IDEAYA Biosciences Reports Third Quarter 2025 Financial Results and Provides Business Update

- Phase 2/3 trial (OptimUM-02) of the darovasertib/crizotinib combination in 1L HLA*A2-negative metastatic uveal melanoma (mUM) to report median PFS data by year-end 2025 to 1Q 2026; on track to complete enrollment by year-end
- 21.1 month median OS and 7.0 month median PFS reported from single-arm Phase 2 trial (OptimUM-01) evaluating the darovasertib/crizotinib combination in 1L mUM
- Phase 1 data reported in SCLC for IDE849 (DLL3 TOP1i ADC) at the World Conference on Lung Cancer. Preliminary evidence of clinical efficacy was also observed in NETs patients, including Partial Responses by RECIST 1.1
- Go-forward dose selected for IDE397 and Trodelvy® clinical combination in MTAP-deleted urothelial cancer (UC), and FPI achieved in non-small cell lung cancer (NSCLC); next clinical update planned for a medical conference in the first half of 2026
- IND clearance for IDE892 (PRMT5) received in 3Q 2025; IND filing for IDE034 (B7H3/PTK7 bispecific TOP1i ADC) complete, with IND filing for IDE574 (KAT6/7) on track for year-end 2025
- Entered into an exclusive license agreement with Servier for rights to darovasertib outside the United States; IDEAYA received $210 million upfront and is eligible for up to $320 million in milestone payments
- ~$1.14 billion of cash, cash equivalents, and marketable securities as of September 30, 2025; expected to fund operations into 2030

SOUTH SAN FRANCISCO, Calif., Nov. 4, 2025 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a leading precision medicine oncology company, provided a business update and announced financial results for the third quarter ended September 30, 2025.

"This quarter we continued to make significant progress across the pipeline and broader business, including the partnership with Servier that extends our runway into 2030 and enables potential commercialization of darovasertib outside of the United States. We have also provided multiple major medical conference clinical data updates at WCLC, ESMO and SMR, and completed our third IND filing in 2025 to further extend our industry leadership in precision medicine oncology," 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 (OptimUM-02) of darovasertib in combination with crizotinib in first line (1L) HLA*A2:01-negative mUM is on track to be reported by year-end 2025 to 1Q 2026; this data has the potential to enable an accelerated approval filing in the United States. The trial is nearing full enrollment, which remains on track to be completed by year-end.
    - In October 2025, data from the single-arm, Phase 2 trial (OptimUM-01) of darovasertib in combination with crizotinib were presented at the Society for Melanoma Research (SMR) Congress in Amsterdam, Netherlands. Data were from a total of 44 1L mUM patients, including both HLA*A2:01-negative and HLA*A2:01-positive patient subsets. Highlights include:
        - 21.1 month median overall survival (OS) and 7.0 month median progression free survival (PFS) across all patients
        - In 41 efficacy-evaluable patients, confirmed overall response rate (ORR) of 34% (14/41) with a 9.0 month median duration of response (mDOR)
        - Disease control rate (DCR) of 90% (37/41), with 85% (35/41) of patients achieving 'any reduction' in target lesions
        - The combination continued to be well-tolerated with the most common treatment-related adverse events (TRAEs >30%) of diarrhea, nausea, edema, vomiting, dermatitis, hypoalbuminemia, and fatigue
- Neoadjuvant therapy for primary uveal melanoma (UM)

- In October 2025, the company presented positive data from the randomized Phase 2 trial (OptimUM-09) in a Proffered Paper Oral Presentation at the European Society for Medical Oncology (ESMO) in Berlin, Germany. Data were from a total of 95 patients, including 56 recommended for enucleation (EN) and 39 eligible for plaque brachytherapy (PB). Highlights include:
    - Ocular tumor shrinkage in ~83% (78/94) of patients assessed, the majority of whom achieved ≥20% tumor shrinkage
    - Among evaluable EN patients, the eye preservation rate was 57% (24/42), which increased to 95% (19/20) in patients achieving ≥20% tumor shrinkage
    - In evaluable PB eligible patients, ~70% (26/37) achieved a reduction in predicted radiation dose to the eye from baseline, resulting in ~65% (24/37) having lower predicted risk of vision loss 3-years post-PB treatment
    - During neoadjuvant treatment with darovasertib, ~55% (29/53) of EN and ~61% (23/38) of PB patients showed an improvement in baseline visual acuity scores (VAS), with a mean gain of 17 and 10 letters, respectively
    - Darovasertib continued to be well-tolerated, with a low rate of serious adverse events and TRAEs leading to discontinuation
- IDEAYA has initiated a randomized Phase 3 registration-enabling trial of darovasertib as a single-agent in the neoadjuvant setting of primary UM. The trial, referred to as OptimUM-10, will enroll a total of approximately 450 patients in two cohorts of PB- and EN-recommended patients.
    - Target enrollment was revised downward from our previous estimate of 520 patients due to a reduction of 70 patients in the PB cohort (prior guidance of 400, now 330 patients) based on additional FDA feedback on the statistical plan (alpha usage) across the two cohorts
- Adjuvant therapy for primary UM
    - In collaboration with Servier, IDEAYA plans to initiate a global Phase 3 combination trial of darovasertib and crizotinib as an adjuvant therapy for primary UM in the first half of 2026.

