



Day One Reports First Quarter 2025 Financial Results and Corporate Progress

May 6, 2025

OJEMDA™ (tovorafenib) prescriptions grew 16% in Q1 2025 compared to Q4 2024

Achieved Q1 2025 OJEMDA™ (tovorafenib) net product revenue of \$30.5 million

Ended the first quarter with \$473.0 million in cash, cash equivalents and short-term investments

Company to host conference call and webcast today, May 6, 4:30 p.m. ET

BRISBANE, Calif., May 06, 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 first quarter 2025 financial results and highlighted recent corporate achievements.

"We continued our successful launch of OJEMDA in 2025 and are energized by the growing impact we are bringing to patients every day," said Jeremy Bender, Ph.D., chief executive officer of Day One. "This is an exciting time of growth for Day One. We remain focused on creating value at every level of the organization, and we are executing on our objectives with urgency and fiscal discipline."

Program Highlights

- OJEMDA net product revenue was \$30.5 million in the first quarter of 2025.
 - U.S. OJEMDA net product revenue increased 11% from the fourth quarter of 2024.
 - OJEMDA prescriptions increased to over 900 (+16%) in the first quarter of 2025.
- Achieved \$87.7 million in OJEMDA net product revenue since launch, representing over 2,500 OJEMDA prescriptions.
- In April 2025, Ipsen announced the regulatory filing for tovorafenib was accepted by the European Medicines Agency for review in the European Union, marking an important step forward for tovorafenib's development outside of the U.S.
- 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's pivotal Phase 3 FIREFLY-2 clinical trial is expected to be fully enrolled in the first half of 2026.
- Day One presented two posters at the 2025 American Association for Cancer Research (AACR) annual meeting in Chicago, April 25-30, 2025.
 - A preclinical study provided evidence for the efficacy of sequencing of MEK inhibitor treatment after tovorafenib by demonstrating mice bearing *AGK::BRAF* fusion tumors maintained significant tumor regression with no emergent tumors when treated with tovorafenib (25 mg/kg) once daily followed by MEK inhibitor treatment. Additionally, long-term efficacy was maintained with continuous dosing of tovorafenib *in vivo*; significant tumor regression was maintained with no emergent tumors indicating no evidence of emerging resistance. The study results demonstrate that anti-tumor activity with MEK inhibitors is observed after treatment with tovorafenib and suggest that acquired resistance may be less common in BRAF fusion-driven tumors treated with tovorafenib. (Abstract 1727: *Sequencing MEK inhibitor therapy after tovorafenib in BRAF fusion-driven cancers: Preclinical evidence of sustained tumor regression*)
 - A clinical trial-in-progress poster on DAY301-001 the first-in-human Phase 1a/1b trial with DAY301 to evaluate its safety, tolerability, pharmacokinetics (PK) and antitumor activity in patients with locally advanced or metastatic solid tumors. (Abstract CT196: *Phase I dose escalation and expansion study of the PTK-7 targeted antibody-drug conjugate DAY301 in patients with locally advanced or metastatic solid tumors*)

First Quarter 2025 Financial Highlights

- **Product Revenue, Net:** OJEMDA net product revenue was \$30.5 million for the first quarter of 2025.
- **License Revenue:** License revenue from the sale of ex-U.S. commercial rights for tovorafenib was \$0.3 million for the first

quarter of 2025.

- **R&D Expenses:** Research and development expenses were \$39.6 million for the first quarter of 2025 compared to \$40.2 million for the first quarter of 2024. The difference was primarily due to a decrease in license agreement payments and employee compensation costs.
- **SG&A Expenses:** Selling, general and administrative expenses were \$29.3 million for the first quarter of 2025 compared to \$26.6 million for the first quarter of 2024. The increase was primarily due to employee compensation costs and professional service expenses to support the launch of OJEMDA.
- **Net Loss:** Net loss totaled \$36.0 million for the first quarter of 2025 with non-cash stock-based compensation expense of \$12.9 million, compared to a net loss of \$62.4 million for the first quarter of 2024, with non-cash stock-based compensation expense of \$12.6 million.
- **Cash Position:** The Company's cash, cash equivalents and short-term investments totaled \$473.0 million as of March 31, 2025.

Upcoming Events

- **Bank of America Securities 2025 Health Care Conference**
 - Management will participate in a fireside chat on Tuesday, May 13 at 8:00 a.m. PT. A live and archived audio webcast of the discussion will be available by visiting the [Events](#) section of the Company's website.
- **Society for Neuro-Oncology's 8th Biennial Pediatric Neuro-Oncology Conference, May 15-17, 2025**
 - A poster sponsored by Day One, "*Managing side effects of MAPK inhibitor therapies in pediatric populations: a Delphi consensus initiative,*" will be presented on May 16 at 6:15 p.m. PT.
- **2025 American Society of Clinical Oncology (ASCO) Annual Meeting, May 30-June 3, 2025**
 - Abstract #10029 titled "*Growth recovery in patients with BRAF altered pediatric low-grade gliomas (LGG) after discontinuation of tovorafenib*" will be presented in a poster session on Saturday, May 31 from 9:00-12:00 p.m. CDT in Hall A.
 - Abstract #10037 titled "*Post hoc analysis of rashes reported in patients (pts) with BRAF-altered relapsed/refractory (r/r) pediatric low-grade glioma (pLGG) treated with the type II RAF inhibitor tovorafenib in FIREFLY-1*" will be presented in a poster session on Saturday, May 31 from 9:00-12:00 p.m. CDT in Hall A.
- **46th Annual Goldman Sachs Global Healthcare Conference**
 - Management will participate in a fireside chat on Tuesday, June 10 at 8:40 a.m. ET. A live and archived audio webcast of the discussion will be available by visiting the [Events](#) section of the Company's website.

Conference Call

Day One will host a conference call and webcast today, May 6 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™), 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, changing interest rates, cybersecurity incidents, significant political or regulatory developments or changes in trade policy, including tariffs or shifting priorities within the U.S. Food and Drug Administration, 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 March 31,	
	2025	2024
Revenue:		
Product revenue, net	\$ 30,503	\$ —
License revenue	258	—
Total revenues	30,761	—
Cost and operating expenses:		
Cost of product revenue	2,884	—
Research and development	39,619	40,210
Selling, general and administrative	29,325	26,557
Total cost and operating expenses	71,828	66,767
Loss from operations	(41,067)	(66,767)
Non-operating income:		
Investment income, net	5,094	4,365
Other expense, net	(23)	(10)
Total non-operating income, net	5,071	4,355
Net loss	(35,996)	(62,412)
Net loss per share - basic	\$ (0.35)	\$ (0.72)
Net loss per share - diluted	\$ (0.35)	\$ (0.72)
Weighted-average number of common shares used in net loss per share - basic	102,710,382	86,679,282
Weighted-average number of common shares used in net loss per share - diluted	102,710,382	86,679,282

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

	March 31, 2025	December 31, 2024
Cash, cash equivalents and short-term investments	\$ 473,020	\$ 531,720
Total assets	534,356	582,788
Total liabilities	54,844	80,037
Accumulated deficit	(590,077)	(554,081)
Total stockholders' equity	479,512	502,751

DAY ONE MEDIA

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DAY ONE INVESTORS

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