

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 05, 2025

DAY ONE BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-40431  
(Commission File Number)

83-2415215  
(IRS Employer  
Identification No.)

1800 Sierra Point Parkway, Suite 200  
Brisbane, California  
(Address of principal executive offices)

94005  
(Zip Code)

Registrant's telephone number, including area code: (650) 484-0899

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	DAWN	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 Results of Operations and Financial Condition.**

On August 5, 2025, Day One Biopharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2025. A copy of the press release is attached as Exhibit 99.1 to this report. A copy of the Company's presentation with respect to its financial results for the quarter ended June 30, 2025 is attached as Exhibit 99.2 to this report.

**Item 7.01 Regulation FD Disclosure.**

On August 5, 2025, the Company updated its corporate presentation. A copy of the updated presentation is attached as Exhibit 99.3 to this report.

The information in this Current Report on Form 8-K, including Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3 to this report, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Current Report on Form 8-K and in the accompanying Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

Exhibit Number	Description
99.1	<a href="#">Press release issued by Day One Biopharmaceuticals, Inc. regarding its financial results for the quarter ended June 30, 2025, dated August 5, 2025.</a>
99.2	<a href="#">Financial Results Presentation.</a>
99.3	<a href="#">Corporate Presentation.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**DAY ONE BIOPHARMACEUTICALS, INC.**

Date: August 5, 2025

By: /s/ Charles N. York II, M.B.A.  
Charles N. York II, M.B.A.  
Chief Operating Officer and Chief Financial Officer

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## Day One Reports Second Quarter 2025 Financial Results and Corporate Progress

*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., August 5, 2025** – 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.
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## 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.
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- **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](http://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.

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Day One is based in Brisbane, California. For more information, please visit [www.dayonebio.com](http://www.dayonebio.com) or find the Company on LinkedIn or X.

Day One uses its Investor Relations website ([ir.dayonebio.com](http://ir.dayonebio.com)), its X handle ([x.com/DayOneBio](https://x.com/DayOneBio)), and LinkedIn Home Page ([linkedin.com/company/dayonebio](https://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.

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**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
<b>Revenue:</b>				
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
<b>Cost and operating expenses:</b>				
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)
<b>Non-operating income:</b>				
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

DAY ONE MEDIA  
Laura Cooper, Head of Communications  
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DAY ONE INVESTORS  
LifeSci Advisors, PJ Kelleher  
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# Second Quarter 2025 Financial Results & Corporate Progress

AUGUST 2025



# Forward Looking Statements

This presentation and the accompanying oral commentary contain forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "intend," "potential," "would," "continue," "ongoing" or the negative of these terms or other comparable terminology. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our future financial performance, including the sufficiency of our cash, cash equivalents and short-term investments to fund our operations, business plans and objectives, timing and success of our commercialization and marketing efforts, timing and success of our planned nonclinical and clinical development activities, the results of any of our strategic collaborations, including the potential achievement of milestones and provision of royalty payments thereunder, efficacy and safety profiles of our products and product candidates, the ability of OJEMDA™ (tovorafenib) to treat pediatric low-grade glioma (pLGG) or related indications, the potential therapeutic benefits and economic value of our products and product candidates, potential growth opportunities, competitive position, industry environment and potential market opportunities, our ability to protect intellectual property and the impact of global business or macroeconomic conditions, including as a result of inflation, changing interest rates, cybersecurity incidents, significant political, trade or regulatory developments, including tariffs, shifting priorities within the U.S. Food and Drug Administration and reduced funding of federal healthcare programs, and global regional conflicts, on our business and operations.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. These factors, together with those that are described under the heading "Risk Factors" contained in our most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) and other documents we file from time to time with the SEC, may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

# Agenda & Day One Participants

## Opening Remarks

**Jeremy Bender** (Chief Executive Officer)

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## OJEMDA™ Launch Performance