IDE397 (MAT2A)

- Positive data were reported from the ongoing Phase 1/2 trial of IDE397 in combination with Gilead's Trodelvy® (sacituzumab govitecan-hziy), a Trop2-directed antibody-drug conjugate (ADC), in patients with MTAP-deleted urothelial cancer (UC).
    - 57% ORR (4/7; 4cPR) at 30 mg IDE397 plus 7.5mg/kg Trodelvy® (Dose level 2).
    - Median PFS and mDOR were not yet reached.
    - Manageable safety profile consistent with known adverse events of both drugs as single agents.
- IDEAYA has selected Dose level 2 as the go-forward dose for the IDE397 and Trodelvy clinical combination in MTAP-deleted UC and has achieved first-patient-in (FPI) in NSCLC. The next clinical update from the combination trial is planned for a medical conference in the first half of 2026.

IDE849 (DLL3 TOP1i ADC)

- IDEAYA's partner, Hengrui Pharma, presented clinical safety and efficacy data from over 70 small-cell lung cancer (SCLC) patients from their Phase 1 clinical trial at the 2025 International Association for the Study of Lung Cancer ("IASLC") World Conference on Lung Cancer (WCLC) in Barcelona, Spain. Data included 87 patients with small-cell lung cancer (SCLC) and 13 patients with other neuroendocrine carcinomas (NEC) as of a cut-off date of June 20, 2025. A total of 71 refractory (2L+) SCLC patients were evaluated for efficacy at doses of IDE849 between 2.4mg/kg and 4.2 mg/kg. Highlights include:
    - At the 2.4 mg/kg expansion dose of IDE849, 2L patients demonstrated an 80.0% (8/10) ORR and 70.0% (7/10) confirmed ORR; across all lines of therapy (2L+) at this dose the ORR and confirmed ORR decreased modestly to 73.7% (14/19) and 57.9% (11/19) (1 pending confirmation), respectively.
    - Across all doses of IDE849 tested, 2L patients showed a 77.1% (27/35) ORR and 60.0% (21/35) confirmed ORR (4 pending confirmation) whereas a 73.2% (52/71) ORR and 47.9% (34/71) confirmed ORR (10 pending confirmation) was observed across all lines of therapy at all doses (≥2.4 mg/kg).
    - Patients with baseline brain metastases had an 83.3% (5/6) confirmed ORR at the 2.4 mg/kg dose and a 66.7%

(12/18) confirmed ORR (1 pending confirmation) across all doses (≥2.4 mg/kg).
    - 6.7 month median PFS achieved across all lines and all doses (≥2.4 mg/kg); the median PFS was not reached in 2L patients.

- In May 2025, IDEAYA initiated a global Phase 1 trial of IDE849 and has achieved FPI in the United States. The company continues to enroll SCLC patients with plans to expand into patients with neuroendocrine tumors (NETs) and other DLL3-overexpressing tumors by the end of 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.
- *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 dose escalation in combination with niraparib, GSK's small molecule inhibitor of PARP, is ongoing in patients with solid tumors.
    - Phase 2 dose expansion in BRCA-mutant solid tumors would trigger a $10 million milestone payment from GSK.
- *IDE892*, a potential best-in-class MTA-cooperative PRMT5 inhibitor, is being developed for patients with MTAP-deleted lung cancer and other high priority MTAP-deleted solid tumor indications. IDEAYA received IND clearance from the FDA in the third quarter and expects to begin a Phase 1 dose escalation trial by the end of the year with the goal of advancing into combination trials with IDE397 in the first half of 2026.
- In the fourth quarter IDEAYA submitted an IND for *IDE034*, a potential first-in-class B7H3/PTK7 bispecific TOP1i ADC, and is on track to file an IND for *IDE574*, a potential first-in-class KAT6/7 dual inhibitor, by the end of the year.

