IDEAYA Biosciences, Inc. Reports Second Quarter 2025 Financial Results and Provides Business Update

- Phase 2/3 trial of the darovasertib and crizotinib combination in 1L HLA-A2-negative metastatic uveal melanoma (MUM) on track to report median PFS data by year-end 2025; potential to enable a U.S. accelerated approval filing
- First-reported median overall survival data in over 40 1L MUM patients from single-arm Phase 2 trial of the darovasertib and crizotinib combination to be provided at a medical conference in 4Q 2025
- Phase 2 data from over 90 plaque brachytherapy and enucleation primary uveal melanoma (UM) patients treated with darovasertib in the neoadjuvant setting will be shared as a Proffered Paper Oral Presentation at the European Society of Medical Oncology (ESMO) in 4Q 2025
- First-in-human Phase 1 clinical efficacy and safety data from over 70 SCLC patients treated with IDE849 (DLL3 TOP1i ADC) will be provided as an Oral Presentation at the IASLC 2025 World Conference on Lung Cancer on September 7th, 2025
- IDEAYA 10-year Anniversary R&D Day will feature multiple clinical data updates, including from over 20 plaque brachytherapy patients in the Phase 2 trial of darovasertib as neoadjuvant therapy for primary UM and from two expansion cohorts in the Phase 1 combination trial of IDE397 and Trodelvy® (sacituzumab govitecan-hziy) in MTAP-deletion urothelial cancer
- Three IND submissions are on track by year-end 2025, including IDE892 (PRMT5), IDE034 (B7H3/PTK7 bispecific TOP1i ADC) and IDE574 (KAT6/7)
- ~$992 million of cash, cash equivalents, and marketable securities as of June 30, 2025; anticipated to fund operations into 2029

SOUTH SAN FRANCISCO, Calif., Aug. 5, 2025 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), an oncology company committed to advancing the discovery, development, and commercialization of transformative precision medicines to address unmet medical needs in cancer, provided a business update and announced financial results for the second quarter ended June 30, 2025.

"We look forward to a catalyst rich period with six clinical data updates guided from now to year-end across three clinical stage programs, including two oral presentations that have been accepted at major medical conferences and our targeted top-line randomized median PFS results for the darovasertib and crizotinib combination in 1L HLA-A2 negative MUM to potentially enable our first accelerated approval filing in the U.S. We are also excited to host our 10-year Anniversary R&D Day in New York City on September 8th, where we will present multiple data updates across our potential first-in-class clinical pipeline and highlight our strategic vision and pioneering research in cancer biology and drug discovery," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

Selected Pipeline Developments and Upcoming Milestones

Darovasertib

- Metastatic uveal melanoma (MUM)
    - Median progression-free survival (PFS) data from the Phase 2/3 trial of darovasertib in combination with crizotinib in first line (1L) HLA-A2-negative MUM is on track to be reported by year-end 2025; this data has the potential to enable an accelerated approval filing in the United States. Over 350 patients have been enrolled in the trial as of August 4, 2025, and the company expects to complete full enrollment of approximately 400 patients by year-end. Based on feedback from the U.S. Food and Drug Administration (FDA), IDEAYA plans to submit median overall survival (OS) data from this trial to support full U.S. approval in HLA-A2-negative MUM.
    - Median OS data from a single-arm, Phase 2 trial of darovasertib in combination with crizotinib will be presented at a medical conference in the fourth quarter of 2025. The readout will include data in over 40 patients, including both HLA-A2-negative and HLA-A2-positive patients. IDEAYA continues to enroll HLA-A2-positive patients in this trial to assess the benefit of the darovasertib/crizotinib combination to support a potential real world evidence (RWE) regulatory submission and/or compendia listing. If granted, this has the potential to broaden the use of darovasertib in MUM patients, independent of HLA status.

- Neoadjuvant therapy for primary uveal melanoma (UM)
    - IDEAYA is also evaluating darovasertib as a monotherapy in the neoadjuvant setting for primary UM, where the goal of treatment is to prevent enucleation (surgical eye removal), preserve vision prior to and post-plaque brachytherapy, and slow disease progression and metastasis. Initial safety and visual benefit data will be reported from the Phase 2 clinical trial from over 20 patients in the plaque brachytherapy-eligible cohort at IDEAYA's R&D Day on September 8th, followed by additional data from over 90 patients in both the enucleation-eligible and plaque brachytherapy-eligible cohorts in a Proffered Paper Oral Presentation at ESMO, taking place from October 17-21, 2025 in Berlin, Germany.
    - Following a successful Type D meeting with the FDA in April 2025, the company initiated a randomized Phase 3 registration-enabling trial of darovasertib in the neoadjuvant setting for primary UM in the third quarter of 2025. The trial, referred to as OptimUM-10, will enroll a total of approximately 520 patients in two cohorts of plaque brachytherapy-eligible and enucleation-eligible patients.