**Lauren Merendino** (Chief Commercial Officer)

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## Financial Performance

**Charles York** (Chief Operating & Chief Financial Officer)

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## Q&A Session

**All, joined by: Mike Vasconcelles** (Head of R&D)

# Opening Remarks

**Jeremy Bender**

Chief Executive Officer

# Second Quarter 2025 Highlights



**\$33.6M** in net product revenue in Q2 2025

**\$113.1M** in net revenue for the most recent 12 months

2025 guidance of **\$140M - \$150M** net product revenue

## Pipeline Progress

Tovorafenib EMA regulatory decision expected 2026<sup>1</sup>

FIREFLY-2 trial enrollment completion expected 1H 2026

3-year follow-up data from FIREFLY-1 expected in 4Q25

Driving momentum across multiple programs with key milestones ahead

## Financial Position

Strong balance sheet with **\$453M in cash**<sup>2</sup>

Focused capital allocation to maintain strong financial position

Financial independence from capital markets

# OJEMDA Launch Performance

**Lauren Merendino**  
Chief Commercial Officer

## Commercial Performance by the Numbers

**\$33.6M**

**Q2 2025 OJEMDA Net  
Product Revenue**

+10% growth vs Q1 2025  
+310% growth vs Q2 2024<sup>2</sup>

**1,062**

**Q2 2025 OJEMDA  
Prescriptions<sup>1</sup>**

+15% growth vs Q1 2025  
+346% growth vs Q2 2024<sup>2</sup>

**\$113.1M**

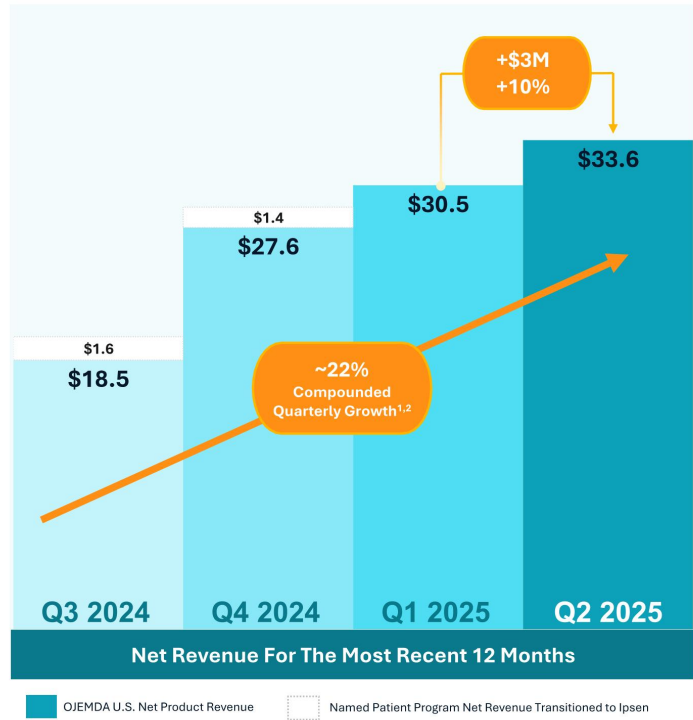
**OJEMDA Net  
Revenue For The  
Most Recent  
12 Months**

# One Year In: OJEMDA Delivering Steady Revenue Growth

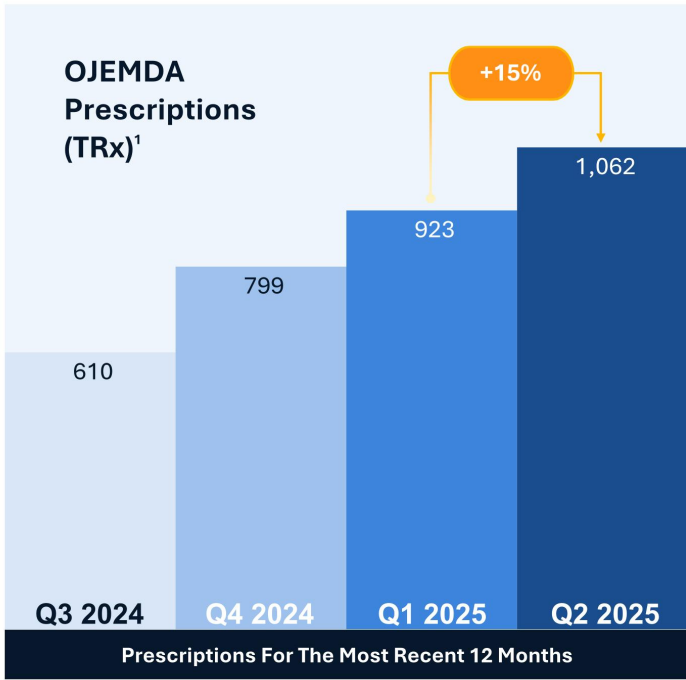
Achieved **\$33.6M** in Q2 2025 OJEMDA net product revenue

## Net Revenue Highlights

- Achieved \$64.1M in net product revenue for the first half of 2025
- Free drug represented ~5% of total scripts in Q2 2025



<sup>1</sup> Q3 2024 and Q4 2024 revenue included approximately \$1.6M and \$1.4M, respectively of revenue associated with Ex-US sales which has been removed for the purposes of calculating compounded quarterly revenue growth rate. <sup>2</sup> Compounded quarterly growth represents the comparison of Q3 2024 to Q2 2025. Net revenue for the most recent 12 months represents results for the 12-month period ended June 30, 2025.



## One Year In: Consistent Uptake Driving Quarterly OJEMDA Growth

Achieved **greater than 1,000** scripts in Q2 2025

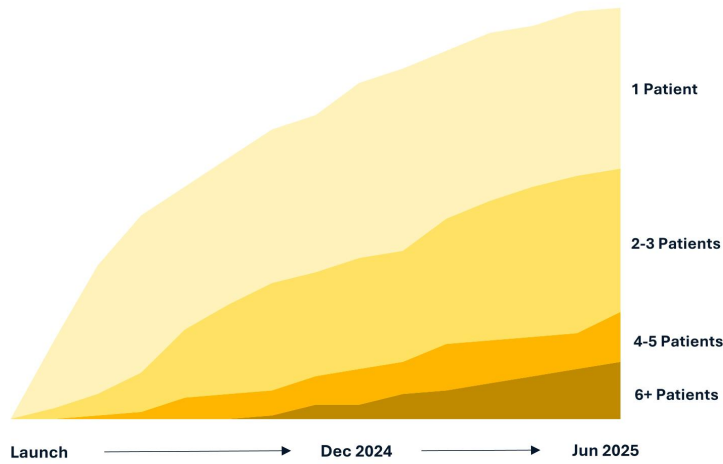
### Prescription Highlights

- Strong and consistent patient demand, driven by new patient starts and high percentage of patients staying on therapy month-to-month
- Continued prescriber adoption accompanied by growing breadth & depth

<sup>1</sup> Prescriptions are approximations based on data available as of June 30, 2025. Prescriptions for the most recent 12 months represents results for the 12-month period ended June 30, 2025.

# Expanding Prescriber Adoption with Meaningful Growth Opportunity Remaining

Growing Depth of Prescribing by Account Since Launch



- Continued growth in breadth of unique prescribers initiating at least one patient on OJEMDA
  - Growth driven by increased penetration of priority 2 & 3 accounts
- Growing number of accounts with multiple patients on OJEMDA
- >60% of prescribing accounts now have treated multiple patients with OJEMDA