License agreement with Servier

- IDEAYA entered into an exclusive license agreement with Servier for rights to darovasertib outside the United States. The company received an upfront payment of $210 million, and is eligible for up to $100 million in regulatory approval-based milestone payments and up to $220 million in commercial milestone payments, as well as double-digit royalties on net sales in all territories outside of the United States. IDEAYA and Servier will collaborate on the development of darovasertib and share the associated costs. IDEAYA retains all rights to darovasertib in the United States.

Financial Results for the Quarter Ended September 30, 2025

As of September 30, 2025, IDEAYA had cash, cash equivalents and marketable securities of approximately $1.14 billion, compared to $991.9 million as of June 30, 2025. The increase was primarily driven by the $210.0 million upfront payment received from Servier related to the exclusive license agreement for darovasertib, offset by the net cash used in operations.

Collaboration revenue for the three months ended September 30, 2025, totaled $207.8 million compared to zero for the three months ended June 30, 2025. Collaboration revenue was recognized for the performance obligations satisfied through September 30, 2025 related to the development and commercialization license recognized upon execution and the research and development services that will be recognized over time under the Servier exclusive license agreement for darovasertib. As of September 30, 2025, the remaining balance for the research and development services performance obligations is $143.1 million related to the clinical development cost reimbursements anticipated under the license agreement that will be recognized as IDEAYA collaboration revenue over time as the research and development services are completed.

Research and development (R&D) expenses for the three months ended September 30, 2025 totaled $83.0 million compared to $74.2 million for the three months ended June 30, 2025. The increase was primarily driven by higher clinical trial and CMC manufacturing expenses to support our programs.

General and administrative (G&A) expenses for the three months ended September 30, 2025 totaled $16.4 million compared to $14.6 million for the three months ended June 30, 2025. The increase was primarily due to higher legal expenses to support company growth and commercial expenses to support the darovasertib commercial preparation activities.

The net income for the three months ended September 30, 2025, was $119.2 million compared to the net loss of $77.5 million for the three months ended June 30, 2025. Total stock compensation expense for the three months ended September 30, 2025, was $12.2 million compared to $11.9 million for the three months ended June 30, 2025.

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: 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 trial programs and updates, including enrollment achievements, regulatory updates, clinical trial data readouts, including those at medical conferences; (ii) the potential for an accelerated approval filing for darovasertib; (iii) the potential therapeutic benefits of IDEAYA therapeutics; (iv) the translation of preliminary clinical trial results into future clinical trial results and/or regulatory approval; (v) timing of development and regulatory milestones; (vi) the timing of new IND application filings; (vii) the potential for milestone payments, royalties and clinical development cost sharing under the Servier License Agreement; and (viii) 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 and commercializing 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 Income (Loss)

(*in thousands, except share and per share amounts*)

	Three Months Ended	Nine Months Ended

	September 30, 2025	June 30, 2025	September 30, 2025	September 30, 2024
	(Unaudited)		(Unaudited)	
Collaboration revenue	$ 207,834	$ —	$ 207,834	$ —
Total revenue	207,834	—	207,834	—
Operating expenses:				
Research and development	$ 82,993	$ 74,226	$ 228,105	$ 154,490
General and administrative	16,389	14,580	44,472	28,347
Total operating expenses	99,382	88,806	272,577	182,837
Income (loss) from operations	108,452	(88,806)	(64,743)	(182,837)
Interest income and other income, net	10,792	11,315	34,318	38,672
Net income (loss)	119,244	(77,491)	(30,425)	(144,165)
Unrealized gains on marketable securities	531	(64)	1,240	3,274
Comprehensive income (loss)	$ 119,775	$ (77,555)	$ (29,185)	$ (140,891)
Net income (loss) per share attributable to common stockholders, basic	$ 1.35	$ (0.88)	$ (0.34)	$ (1.81)
Weighted-average number of shares outstanding, basic	88,526,781	88,472,197	88,452,395	79,776,728
Net income (loss) per share attributable to common stockholders, diluted	$ 1.33	$ (0.88)	$ (0.34)	$ (1.81)
Weighted-average number of shares outstanding, diluted	89,690,878	88,472,197	88,452,395	79,776,728

IDEAYA Biosciences, Inc.

Condensed Balance Sheet Data

(*in thousands*)

	September 30, 2025	December 31, 2024
	(Unaudited)	
Cash and cash equivalents and short-term and long-term marketable securities	$ 1,136,854	$ 1,082,151
Total assets	1,185,136	1,124,091
Total liabilities	93,102	64,944
Total liabilities and stockholders' equity	$ 1,185,136	$ 1,124,091

SOURCE IDEAYA Biosciences, Inc.

https://media.ideayabio.com/2025-11-04-IDEAYA-Biosciences-Reports-Third-Quarter-2025-Financial-Results-and-Provides-Business-Update