IDE397 (MAT2A)

- IDEAYA is conducting a Phase 1/2 clinical trial pursuant to a clinical study collaboration and supply agreement with Gilead to evaluate IDE397 in combination with Trodelvy® (sacituzumab govitecan-hziy), Gilead's Trop-2 directed ADC, in patients with MTAP-deletion urothelial cancer, or UC, and non-small cell lung cancer, or NSCLC.
- In April 2025, the companies announced expansion of the IDE397 and Trodelvy® (sacituzumab govitecan-hziy) combination trial in NSCLC. IDEAYA will provide initial Phase 1 safety and efficacy data from two expansion cohorts in the IDE397 and Trodelvy® (sacituzumab govitecan-hziy) combination trial in MTAP-deletion UC patients at the company's R&D Day September 8th, with additional data targeted for a medical conference in the first half of 2026.

IDE849 (DLL3 TOP1i ADC)

- IDEAYA's partner, Hengrui Pharma, is conducting a multi-site, open label Phase 1 clinical trial for IDE849 in China for patients with small-cell lung cancer (SCLC). Hengrui will present clinical safety and efficacy data from over 70 patients in the trial at the International Association for the Study of Lung Cancer ("IASLC") 2025 World Conference on Lung Cancer (WCLC) taking place from September 6-9, 2025 in Barcelona, Spain. The presentation will include data from the dose escalation and multiple expansion doses.
- In May 2025, IDEAYA initiated a Phase 1 trial in the U.S. in SCLC. Patient dosing in NETs and other DLL3-expressing tumors is targeted by year-end 2025.

Other programs

- *IDE161*, a potential first-in-class small molecule poly-(ADP-ribose) glycohydrolase, or PARG, inhibitor is currently in Phase 1 dose optimization to inform future combination studies with IDE849 and other TOP1i-based ADCs where PARG inhibition may synergize with the payload to deepen responses. IDEAYA plans to initiate a Phase 1 combination trial of IDE849 and IDE161 by the end of 2025. The company will also share preclinical data in a poster presentation at WCLC providing combination mechanism and pre-clinical synergy data between TOP1-payload based ADCs and IDE161.
- *IDE275 (GSK959)*, a potential first-in-class small molecule inhibitor of Werner Helicase, is being developed in collaboration with GlaxoSmithKline (GSK). A Phase 1 dose escalation in patients with MSI-High solid tumors is ongoing.
- *IDE705 (GSK101)*, a potential first-in-class small molecule inhibitor of DNA Polymerase Theta Helicase, or Pol Theta, is being developed in collaboration with GSK. A Phase 1 clinical trial in combination with niraparib, GSK's small molecule inhibitor of PARP, is ongoing in patients with BRCA-positive or other HRD-positive tumors.
    - Phase 2 expansion in HRD-positive solid tumors would trigger a $10 million milestone payment from GSK.
- IDEAYA also plans to submit three investigational new drug, or IND, applications before the end of the year:
    - *IDE892*, a potential best-in-class MTA-cooperative PRMT5 inhibitor, in mid-2025;
    - *IDE034*, a potential first-in-class B7H3/PTK7 bispecific TOP1i ADC, in the fourth quarter of 2025; and
    - *IDE574*, a potential first-in-class KAT6/7 dual inhibitor, in the fourth quarter of 2025.

R&D Day - September 8, 2025

- IDEAYA will host an in-person and virtual R&D Day on September 8th, 2025 from 8:00-10:00 AM ET in New York City. The company will present multiple clinical data updates across the pipeline and highlight future growth drivers and upcoming milestones. Speakers will include members of IDEAYA's senior leadership team and key opinion leader(s). Additional agenda details will be provided by the end of August 2025.
- Registration for this event can be accessed here or at the investors section of the IDEAYA website at https://ir.ideayabio.com/events.

Other corporate updates

- IDEAYA continues efforts to scale the organization in preparation for the potential U.S. launch of darovasertib, including key hires within the commercial, medical affairs and market access functions.
    - Gary Palmer, M.D., joined as Senior Vice President, Medical Affairs, where he will lead the company's medical affairs activities. Gary joined IDEAYA with over 25 years of global leadership experience in medical affairs from biopharmaceutical companies of various sizes and stages, and across multiple therapeutic areas including oncology, pulmonary medicine, immunology and neurology. Most recently Gary was Senior Vice President of Medical Affairs at Pliant Therapeutics, and prior to that he was Senior Vice President of Global Medical Affairs Immunology & Neuroscience at Bristol-Myers Squibb Co (BMS) where he led the Worldwide Immunology, Fibrosis and Neuroscience Medical Affairs team covering a portfolio spanning four globally marketed medications and more than 15 development candidates across the areas of pulmonary fibrosis, dermatology, gastroenterology, rheumatology and neurology.

