- Industry leader Michael Vasconcelles, M.D., joined Day One in June 2025 as Head of Research and Development. Dr. Vasconcelles brings more than 25 years of extensive oncology research and development experience to the Company, most recently as Executive Vice President and Head of Research, Development and Medical Affairs at ImmunoGen.

Second Quarter 2025 Financial Highlights

- **Product Revenue, Net:** OJEMDA net product revenue was $33.6 million for the second quarter of 2025 compared to $8.2 million for the second quarter of 2024.
- **License Revenue:** License revenue from the sale of ex-U.S. commercial rights for tovorafenib was $0.3 million for the second quarter of 2025.
- **R&D Expenses:** Research and development expenses were $36.1 million for the second quarter of 2025 compared to $92.1 million for the second quarter of 2024. The decrease was primarily due to the MabCare Therapeutics license agreement upfront payment of $55.0 million in the second quarter of 2024.
- **SG&A Expenses:** Selling, general and administrative expenses were $29.0 million for the second quarter of 2025 compared to $30.2 million for the second quarter of 2024. The decrease was primarily due to lower employee compensation costs.
- **Net Loss:** Net loss totaled $30.3 million for the second quarter of 2025 with non-cash stock-based compensation expense of $10.9 million, compared to a net loss of $4.4 million for the second quarter of 2024, with non-cash stock-based compensation expense of $13.0 million and gain from sale of priority voucher of $108.0 million.
- **Cash Position:** The Company's cash, cash equivalents and short-term investments totaled $453.1 million as of June 30, 2025.

Conference Call

Day One will host a conference call and webcast today, August 5 at 4:30 p.m. ET. 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 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™) and DAY301.

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, changing interest rates, cybersecurity incidents, significant political or regulatory developments or changes in trade policy, including tariffs, shifting priorities within the U.S. Food and Drug Administration and reduced funding to federal healthcare programs, global regional 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.
Condensed Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Revenue:				
Product revenue, net	$ 33,562	$ 8,192	$ 64,065	$ 8,192
License revenue	346	—	604	—
Total revenues	33,908	8,192	64,669	8,192
Cost and operating expenses:				
Cost of product and license revenue	3,765	707	6,649	707
Research and development	36,149	92,106	75,768	132,316
Selling, general and administrative	28,968	30,186	58,293	56,743
Total cost and operating expenses	68,882	122,999	140,710	189,766
Loss from operations	(34,974)	(114,807)	(76,041)	(181,574)
Non-operating income:				
Gain from sale of priority review voucher	—	108,000	—	108,000
Investment income, net	4,671	3,962	9,765	8,327
Other expense, net	(19)	(10)	(42)	(20)
Total non-operating income, net	4,652	111,952	9,723	116,307
Loss before income taxes	(30,322)	(2,855)	(66,318)	(65,267)
Income tax expense	—	(1,552)	—	(1,552)
Net loss	(30,322)	(4,407)	(66,318)	(66,819)
Net loss per share - basic	$ (0.29)	$ (0.05)	$ (0.64)	$ (0.77)
Net loss per share - diluted	$ (0.29)	$ (0.05)	$ (0.64)	$ (0.77)
Weighted-average number of common shares used in net loss per share - basic	103,069,154	87,121,310	102,890,506	86,864,545
Weighted-average number of common shares used in net loss per share - diluted	103,069,154	87,121,310	102,890,506	86,864,545

Day One Biopharmaceuticals, Inc.

Selected Condensed Balance Sheets Data
(in thousands)
(unaudited)

	June 30, 2025	December 31, 2024
Cash, cash equivalents and short-term investments	$ 453,103	$ 531,720
Total assets	519,037	582,788
Total liabilities	58,203	80,037
Accumulated deficit	(620,399)	(554,081)
Total stockholders' equity	460,834	502,751

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