# OJEMDA Priorities to Drive Revenue Growth in 2025

Drive depth of prescribing with current prescribers

Encourage non-user HCPs to try OJEMDA in their next r/r pLGG patient

Establish OJEMDA as standard of care in 2nd line r/r BRAF-altered pLGG

Support prescribers and patients to allow for optimal duration of treatment

# Financial Performance

**Charles York**

Chief Operating Officer &  
Chief Financial Officer

## Second Quarter 2025 Financial Results

Financial Summary (\$ in millions)	Three Months Ended 6/30/25	Three Months Ended 6/30/24	Six Months Ended 6/30/25	Six Months Ended 6/30/24
OJEMDA Net Revenue	33.6	8.2	64.1	8.2
License Revenue	0.3	--	0.6	--
<b>Total Revenue</b>	<b>\$33.9</b>	<b>\$8.2</b>	<b>\$64.7</b>	<b>\$8.2</b>
Cost of Product and License Revenue	3.8	0.7	6.6	0.7
Research and Development Expense <sup>1</sup>	36.1	92.1	75.8	132.3
Selling, General and Administrative Expense <sup>2</sup>	29.0	30.2	58.3	56.8
<b>Total Cost and Operating Expenses</b>	<b>\$68.9</b>	<b>\$123.0</b>	<b>\$140.7</b>	<b>\$189.8</b>
Non-operating Income <sup>3</sup>	4.7	111.9	9.7	116.3
Income Tax Expense	--	1.5	--	1.5
<b>Net Income (Loss)</b>	<b>(\$30.3)</b>	<b>(\$4.4)</b>	<b>(\$66.3)</b>	<b>(\$66.8)</b>
		6/30/25		12/31/24
Cash, cash equivalents and short-term investments		\$453.1		\$531.7

All financial information as of 6/30/25 is unaudited. <sup>1</sup> Includes stock-based compensation expense of \$3.6 million and \$7.8 million for the three and six months ended 6/30/25, and \$4.7 million and \$9.4 million for the three and six months ended 6/30/24. <sup>2</sup> Includes stock-based compensation expense of \$7.3 million and \$15.9 million for the three and six months ended 6/30/25, and \$8.3 million and \$16.3 million for the three and six months ended 6/30/24. <sup>3</sup> Includes sale of Priority Review Voucher of \$108.0 million for the three and six months ended 6/30/24.



# Thank You



# Day One Biopharmaceuticals

Targeted therapies for people of all ages

August 2025



# Disclaimer

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Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. These factors, together with those that are described under the heading "Risk Factors" contained in our most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) and other documents we file from time to time with the SEC, may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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Inspired by the urgent needs of children, Day One creatively and intentionally develops new medicines for people of all ages with life-threatening diseases



# Bringing life-changing medicines to patients sooner

## Who we are

- Commercial-stage biopharmaceutical company
- Our goal is to develop and provide access to targeted new medicines to patients of all ages as rapidly as possible
- Focused on advancing first- or best-in-class medicines for childhood and adult diseases



Nasdaq: DAWN

OJEMDA received approval in April 2024 and is indicated for the treatment of pediatric patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.



# Compelling near-term opportunities to help patients are the foundation for long-term growth and sustainability

## Proven Track Record

### Intentional in our approach

- Expertise developing and commercializing products
- Demonstrated ability to find and acquire first- or best-in-class medicines

## Pillars to Support Growth

### Accomplishments

- ✓ Launched OJEMDA in the U.S., delivering growing revenues
- ✓ Ex-U.S. commercial partnership with Ipsen for OJEMDA, EMA regulatory submission Q1 2025
- ✓ Acquisition of DAY301 (PTK7-targeted ADC) meaningfully expands our pipeline
- ✓ Strong balance sheet with ~\$453M cash<sup>1</sup> (no debt)

## Day One's Future Potential

### Value creation

- Continued revenue growth from OJEMDA globally
- Indication expansion in front-line pLGG with FIREFLY-2
- Generate clinical POC data in DAY301 program
- Fund pipeline expansion
- Focused capital allocation, leveraging our efficient operating model to maintain strong financial position

# Our pipeline

Our goal is to take aim at the gaps that have left patients and their families behind.

Product Candidate	Therapeutic Area	Preclinical	Phase 1	Phase 2	Phase 3/ Registrational	Approved	Recent & Anticipated Milestones
<b>Tovorafenib<sup>3</sup></b> Type II RAF Inhibitor  OJEMDA brand name in U.S. <sup>1</sup>  Ex-U.S. Rights:  	BRAF-altered relapsed pLGG  						<b>FDA accelerated approval</b> April 2024  <b>EMA regulatory submission</b> Q1 2025  <b>3-year follow-up data expected</b> Q4 2025
	Front-line RAF-altered pLGG  						
<b>DAY301</b> PTK7-Targeted ADC	Adult and pediatric solid tumors  						<b>First dose cohort cleared</b> January 2025

<sup>1</sup> OJEMDA has received accelerated approval by the U.S. Food and Drug Administration. <sup>2</sup> FIREFLY-1 is an open-label, pivotal Phase 2 trial. <sup>3</sup> Ex-U.S. license agreement with Ipsen to commercialize OJEMDA (tovorafenib) outside the U.S. DAY301 is a license agreement with MabCare Therapeutics for exclusive worldwide rights, excluding Greater China, for MTX-13/CB-002, a novel ADC targeting PTK7. The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established.

# OJEMDA

Relapsed or refractory  
BRAF-altered pLGG



**Nora**  
Living with pLGG

# Pediatric low-grade glioma: The most common type of brain tumor in children

## A serious and life-threatening disease

- For the majority of pLGG patients in the relapsed setting, there is no standard of care, and until recently, no approved therapies
- Up to 75% of pLGGs have a BRAF alteration\*, of those ~80% are BRAF fusions and ~20% are BRAF V600 mutations<sup>2-6</sup>
- Despite surgery playing a significant role in treatment, the vast majority of patients still require systemic therapy<sup>7,8</sup>
- Due to high rate of disease recurrence, most patients will undergo multiple lines of systemic therapy over the course of their disease

**pLGGs are chronic and relentless, with patients suffering profound tumor and treatment-associated morbidity that can impact their life trajectory over the long term<sup>1</sup>**

\*Incidence of BRAF alterations varies across pLGG subtypes. <sup>1</sup> Sievert AJ, Fisher MJ. Pediatric low-grade gliomas. *J Child Neurol.* 2009;24(11):1397-1408. doi:10.1177/0883073809342005. <sup>2</sup> Penman CL et al. *Front Oncol.* 2015;5:54. <sup>3</sup> Cohen AR., *N Engl J Med.* 2020;386(20):1922-1931. <sup>4</sup> Lassaletta A, et al. *J Clin Oncol.* 2017;35(25):2934-2941. <sup>5</sup> Faulkner G, et al. *J Neuropathol Exp Neurol.* 2015;74(9):867-872. <sup>6</sup> Packer RJ, et al. *Neuro Oncol.* 2017;19(6):750-761. <sup>7</sup> Ostrum QT et al., *Neuro Oncol.* 2015; 16(Suppl 10):x1-x36; <sup>8</sup> De Blank P, et al., *Curr Opin Pediatr.* 2019 Feb; 31(1):21-27.

