Day One Reports Third Quarter 2024 Financial Results and Corporate Progress

Oct 30, 2024

Achieved $20.1 million in OJEMDA™ (tovorafenib) net product revenue

Ended the third quarter with $558.4 million in cash, cash equivalents and short-term investments

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

BRISBANE, Calif., Oct. 30, 2024 (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 2024 financial results and highlighted recent corporate achievements.

"Our third quarter results demonstrate continued patient demand for OJEMDA, driven by the need for new therapies for children living with pediatric low-grade glioma," said Jeremy Bender, Ph.D., chief executive officer of Day One. "Looking ahead to 2025, we plan to continue to drive growth by advancing our programs and pipeline, including DAY301, a potential first-in-class ADC targeting PTK7 that we expect to be in the clinic in the coming months."

Program Highlights

- Strong growth in OJEMDA net revenue with $20.1M in the third quarter of 2024, representing a 145% increase over the second quarter of 2024.
- Quarterly prescriptions (TRx) grew to 619 in the third quarter of 2024, representing a 159% increase over the second quarter of 2024.
- Day One expects to dose the first patient in the Phase 1a portion of the Phase 1a/b clinical trial of DAY301 by the end of 2024 or in the first quarter of 2025.
- Day One provided updated duration of response data from the registrational Phase 2 FIREFLY-1 trial investigating tovorafenib in patients with BRAF-altered, relapsed or progressive pLGG. For the 77 patients enrolled on Arm 1, which was the dataset used to assess OJEMDA's efficacy, the median duration of response is 18 months.
- The pivotal Phase 3 FIREFLY-2/LOGGIC clinical trial evaluating tovorafenib as a front-line therapy in patients aged 6 months to 25 years with pLGG continues to enroll patients in the United States, Canada, Europe, Australia and Asia, with more than 100 sites activated.

Corporate Highlights and Upcoming Milestones

- Day One and Ipsen entered into an exclusive licensing agreement to commercialize tovorafenib outside of the U.S. in July 2024. Under the agreement, Day One received approximately $111 million upfront in cash and equity investment at a premium with up to approximately $350 million in additional launch and sales milestone payments as well as tiered double-digit royalties starting at mid-teens percentage on net sales.
- Day One entered into a definitive agreement for an oversubscribed private placement of its securities for total gross proceeds of approximately $175 million in July 2024.

Third Quarter 2024 Financial Highlights

- **Product Revenue, Net:** OJEMDA net product revenues were $20.1 million for the third quarter of 2024, the first full quarter of the U.S. launch.
- **License Revenue:** License revenue from the sale of ex-U.S. commercial rights for tovorafenib was $73.7 million for the third quarter of 2024.
- **R&D Expenses:** Research and development expenses were $33.6 million for the third quarter of 2024 compared to $33.2 million for the third quarter of 2023. The increase was primarily due to the clinical trial activities related to tovorafenib and additional employee compensation costs.
- **SG&A Expenses:** Selling, general and administrative expenses were $29.0 million for the third quarter of 2024 compared to $18.3 million for the third quarter of 2023. The increase was primarily due to employee compensation costs, commercial launch activities, and professional service expenses to support the launch of OJEMDA.
- **Net Income/Loss:** Net income totaled $37.0 million for the third quarter of 2024 with non-cash stock-based compensation expense of $11.6 million, compared to a net loss of $46.2 million for the third quarter of 2023, with non-cash stock-based compensation expense of $9.6 million.
- **Cash Position:** The Company's cash, cash equivalents and short-term investments totaled $558.4 million as of September 30, 2024.

Upcoming Events

- Two posters on health-related quality of life and drug holiday from the registrational Phase 2 FIREFLY-1 trial investigating tovorafenib in patients with BRAF-altered, relapsed or progressive pLGG will be presented at the Society for Neuro-Oncology Annual Meeting on November 22, 2024.
- Piper Sandler 36th Annual Healthcare Conference, December 3-5, 2024.

Conference Call

Day One will host a conference call and webcast today, October 30 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 Investors & Media 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, rising interest rates, instability in the global banking system, 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.
Condensed Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenue:				
Product revenue, net	$ 20,070	$ —	$ 28,262	$ —
License revenue	73,691	—	73,691	—
Total revenues	93,761	—	101,953	—
Cost and operating expenses:				
Cost of product revenue	1,590	—	2,297	—
Research and development	33,563	33,163	165,879	93,173
Selling, general and administrative	28,972	18,275	85,715	53,374
Total cost and operating expenses	64,125	51,438	253,891	146,547
Income (loss) from operations	29,636	(51,438)	(151,938)	(146,547)
Non-operating income:				
Gain from sale of priority review voucher	—	—	108,000	—
Investment income, net	5,322	5,291	13,649	12,163
Other income (expense), net	1,197	(3)	1,177	(22)
Total non-operating income, net	6,519	5,288	122,826	12,141
Income (loss) before income taxes	36,155	(46,150)	(29,112)	(134,406)
Income tax benefit (expense)	882	—	(670)	—
Net income (loss)	37,037	(46,150)	(29,782)	(134,406)
Net income (loss) per share - basic	$ 0.38	$ (0.54)	$ (0.33)	$ (1.73)
Net income (loss) per share - diluted	$ 0.38	$ (0.54)	$ (0.33)	$ (1.73)
Weighted-average number of common shares used in net income (loss) per share - basic	96,623,123	85,952,501	90,164,895	77,682,237
Weighted-average number of common shares used in net income (loss) per share - diluted	96,937,759	85,952,501	90,164,895	77,682,237

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

	September 30, 2024	**December 31, 2023**
Cash, cash equivalents and short-term investments	$ 558,383	$ 366,347
Total assets	600,807	376,048
Total liabilities	45,344	29,508
Accumulated deficit	(488,367)	(458,585)
Total stockholders' equity	555,463	346,540

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