Day One Reports Third Quarter 2025 Financial Results and Corporate Progress

Nov 4, 2025

Commercial execution delivers best quarter launch-to-date with growth across all dimensions of core business

Raising OJEMDA full-year 2025 net product revenue guidance to $145 to $150 million

Three-year FIREFLY-1 data to be released in oral presentation at Society for Neuro-Oncology on Nov. 23, 2025

Ended the third quarter with $451.6 million in cash, cash equivalents and short-term investments

Company to host conference call and webcast today, November 4, 4:30 p.m. Eastern Time

BRISBANE, Calif., Nov. 04, 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 third quarter 2025 financial results and highlighted recent corporate achievements.

"Our third quarter results reflect acceleration across every key dimension of OJEMDA's performance and growing confidence among prescribers as we continue to build the case for second-line standard-of-care through execution and additional data readouts," said Jeremy Bender, Ph.D., chief executive officer of Day One. "Combined with steady pipeline progress, we are well positioned to deliver sustainable growth for shareholders while we continue our mission to bring meaningful therapies to patients."

OJEMDA™ Commercial Performance

- OJEMDA net product revenue was $38.5 million in the third quarter of 2025, an increase of 15% from the second quarter of 2025.
- Achieved $102.6 million in U.S. OJEMDA net product revenue for 2025 year-to-date through the third quarter of 2025, representing an 89% increase over fiscal year 2024.
- Quarterly prescriptions (TRx) grew to 1,256 in the third quarter of 2025, representing an 18% increase compared to the second quarter of 2025.
- Third quarter new patient starts grew 19% compared to the second quarter of 2025, driven by the FIREFLY-1 clinical trial 2-year follow-up data.
- The Company is raising the OJEMDA full-year 2025 net product revenue guidance to $145 to $150 million, reflecting continued strength in underlying demand.

Program Highlights

- Progressing enrollment in the pivotal Phase 3 FIREFLY-2 clinical trial in first-line pediatric low-grade glioma (pLGG), with enrollment completion anticipated in the first half of 2026.
- Advancing dose escalation in the Phase 1a clinical trial of DAY301, a PTK7-targeted antibody drug conjugate (ADC).
- Tovorafenib added as a category 2a recommended therapy in the National Comprehensive Cancer Network (NCCN) treatment guidelines for adult patients with recurrent or progressive BRAF-altered glioma.

Corporate Highlights

- Seasoned biopharmaceutical executive Heather Adkins Huet, PhD, joined Day One in September 2025 as Chief Scientific Officer. Dr. Huet brings over two decades of experience leading and managing the full life cycle of oncology therapeutics, from discovery through life-cycle management of approved products, in biotech startup, mid-cap and large-cap companies including ImmunoGen, Takeda Pharmaceuticals, and Unum Therapeutics.

Third Quarter 2025 Financial Highlights

- **Product Revenue, Net:** OJEMDA net product revenue was $38.5 million for the third quarter of 2025 compared to $20.1 million for the third quarter of 2024 driven by higher patient demand.

- **License Revenue:** License revenue from the sale of ex-U.S. commercial rights for tovorafenib was $1.3 million for the third quarter of 2025 compared to $73.7 million for the third quarter of 2024 during which period the upfront consideration received from Ipsen for the pLGG license rights of $73.5 million was recognized.

- **R&D Expenses:** Research and development expenses were $31.4 million for the third quarter of 2025 compared to $33.6 million for the third quarter of 2024.

- **SG&A Expenses:** Selling, general and administrative expenses were $28.1 million for the third quarter of 2025 compared to $29.0 million for the third quarter of 2024.

- **Net Loss:** Net loss totaled $19.7 million for the third quarter of 2025 with non-cash stock-based compensation expense of $9.6 million, compared to a net income of $37.0 million for the third quarter of 2024, with non-cash stock-based compensation expense of $11.6 million.

- **Cash Position:** The Company's cash, cash equivalents and short-term investments totaled $451.6 million as of September 30, 2025.

Upcoming Events

- Three-year data from the pivotal FIREFLY-1 trial will be presented in an oral presentation titled *'Clinical stability following tovorafenib treatment in relapsed/refractory pediatric low-grade glioma: updated results from the phase 2 FIREFLY-1 trial'* on Sunday, Nov. 23 at 11:49 a.m. HST during the 2025 Society for Neuro Oncology Annual Meeting.

- Piper Sandler 37th Annual Healthcare Conference, December 2-4, 2025.

Conference Call

Day One will host a conference call and webcast today, Nov. 4 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 Events 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 Media & Investors 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, government shutdowns, 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.
Statements of Operations
(unaudited)
(in thousands, except share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Revenue:				
Product revenue, net	$ 38,522	$ 20,070	$ 102,587	$ 28,262
License revenue	1,273	73,691	1,877	73,691
Total revenues	39,795	93,761	104,464	101,953
Cost and operating expenses:				
Cost of product and license revenue	4,480	1,590	11,129	2,297
Research and development	31,419	33,563	107,187	165,879
Selling, general and administrative	28,147	28,972	86,440	85,715
Total cost and operating expenses	64,046	64,125	204,756	253,891
(Loss) income from operations	(24,251)	29,636	(100,292)	(151,938)
Non-operating income:				
Gain from sale of priority review voucher	—	—	—	108,000
Investment income, net	4,559	5,322	14,324	13,649
Other (expense) income, net	(34)	1,197	(76)	1,177
Total non-operating income, net	4,525	6,519	14,248	122,826
(Loss) income before income taxes	(19,726)	36,155	(86,044)	(29,112)
Income tax benefit (expense)	—	882	—	(670)
Net (loss) income	(19,726)	37,037	(86,044)	(29,782)
Net (loss) income per share - basic	$ (0.19)	$ 0.38	$ (0.83)	$ (0.33)
Net (loss) income per share - diluted	$ (0.19)	$ 0.38	$ (0.83)	$ (0.33)
Weighted-average number of common shares used in net (loss) income per share - basic	103,381,315	96,623,123	103,056,046	90,164,895
Weighted-average number of common shares used in net (loss) income per share - diluted	103,381,315	96,937,759	103,056,046	90,164,895

Day One Biopharmaceuticals, Inc.
Selected Balance Sheet Data

(unaudited)
(in thousands)

	September 30, 2025	December 31, 2024
Cash, cash equivalents and short-term investments	$ 451,580	$ 531,720
Total assets	513,780	582,788
Total liabilities	62,912	80,037
Accumulated deficit	(640,125)	(554,081)
Total stockholders' equity	450,868	502,751

DAY ONE MEDIA
Laura Cooper, Head of Communications
media@dayonebio.com

DAY ONE INVESTORS
LifeSci Advisors, PJ Kelleher
pkelleher@lifesciadvisors.com