# Overview U.S. prescribing information for OJEMDA

## Available in tablet formulation and pediatric-friendly powder for oral suspension

### Indication

OJEMDA is indicated for the treatment of pediatric patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma harboring a BRAF fusion or rearrangement, or BRAF V600 mutation

### Recommended Dose

380 mg/m<sup>2</sup> administered orally once weekly (not to exceed a dose of 600mg once weekly); OJEMDA can be taken with or without food

**For full prescribing information, visit [dayonebio.com](http://dayonebio.com)**



# Product profile aligns with what physicians are looking for in a therapy

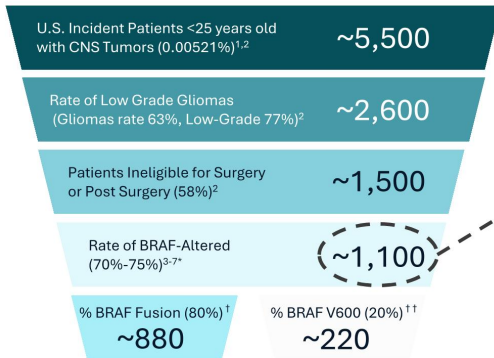


<b>Efficacy</b>	<ul style="list-style-type: none"><li>• Meaningful tumor stabilization or shrinkage may be possible with OJEMDA, in the clinical trial:<ul style="list-style-type: none"><li>• 51% of children experienced tumor shrinkage by at least 25%</li><li>• 82% of children saw their tumors shrink or remain stable</li></ul></li></ul>
<b>Safety</b>	<ul style="list-style-type: none"><li>• Generally well-tolerated therapy, with 9 out of 10 patients staying on treatment in the clinical trial</li><li>• Most common grade 3 / 4 adverse events include: anemia, elevated CPK, maculo-papular rash, fatigue &amp; vomiting</li></ul>
<b>Dosing</b>	<ul style="list-style-type: none"><li>• Once-weekly, taken with or without food conveniently from home can mean fewer daily interruptions</li></ul>

**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, rearrangement, or BRAF V600 mutation.**

# Foundational U.S. opportunity for OJEMDA in both relapsed and frontline pLGG

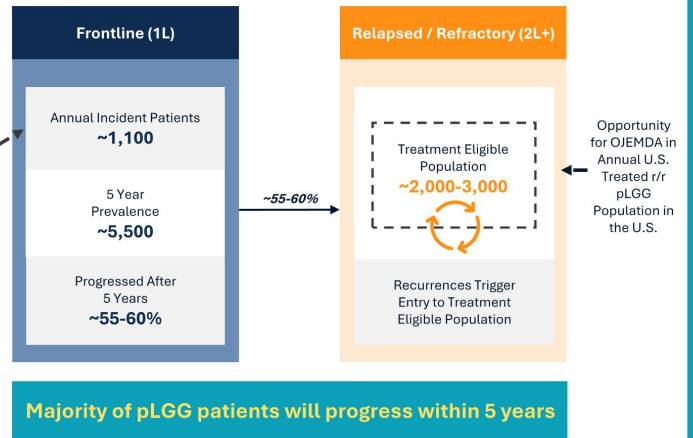
## Incident Therapeutic Build for New pLGG Patients to be Treated in Frontline Setting



1L BRAF-Altered pLGG Patients Eligible for Systemic Therapy

## Illustrative pLGG Patient Flow<sup>8</sup>

Prevalence of Systemically-Treated Patients Under 25 Years ~26,000



Majority of pLGG patients will progress within 5 years

<sup>1</sup> US Census. <sup>2</sup> CBTRUS, Qaddoumi et al 2009, Schreck et al 2019, ClearView Analysis. <sup>3</sup> Penman CL et al. Front Oncol. 2015;5:54. <sup>4</sup> Cohen AR., N Engl J Med. 2020;386(20):1922-1931. <sup>5</sup> Lassaletta A, et al. J Clin Oncol. 2017;35(25):2934-2941. <sup>6</sup> Faulkner C, et al. J Neuropathol Exp Neurol. 2015;74(9):867-872. <sup>7</sup> Packer RJ, et al. Neuro Oncol. 2017;19(6):750-761. <sup>8</sup> Incidence of BRAF alterations varies across pLGG subtypes. <sup>†</sup> Predominantly seen in pilocytic astrocytomas. <sup>††</sup> May vary across pLGG subtypes. BRAF, V-Raf murine sarcoma viral oncogene homolog B; MAPK, mitogen-activated protein kinase; pLGG, pediatric low-grade glioma. <sup>9</sup> Estimated annual incidence, estimated prevalence, estimated progression rates, and estimated recurrent/progressive total addressable opportunity are Day One calculations based on publicly available data. The estimated recurrent/progressive total addressable opportunity is based on progression free survival curves modeled from published literature and internal market research conducted by EpidStrategies, A Division of ToxStrategies, Inc. on behalf of Day One. r/r, relapsed or refractory.

