IDEAYA Biosciences Reports First Quarter 2026 Financial Results and Provides Business Update

- Phase 2/3 registrational trial (OptimUM-02) of darovasertib combination met its primary endpoint; complete data will be provided in a late-breaking oral presentation at ASCO
- IDEAYA to initiate RTOR submission process with first pre-submission in May; targeting completion of the NDA filing in H2 2026
- Clinical updates from Phase 2 OptimUM-01 trial in HLA*A2-positive mUM, Phase 2 OptimUM-09 in neoadjuvant primary UM and Phase 1/2 trials with IDE849 (DLL3 TOP1 ADC) and IDE034 (B7H3/PTK7 bispecific TOP1 ADC) planned for H2 2026
- Initiation of registrational trial for IDE849 monotherapy in DLL3-positive solid tumors planned by year-end 2026; Phase 1 combination cohort of IDE892 (PRMT5) + IDE397 (MAT2A) in MTAP-deleted cancers to begin in mid-2026
- ~$973 million of cash, cash equivalents, and marketable securities as of March 31, 2026; current cash runway guidance into 2030 remains unchanged

SOUTH SAN FRANCISCO, Calif., May 5, 2026 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a leading precision medicine oncology company, provided a business update and announced financial results for the first quarter ended March 31, 2026.

"This was a transformational quarter for IDEAYA, with positive topline results from the OptimUM-02 registrational trial in first line HLA*A2-negative metastatic uveal melanoma to enable the company's first NDA submission for potential U.S. accelerated approval. We look forward to a catalyst rich second half of 2026, including targeted clinical data updates for the darovasertib combination in HLA*A2-positive mUM, IDE849 in DLL3-positive solid tumors, and IDE034, our potential first-in-class B7H3/PTK7 bispecific TOP1 ADC, in multiple large solid tumor indications. Finally, clinical dose escalation is advancing rapidly for our potential first-in-class KAT6/7 dual inhibitor, IDE574, and our PRMT5 inhibitor, IDE892, with the goal of initiating clinical expansion and combination trials with IDE892 in MTAP-deleted PDAC and NSCLC in the second half of this year," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

Selected Pipeline Developments and Corporate Updates

Darovasertib in Uveal Melanoma

- On April 13th IDEAYA reported positive topline data from the Phase 2/3 OptimUM-02 trial of darovasertib in combination with crizotinib (darovasertib combination) in first line (1L) HLA*A2-negative metastatic uveal melanoma (mUM).
    - The trial met its primary endpoint, with the combination reducing the risk of disease progression by 58% (Hazard Ratio of 0.42; 95% CI: 0.30, 0.59; p-value: <0.0001) and achieving a statistically significant improvement in median progression-free survival (PFS) of 6.9 months versus 3.1 months in the investigator choice of therapy (ICT) arm as assessed by blinded independent central review (BICR).
    - On secondary endpoints, an overall response rate (ORR) of 37.1%, including 5 complete responses, was observed in patients treated with the darovasertib combination versus 5.8% in the ICT arm (p-value: <0.0001) with a median duration of response (DOR) of 6.8 months.
    - Overall survival (OS) data were not yet mature, however the darovasertib combination did show an early trend in OS improvement versus the ICT arm.
    - The combination was generally well-tolerated with a manageable safety profile consistent with

previously reported results and known side-effects of each drug.

- IDEAYA will provide complete data from the primary analysis of OptimUM-02 in a late-breaking oral presentation at the 2026 American Society of Clinical Oncology (ASCO) meeting in Chicago, Illinois, and plans to submit a manuscript for publication in the second half of 2026. A new drug application (NDA) submission to the U.S. Food and Drug Association (FDA) is planned in the second half of 2026 to support a potential U.S. accelerated approval.
    - The FDA has agreed to review IDEAYA's NDA under the Oncology Center of Excellence (OCE) Real-Time Oncology Review (RTOR) program, which allows an applicant to pre-submit components of its NDA for review before the complete filing is submitted to provide a more efficient review process and ensure safe and effective treatments are available to patients as early as possible.
- IDEAYA has completed enrollment of approximately 100 HLA*A2-positive mUM patients in the single-arm Phase 2 OptimUM-01 trial of darovasertib in combination with crizotinib. The company plans to present data at a major medical conference from over 85 efficacy-evaluable HLA*A2-positive mUM patients in the second half of 2026.
    - Data will include updated ORR, PFS, and OS results, which will be used to support a potential regulatory submission to the FDA to expand the labeled use of darovasertib and/or guideline inclusion to enable the use of the darovasertib combination in HLA*A2-positive mUM patients.
- In collaboration with Servier, IDEAYA successfully completed a Type C meeting with the U.S. FDA to align on the Phase 3 registrational design of the OptimUM-11 trial evaluating darovasertib in combination with crizotinib in the adjuvant setting of primary uveal melanoma. The trial will enroll approximately 450 primary uveal melanoma patients with increased risk of metastasis, irrespective of HLA status, randomized 1:1 to treatment with darovasertib combined with crizotinib for 12-months or observation. The primary endpoint is superiority by relapse-free survival (RFS). OptimUM-11 is a global trial being conducted as part of IDEAYA's partnership with Servier and is expected to initiate in the first half of 2026.
- IDEAYA is continuing site activation and patient enrollment in the Phase 3 OptimUM-10 trial of neoadjuvant darovasertib in primary uveal melanoma. Full enrollment in the trial is estimated to be complete by the end of 2027, revised from prior guidance of first half of 2027.
    - IDEAYA is targeting to provide a clinical data update from the ongoing Phase 2 OptimUM-09 trial at a medical conference in the second half of 2026.