Financial Results for the Quarter Ended June 30, 2025

As of June 30, 2025, IDEAYA had cash, cash equivalents and marketable securities of approximately $991.9 million, compared to $1.05 billion as of March 31, 2025. The decrease was primarily driven by net cash used in operations.

Research and development (R&D) expenses for the three months ended June 30, 2025 totaled $74.2 million compared to $70.9 million for the three months ended March 31, 2025. The increase was primarily due to higher clinical trial expenses to support our clinical pipeline and personnel-related expenses.

General and administrative (G&A) expenses for the three months ended June 30, 2025 totaled $14.6 million compared to $13.5 million for the three months ended March 31, 2025. The increase was primarily due to higher personnel-related expenses to support our growth.

The net loss for the three months ended June 30, 2025, was $77.5 million compared to the net loss of $72.2 million for the three months ended March 31, 2025. Total stock compensation expense for the three months ended June 30, 2025, was $11.9 million compared to $10.2 million for the same period in 2024.

About IDEAYA Biosciences

IDEAYA is a precision medicine oncology company committed to the discovery, development, and commercialization of transformative therapies for cancer. Our approach integrates expertise in small-molecule drug discovery, structural biology and bioinformatics with robust internal capabilities in identifying and validating translational biomarkers to develop tailored, potentially first-in-class targeted therapies aligned to the genetic drivers of disease. We have built a deep pipeline of product candidates focused on synthetic lethality and antibody-drug conjugates, or ADCs, for molecularly defined solid tumor indications. Our mission is to bring forth the next wave of precision oncology therapies that are more selective, more effective, and deeply personalized with the goal of altering the course of disease and improving clinical outcomes for patients with cancer. IDEAYA's corporate presentation is available on its website, at its Investor Relations page: https://ir.ideayabio.com/.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to (i) the timing and content of clinical program updates, regulatory updates, clinical trial data readouts, including those at medical conferences and IDEAYA's R&D Day; (ii) the potential therapeutic benefits of IDEAYA therapeutics; (iii) the translation of preliminary clinical trial results into future clinical trial results and/or regulatory approval; (iv) timing of development and regulatory milestones; (v) the timing of new IND applications; and (vi) the extent to which IDEAYA's existing cash, cash equivalents, and marketable

securities will fund its planned operations. Such forward-looking statements involve substantial risks and uncertainties that could cause IDEAYA's preclinical and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including IDEAYA's programs' early stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, IDEAYA's ability to successfully establish, protect and defend its intellectual property, and other matters that could affect the sufficiency of existing cash to fund operations. IDEAYA undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of IDEAYA in general, see IDEAYA's Annual Report on Form 10-K dated February 18, 2025 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

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IDEAYA Biosciences, Inc.

Condensed Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Three Months Ended		Six Months Ended	
	June 30, 2025	**March 31, 2025**	**June 30, 2025**	**June 30, 2024**
	(Unaudited)		**(Unaudited)**	
Operating expenses:				
Research and development	$ 74,226	$ 70,886	$ 145,112	$ 97,338
General and administrative	14,580	13,503	28,083	18,606
Total operating expenses	88,806	84,389	173,195	115,944
Loss from operations	(88,806)	(84,389)	(173,195)	(115,944)
Interest income and other income, net	11,315	12,211	23,526	23,600

Net loss	(77,491)	(72,178)	(149,669)	(92,344)
Unrealized (losses) gains on marketable securities	(64)	773	709	(1,978)
Comprehensive loss	$ (77,555)	$ (71,405)	$ (148,960)	$ (94,322)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.88)	$ (0.82)	$ (1.69)	$ (1.21)
Weighted-average number of shares outstanding, basic and diluted	88,472,197	88,356,335	88,414,586	76,535,607

IDEAYA Biosciences, Inc.

Condensed Balance Sheet Data

(*in thousands*)

	June 30, 2025	December 31, 2024
	(Unaudited)	
Cash and cash equivalents and short-term and long-term marketable securities	$ 991,869	$ 1,082,151
Total assets	1,041,270	1,124,091
Total liabilities	81,617	64,944
Total liabilities and stockholders' equity	$ 1,041,270	$ 1,124,091

SOURCE IDEAYA Biosciences, Inc.

Update