## Commercial performance by the numbers

**\$33.6M**

**Q2 2025 OJEMDA Net  
Product Revenue**

+10% growth vs Q1 2025  
+310% growth vs Q2 2024<sup>2</sup>

**1,062**

**Q2 2025 OJEMDA  
Prescriptions<sup>1</sup>**

+15% growth vs Q1 2025  
+346% growth vs Q2 2024<sup>2</sup>

**\$113.1M**

**OJEMDA Net  
Revenue For The  
Most Recent  
12 Months**

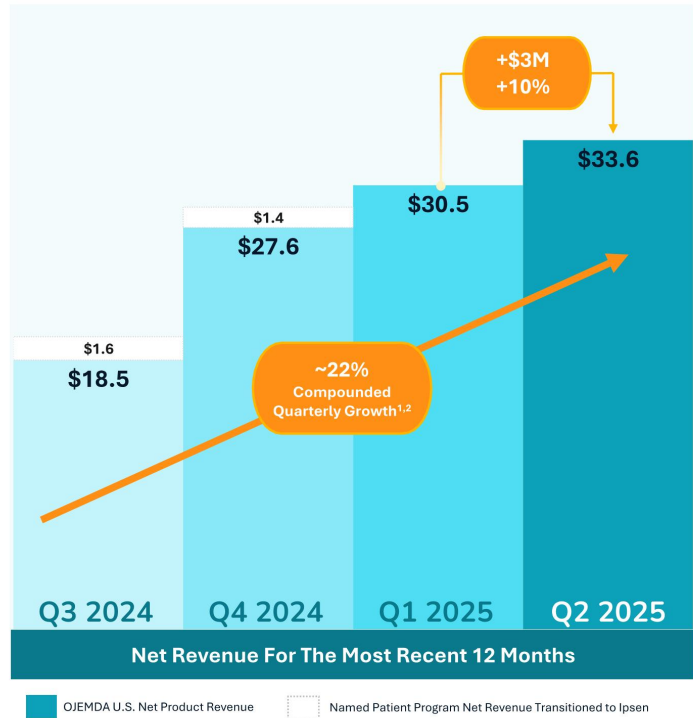
Expected 2025 OJEMDA Revenue of **\$140 to \$150M**

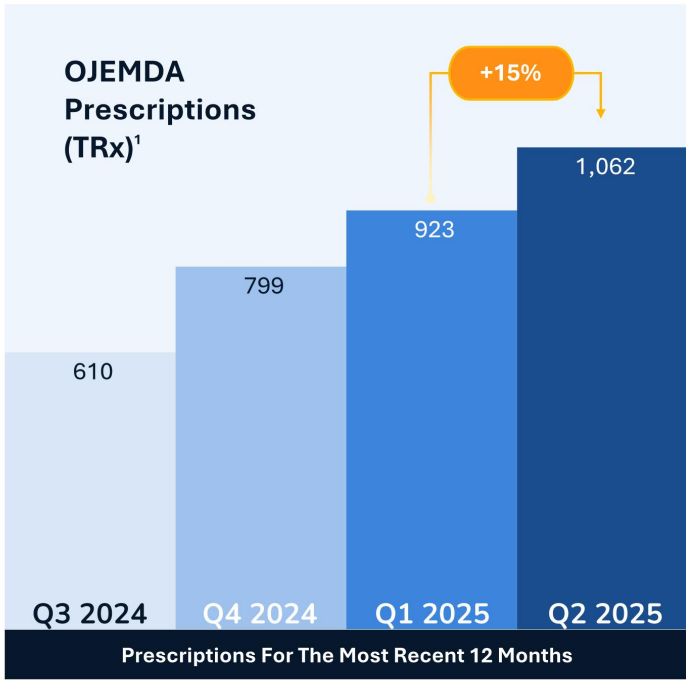
## One year in: OJEMDA delivering steady revenue growth

Achieved **\$33.6M** in Q2 2025 OJEMDA net product revenue

### Net Revenue Highlights

- Achieved \$64.1M in net product revenue for the first half of 2025
- Free drug represented ~5% of total scripts in Q2 2025





## One year in: Consistent uptake driving quarterly OJEMDA growth

Achieved **greater than 1,000** scripts in Q2 2025

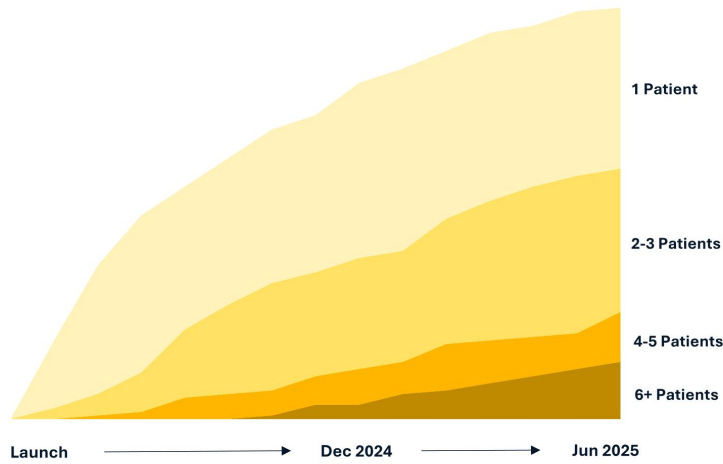
### Prescription Highlights

- Strong and consistent patient demand, driven by new patient starts and high percentage of patients staying on therapy month-to-month
- Continued prescriber adoption accompanied by growing breadth & depth

<sup>1</sup> Prescriptions are approximations based on data available as of June 30, 2025. Prescriptions for the most recent 12 months represents results for the 12-month period ended June 30, 2025.

# Expanding Prescriber Adoption with Meaningful Growth Opportunity Remaining

Growing Depth of Prescribing by Account Since Launch



- Continued growth in breadth of unique prescribers initiating at least one patient on OJEMDA
  - Growth driven by increased penetration of priority 2 & 3 accounts
- Growing number of accounts with multiple patients on OJEMDA
- >60% of prescribing accounts now have treated multiple patients with OJEMDA

# OJEMDA priorities to drive revenue growth in 2025

Drive depth of prescribing with current prescribers

Encourage non-user HCPs to try OJEMDA in their next r/r pLGG patient

Establish OJEMDA as standard of care in 2nd line r/r BRAF-altered pLGG

Support prescribers and patients to allow for optimal duration of treatment

# FIREFLY-2

Pivotal Phase 3 trial of  
tovorafenib in front-line pLGG



**Bradon**  
Living with pLGG  
since age 11



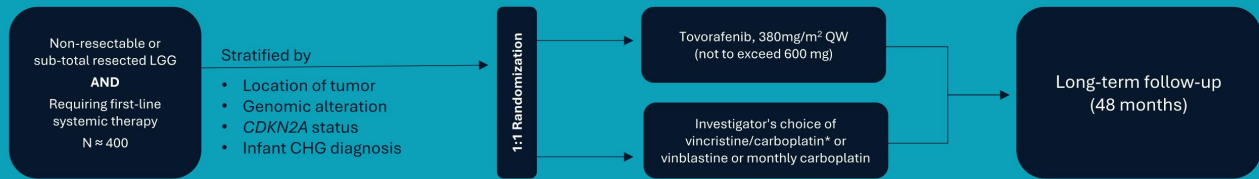
# Expansion into front-line treatment represents a meaningful expansion opportunity for tovorafenib in pLGG