ADC / DDR combinations

- IDE849 (DLL3 TOP1 ADC): targeting to provide a clinical data update from the ongoing IDEAYA-sponsored global Phase 1/2 trial of IDE849 in small-cell lung cancer (SCLC) and neuroendocrine carcinomas (NEC) by the end of 2026. The company is planning to initiate a monotherapy registrational trial by the end of 2026.
    - In April, IDEAYA entered into a clinical collaboration agreement with AstraZeneca plc to evaluate the efficacy and safety of IDE849 in combination with Imfinzi® (durvalumab), a programmed death-ligand 1 (PD-L1) inhibitor, in extensive-stage SCLC. IDEAYA will sponsor the clinical combination trial; AstraZeneca will supply Imfinzi® at no cost.
    - Achieved first-patient-in (FPI) in Phase 1 combination trial of IDE849 and IDE161, IDEAYA's proprietary inhibitor of poly(ADP-ribose) glycohydrolase (PARG). Data from this trial are intended to help evaluate the potential synergy between TOP1 and PARG inhibition to drive deeper, more durable anti-tumor responses in patients
- IDEAYA's China-region partner, Jinagsu Hengrui Pharmaceuticals Co. Ltd., is targeting to initiate Phase 3

registrational trials in China in 2027 for IDE849 in SCLC and provide a clinical update from their Phase 1 trial in SCLC and NEC at a medical conference in the second half of 2026.
- IDE034 (B7H3/PTK7 bispecific TOP1 ADC): achieved FPI in Phase 1 dose escalation trial to evaluate IDE034 in solid tumors, and is targeting to provide a clinical data update by the end of 2026. IDE034 is a potentially first-in-class B7H3/PTK7 bispecific TOP1 ADC designed to be internalized only when its target antigens are co-expressed on the same tumor cell, which may enhance its selectivity and tolerability profile relative to monovalent antibody formats.

    - Patient dosing triggered a $5 million milestone payment from IDEAYA to Biocytogen, pursuant to the Option and License Agreement between the companies.

MTAP pathway

- IDE892 (PRMT5): achieved FPI in Phase 1 dose escalation trial of IDE892 in MTAP-deleted solid tumors, including non-small cell lung cancer (NSCLC) and pancreatic ductal adenocarcinoma (PDAC). IDEAYA is planning to initiate a Phase 1 combination cohort with IDE397, its proprietary MAT2A inhibitor, in MTAP-deleted cancers in mid-2026 and expansion in the second half of 2026. Dual inhibition of IDE892 and IDE397 has demonstrated durable and well-tolerated tumor regressions in preclinical MTAP-deleted tumor models, including in NSCLC.
- In March, IDEAYA announced it will deprioritize clinical activity with Gilead evaluating the combination of IDE397 and Trodelvy and conclude enrollment in the Phase 1/2 trial in MTAP-deleted urothelial and lung cancers.

Other programs

- IDE574 (KAT6/7): achieved FPI in Phase 1 dose escalation trial of IDE574 in solid tumors including breast, prostate, colorectal and lung cancer. IDE574 is a selective, equipotent dual inhibitor of both KAT6 and KAT7 which spares other structurally similar paralogs, including KAT5 and KAT8, which are required for normal cell function. KAT6 and KAT7 are epigenetic modulators of cell identity and lineage commitment programs that are corrupted by oncogenic transformation.
- Following termination of the Collaboration, Option and License Agreement with GlaxoSmithKline in 2025, IDEAYA plans to discontinue development of IDE275, a small molecule inhibitor of Werner helicase (WRN), and IDE705, a small molecule inhibitor of Pol-Theta helicase (POLQ). The company is currently evaluating strategic options for these assets.

Corporate

- In February, IDEAYA announced the appointment of Dr. Theodora (Theo) Ross into the newly created role of Chief Development Officer. Dr. Ross will be responsible for leading early clinical development for IDEAYA's emerging oncology pipeline and play a crucial role in guiding the company's long-term R&D strategy. She joins IDEAYA from AbbVie, where she served as Vice President, Head of Early Oncology R&D and Site Head for the Bay Area.
- As of March 31, 2026, IDEAYA had $972.9 million of cash, cash equivalents and marketable securities; current cash runway guidance into 2030 remains unchanged.

Financial Results for the Quarter Ended March 31, 2026

As of March 31, 2026, IDEAYA had cash, cash equivalents and marketable securities of approximately $972.9 million, compared to $1.05 billion as of December 31, 2025. The decrease was primarily driven by net cash used in operations.

Collaboration revenue for the three months ended March 31, 2026, totaled $6.6 million compared to $10.9 million for the three months ended December 31, 2025. Collaboration revenue was recognized for the performance obligations satisfied through March 31, 2026 related to the research and development services that are recognized over time under the Servier exclusive license agreement for darovasertib. As of March 31, 2026, the remaining balance for the research and development services performance obligations is $155.3 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 March 31, 2026 totaled $95.7 million compared to $86.6 million for the three months ended December 31, 2025. The increase was primarily driven by higher clinical trial and personnel-related expenses to support our programs.

General and administrative (G&A) expenses for the three months ended March 31, 2026 totaled $19.4 million compared to $18.8 million for the three months ended December 31, 2025. The increase was primarily due to higher personnel-related expenses to support company growth and darovasertib commercial preparation activities.

The net loss for the three months ended March 31, 2026, was $98.5 million compared to the net loss of $83.3 million for the three months ended December 31, 2025. Total stock compensation expense for the three months ended March 31, 2026, was $14.5 million compared to $11.8 million for the three months ended December 31, 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 within the meaning of the Private Securities Litigation Reform Act of 1995 and other applicable securities laws. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding IDEAYA Biosciences, Inc.'s ("IDEAYA") expectations with respect to the timing, progress, and results of its clinical trials and preclinical programs; the potential safety, efficacy, and therapeutic benefits of its product candidates; the planned presentation and publication of clinical data; the timing and likelihood of regulatory submissions, including the planned new drug application (NDA) for darovasertib and participation in the FDA's Real-Time Oncology Review (RTOR) program; the potential for accelerated approval and label expansion; the initiation, design, and enrollment of current and future clinical trials; the development and advancement of IDEAYA's pipeline programs, including IDE849, IDE034, IDE892, IDE397, and IDE574; the expected timing of clinical updates and milestones; the potential benefits of collaborations; and IDEAYA's financial position, including its expected cash runway.

These forward-looking statements are based on management's current expectations and assumptions and are subject to a number of risks, uncertainties, and other factors that could cause actual results to differ materially

from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to: risks related to the timing, progress, and results of clinical trials and preclinical studies; the ability of IDEAYA to obtain and maintain regulatory approvals; uncertainties regarding the regulatory review process, including participation in the RTOR program; the potential for clinical data to differ from preliminary or interim results; the ability to successfully develop, manufacture, and commercialize product candidates; competition from other biotechnology and pharmaceutical companies; the impact of global economic conditions; 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 and other risks described in IDEAYA's filings with the U.S. Securities and Exchange Commission (SEC), including its most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K.

Forward-looking statements speak only as of the date of this press release, and IDEAYA undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

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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	
	March 31, 2026	**December 31, 2025**
	(Unaudited)	
Collaboration revenue	$ 6,560	$ 10,876
Operating expenses:		
Research and development	95,726	86,599
General and administrative	19,378	18,847
Total operating expenses	115,104	105,446
Loss from operations	(108,544)	(94,570)

Interest income and other income, net		10,005		11,297
Net loss		(98,539)		(83,273)
Unrealized (losses) gains on marketable securities		(2,761)		215
Comprehensive loss	$	(101,300)	$	(83,058)
Net loss per share attributable to common stockholders, basic and diluted	$	(1.11)	$	(0.94)
Weighted-average number of shares outstanding, basic and diluted		88,699,754		88,582,694

IDEAYA Biosciences, Inc.

Condensed Balance Sheet Data

(*in thousands*)

	March 31, 2026	**December 31, 2025**
	(Unaudited)	
Cash and cash equivalents and short-term and long-term marketable securities	$ 972,914	$ 1,049,685
Total assets	1,030,348	1,109,324
Total liabilities	93,081	86,390
Total liabilities and stockholders' equity	$ 1,030,348	$ 1,109,324

SOURCE IDEAYA Biosciences, Inc.

https://media.ideayabio.com/2026-05-05-IDEAYA-Biosciences-Reports-First-Quarter-2026-Financial-Results-and-Provides-Business-Update