## Trial design

- Randomized, global, registrational Phase 3 trial of monotherapy tovorafenib vs SoC chemotherapy
- Eligibility: Patients aged up to <25 years with LGG harboring a RAF alteration and requiring first-line systemic therapy
- Tovorafenib available as tablets and pediatric-friendly liquid suspension
- Patients who progress after stopping tovorafenib may be re-challenged
- Patients who progress in the SoC arm during or post-treatment may cross-over to receive tovorafenib

## Endpoints

- **Primary endpoint: ORR based on RAPNO-LGG criteria, assessed by blinded independent central review**
  - **The ORR primary analysis is expected to occur ~12 months after the last patient randomized**
- Key secondary endpoints: PFS and DoR by RAPNO-LGG criteria
- Other secondary endpoints: changes in neurological and visual function, safety, and tolerability
- Key exploratory objectives: QoL and health utilization measures



# DAY301

PTK7-targeted antibody-drug conjugate (ADC)



## DAY301: Next generation ADC targeting PTK7

### PTK7: clinically-validated ADC target

Anti-tumor activity of anti-PTK7 ADC demonstrated in Phase 1b trial of Pfizer / Abbvie's cofetuzumab pelidotin<sup>1</sup>

### DAY301: potential first-in-class asset

Novel ADC active in preclinical models, designed to maximize therapeutic window

### Substantial development and commercial potential for DAY301

High PTK7 expression in multiple adult and pediatric tumor indications

**First dose cohort cleared January 2025**

## PTK7: A clinically-validated ADC target

### Potential opportunity for a next-generation PTK7 ADC with improved therapeutic index

- Clinical results for cofetuzumab pelidotin<sup>1</sup> demonstrated proof of concept for PTK7-targeted ADCs
- Cofetuzumab pelidotin activity seen in multiple tumor types:
  - Ovarian (Pt-resistant): ORR 27% (n=63)
  - TNBC: ORR 21% (n=29)
  - NSCLC: ORR 19% (n=31)
  - mDOR: 4.2-5.7m for Ovarian (Pt-resistant)/TNBC/NSCLC
  - mPFS: 1.5-2.9m for Ovarian (Pt-resistant)/TNBC/NSCLC
- Aur0101 program limited by toxicity, resulting in reduced dose intensity and duration
- A next generation product with optimized properties and a better therapeutic index may achieve greater clinical efficacy

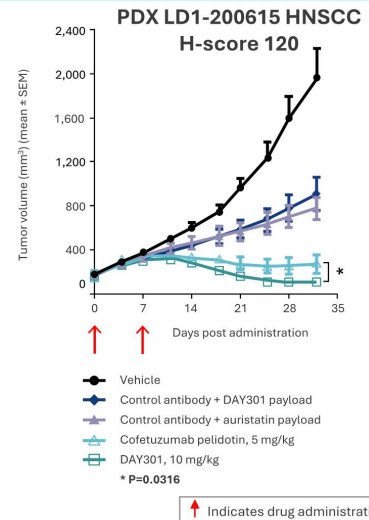
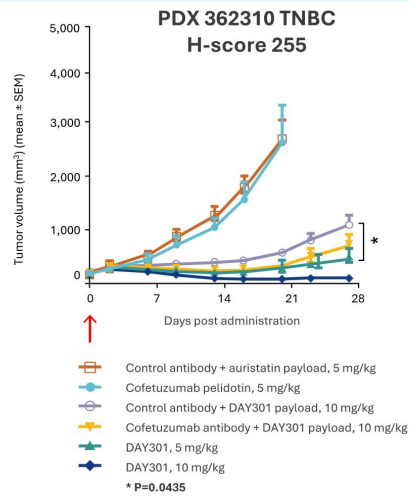
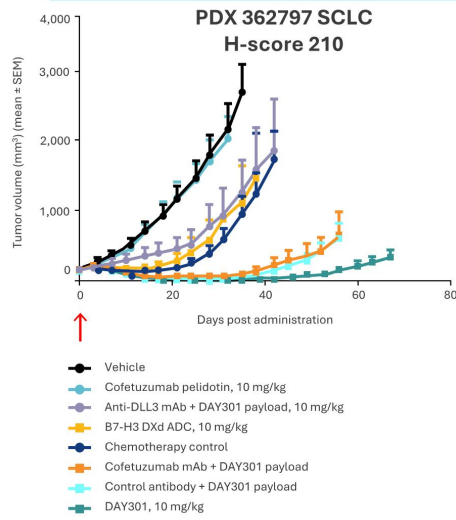
## DAY301: Potential first-in-class asset

**DAY301 has been designed to maximize therapeutic index and overcome limitations of prior programs**

- Tumor regression at tolerable doses seen in multiple preclinical models
- Higher HNSTD in cyno toxicology studies; payload with known safety profile
- High cell permeability / bystander effect; low efflux (not a P-gp substrate)
- Novel, highly hydrophilic, cleavable linker
- Moderate-to-high affinity antibody with favorable stability and developability profile
- Drug-antibody-ratio (DAR) of 8, shown to be effective for other ADCs in solid tumors
- IP: Composition of Matter patent term expected 2044, once issued

# DAY301: First-in-class potential

Improved tumor regression activity demonstrated for DAY301 vs. benchmarks in multiple preclinical models



## DAY301: Encouraging development and commercial opportunities

Indication	PTK7 Expression ( $\geq 1+$ )	U.S. Patient Population Cases/Deaths	ORR at Relapse	Median OS at Relapse
Endometrial	100% <sup>2</sup>	67,880/13,250 <sup>3</sup>	39% <sup>7</sup>	9 months <sup>7</sup>
Esophageal SCC	76% <sup>1</sup>	22,370/16,130 <sup>3</sup>	5% <sup>4</sup>	3 months <sup>4</sup>
Gastric	35% <sup>2</sup>	26,890/10,880 <sup>3</sup>	12% <sup>14</sup>	6-14 months <sup>15</sup>
Head & Neck SCC	75% <sup>1</sup>	54,540/11,580 <sup>3</sup>	32% <sup>5</sup>	7.8 months <sup>5</sup>
NSCLC	50% <sup>2</sup>	199,393/106,310 <sup>3</sup>	45-60% <sup>8</sup>	7-12 months <sup>9</sup>
Ovarian (platinum resistant)	30% <sup>2</sup> (95%)*	19,710/13,270 <sup>3</sup>	20-35% <sup>3</sup>	17.2 months <sup>6</sup>
Small Cell Lung	50% <sup>2</sup>	35,187/18,760 <sup>3</sup>	10-40% <sup>10</sup>	9-12 months <sup>11</sup>
TNBC	70% <sup>2</sup>	46,608/12,675 <sup>3,16</sup>	5-35% <sup>12</sup>	28 months <sup>13</sup>

Potential pediatric indications include: neuroblastoma, rhabdomyosarcoma and osteosarcoma

# DAY301: Initial Phase 1a/b clinical trial design

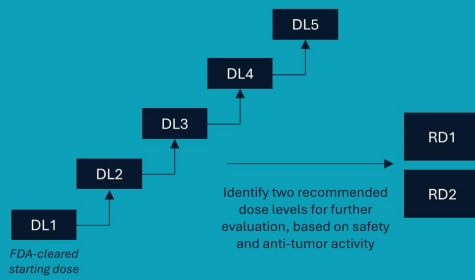
## Key design elements

- BOIN design for efficiency of dose escalation
- Backfill active dose levels to generate additional safety data
- Enroll tumor types with known high PTK7 expression
- Advance two recommended dose levels to Phase 1b
- Final dose optimization scheme and possible registrational path(s) pending discussions with FDA at end of dose escalation/expansion

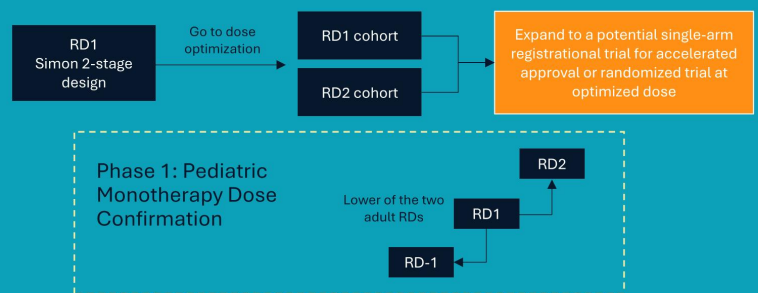
## Adult & pediatric development

- Potential adult indications include platinum resistant ovarian cancer, squamous NSCLC, esophageal SCC, HNSCC, endometrial, and/or SCLC
  - Patients to be selected based on PTK7 expression clinical trial assay
- Pediatric dose confirmation and efficacy assessment to begin near/at the end of adult dose escalation
  - Initial target indications include neuroblastoma, osteosarcoma, rhabdomyosarcoma

### Phase 1a: Monotherapy Dose Escalation



### Phase 1b: Monotherapy Dose Expansion and Optimization



# Summary



## Second quarter 2025 financial results

Financial Summary (\$ in millions)	Three Months Ended 6/30/25	Three Months Ended 6/30/24	Six Months Ended 6/30/25	Six Months Ended 6/30/24
OJEMDA Net Revenue	33.6	8.2	64.1	8.2
License Revenue	0.3	--	0.6	--
<b>Total Revenue</b>	<b>\$33.9</b>	<b>\$8.2</b>	<b>\$64.7</b>	<b>\$8.2</b>
Cost of Product and License Revenue	3.8	0.7	6.6	0.7
Research and Development Expense <sup>1</sup>	36.1	92.1	75.8	132.3
Selling, General and Administrative Expense <sup>2</sup>	29.0	30.2	58.3	56.8
<b>Total Cost and Operating Expenses</b>	<b>\$68.9</b>	<b>\$123.0</b>	<b>\$140.7</b>	<b>\$189.8</b>
Non-operating Income <sup>3</sup>	4.7	111.9	9.7	116.3
Income Tax Expense	--	1.5	--	1.5
<b>Net Income (Loss)</b>	<b>(\$30.3)</b>	<b>(\$4.4)</b>	<b>(\$66.3)</b>	<b>(\$66.8)</b>
		6/30/25		12/31/24
Cash, cash equivalents and short-term investments		\$453.1		\$531.7

All financial information as of 6/30/25 is unaudited. <sup>1</sup> Includes stock-based compensation expense of \$3.6 million and \$7.8 million for the three and six months ended 6/30/25, and \$4.7 million and \$9.4 million for the three and six months ended 6/30/24. <sup>2</sup> Includes stock-based compensation expense of \$7.3 million and \$15.9 million for the three and six months ended 6/30/25, and \$8.3 million and \$16.3 million for the three and six months ended 6/30/24. <sup>3</sup> Includes sale of Priority Review Voucher of \$108.0 million for the three and six months ended 6/30/24



## **Day One is well positioned for sustainable growth and long-term success**

**Drive OJEMDA  
revenue growth**

**Execute on clinical  
development pipeline for  
FIREFLY-2 and DAY301**

**Leverage our development and  
commercialization expertise to  
further expand our multiple  
asset portfolio**

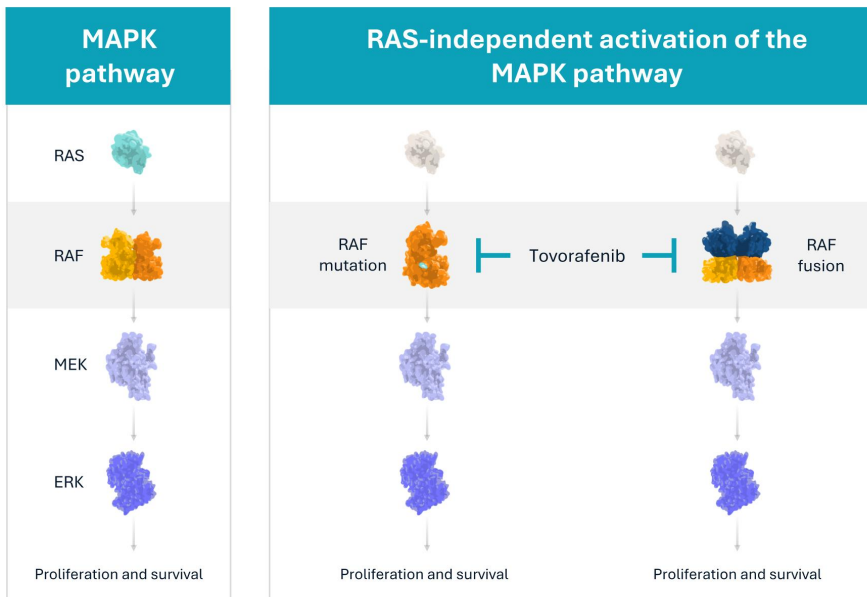
**Maintain strong capital  
position while investing in  
our pipeline**



## Appendix



# Tovorafenib inhibits both BRAF fusions and BRAF V600 mutations



Tovorafenib is an investigational, oral, selective, CNS-penetrant, type II RAF inhibitor that was designed to inhibit both monomeric and dimeric RAF kinase

- Activity in tumors driven by both RAF fusions and BRAF V600E mutations
- Tablet and pediatric-friendly liquid suspension
- Once weekly dosing

Currently approved type I BRAF inhibitors are indicated for use in patients with tumors bearing BRAF V600 mutations

- Type I BRAF inhibitors cause paradoxical MAPK activation in the setting of wild-type RAF, increasing the risk of tumor growth in BRAF fusion-driven

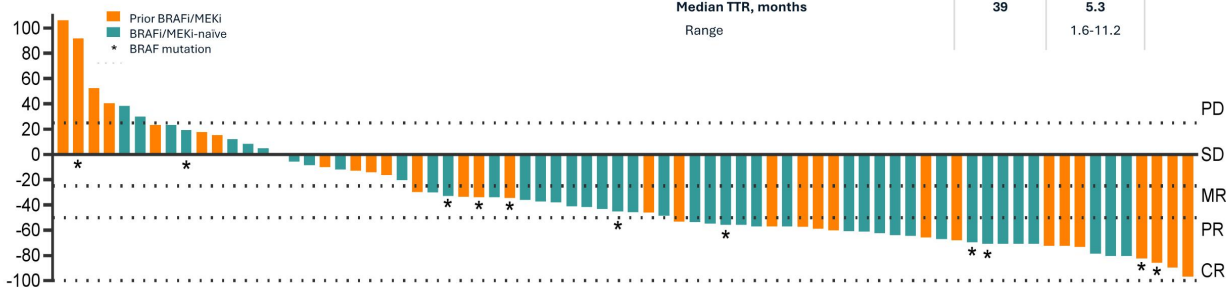


# Efficacy summary from OJEMDA prescribing information

# 51%

Overall response rate (RAPNO-LGG) in 76 evaluable patients

Response (IRC)	RAPNO-LGG		
	n	n (%)	95% CI
<b>ORR, n (%)</b>	<b>76</b>	<b>39 (51)</b>	<b>40-63</b>
BRAF fusion or rearrangement	64	33 (52)	39-64
BRAF V600 mutation	12	6 (50)	21-79
Prior MAPKi use	45	22 (49)	31-64
MAPKi-naïve	31	17 (55)	36-73
<b>Median DOR, months</b>	<b>39</b>	<b>13.8</b>	<b>11.3-NR<sup>†</sup></b>
<b>Median TTR, months</b>	<b>39</b>	<b>5.3</b>	
Range		1.6-11.2	



June 5, 2023 data cutoff. CI, confidence interval; DOR, duration of response; IRC, independent radiology review committee; LGG, low-grade glioma; NR, not reached; ORR, overall response rate; RAPNO, Response Assessment in Pediatric Neuro-Oncology; TTR, time to response; CR, complete response; PR, partial response; MR, minor response; SD, stable disease; PD, progressive disease. <sup>†</sup> As of the data cutoff, 66% remain on tovorafenib.



# Safety summary from OJEMDA prescribing information

## Warnings and Precautions

- Hemorrhage
- Skin toxicity, including photosensitivity
- Hepatotoxicity
- Effect on growth
- Embryo-fetal toxicity
- Use in NF1- associated tumors

No boxed warnings or contraindications

Preferred Term, n (%)	TEAEs (≥ 30% of patients [n=137])	
	Any Grade	Grade ≥3
Any AE	137 (100)	86 (63)
Hair color changes	104 (76)	0
Anemia	81 (59)	15 (11)
Elevated CPK	80 (58)	16 (12)
Fatigue	76 (55)	6 (4)
Vomiting	68 (50)	6 (4)
Hypophosphatemia	64 (47)	0
Headache	61 (45)	2 (1)
Maculo-papular rash	60 (44)	11 (8)
Pyrexia	53 (39)	5 (4)
Dry skin	49 (36)	0
Elevated LDH	48 (35)	0
Increased AST	47 (34)	4 (3)
Constipation	45 (33)	0
Nausea	45 (33)	0
Upper RTI	43 (31)	2 (1)
Dermatitis acneiform	42 (31)	1 (1)
Epistaxis	42 (31)	1 (1)

June 5, 2023 data cutoff. OJEMDA safety data (n=137). Treatment-emergent AEs ≥20% any grade in arms 1 & 2. AE, adverse event; AST, aspartate aminotransferase; CPK, creatine phosphokinase; LDH, lactate dehydrogenase; RTI, respiratory tract infection; TEAEs, treatment-emergent adverse events.