IDEAYA Biosciences, Inc. Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

- Over 230 patients enrolled in potential registration-enabling trial in 1L HLA-A2-negative MUM, and median PFS readout targeted by year-end 2025
- 95 patients enrolled in neoadjuvant UM trial and targeting clinical data and regulatory update(s) in H1 2025, including vision data in plaque brachytherapy patients
- Targeting median OS readout in ~40 1L MUM patients in 2025
- Targeting expansion of study in Q1 2025 of IDE397 in combination with Trodelvy® (sacituzumab govitecan-hziy) in MTAP-deletion UC and clinical data update in 2025; expanded clinical study collaboration into NSCLC
- Targeting to enable wholly owned IDE397 and IDE892 (IDEAYA PRMT5) clinical combination in H2 2025; IDEAYA and Amgen mutually agree to wind down the IDE397 and AMG 193 clinical combination study
- Clinical expansion doses selected for DLL3 TOP1i ADC IDE849 by collaboration partner Hengrui, and targeting clinical data update and combo initiation with IDE161 in 2025
- Ph1 initiated for Werner Helicase IDE275 (GSK959) and received $7 million milestone from GSK, and targeting medical conference update in H1 2025
- Targeting IDE161 expansion with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, and combo(s) with TOP1i ADCs in solid tumors in 2025
- Targeting 2025 INDs: IDE892 (PRMT5); IDE034 (B7H3/PTK7 ADC); IDE251 (KAT6/7)
- ~$1.1 billion of cash, cash equivalents and marketable securities as of December 31, 2024, anticipated to fund operations into at least 2028

SOUTH SAN FRANCISCO, Calif., Feb. 13, 2025 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, announced financial results for the quarter and full year ended December 31, 2024, and provided a business update.

"We are excited to be targeting multiple clinical data readouts and program updates across our clinical pipeline in 2025, including the darovasertib neoadjuvant UM data update in the first half and median PFS readout in HLA-A2 negative 1L MUM by year-end, update on the Werner Helicase inhibitor program IDE275 at a major medical conference in the first half, clinical combination results from the IDE397 and Trodelvy combination in MTAP-deletion UC where the Gilead collaboration has expanded to evaluate both UC and NSCLC, among others. Next, we are excited to target a clinical data update for potential first-in-class DLL3 TOP1 ADC IDE849 in SCLC in 2025, including potentially at a medical conference, and we believe the clinical profile observed supports a potential monotherapy regulatory path in SCLC," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

"We had multiple positive clinical updates across our pipeline throughout the past year that were presented at major medical conferences, including compelling results such as tumor shrinkage and eye preservation for neoadjuvant darovasertib which was presented as an oral presentation at ASCO 2024, and evidence for monotherapy activity with IDE397 which delivered a high disease control rate and multiple confirmed RECIST 1.1 responses in MTAP-deletion lung and urothelial cancer, which was presented as a late breaker oral presentation at ENA 2024. Next, we believe we have generated important proof-of-concept preclinically and preliminary clinical data for the MAT2A and PRMT5 combination in the MTAP-deletion setting and are excited to advance IDEAYA's wholly-owned IDE397 and IDE892 combination that we are targeting to have in the clinic in the second half of 2025," commented Darrin Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences. "Additionally,

in the last several quarters we made significant progress in enhancing our potential first-in-class clinical pipeline with the in-licensing of the Phase 1 DLL3 TOP1i ADC IDE849 and FDA clearance of the Phase 1 trial for the Werner Helicase inhibitor IDE275. We are also advancing three programs into IND-enabling studies: our PRMT5 inhibitor IDE892, the B7H3/PTK7 ADC IDE034 and a KAT6/7 inhibitor IDE251," said Michael White, Ph.D., Chief Scientific Officer, IDEAYA Biosciences.

Recent Key Developments and Upcoming Milestones

Research and Clinical Development

- Darovasertib, a potential first-in-class Phase 2/3 PKC inhibitor for the treatment of metastatic uveal melanoma (MUM) and neoadjuvant uveal melanoma (UM).
    - MUM
        - Independent Data Monitoring Committee (IDMC) recommended move-forward dose and the completion of the Part 2a dose optimization for the potential registration-enabling trial of darovasertib and crizotinib in first line (1L) HLA-A2-negative MUM.
        - Targeting median progression free survival (PFS) readout for Phase 2/3 registration-enabling trial of the darovasertib and crizotinib combination in 1L HLA-A2-negative MUM by year-end 2025. Rapid enrollment in the trial continues with over 230 patients as of February 7, 2025.
        - Phase 2 median overall survival (OS) readout from study IDE196-001 in ~40 1L MUM patients targeted in 2025.
    - Neoadjuvant UM
        - A clinical update in over 75 patients in the Company-sponsored Phase 2 trial and regulatory update(s) is targeted for the first half of 2025, including vision data in plaque brachytherapy patients. 95 patients enrolled as of December 31, 2024 in the Company-sponsored Phase 2 trial.
        - Initiation of the Phase 3 registration-enabling trial for darovasertib in neoadjuvant UM is targeted for the first half of 2025.
- IDE397, a potential first-in-class Phase 2 MAT2A Inhibitor for the treatment of MTAP-Deletion Solid Tumors.
    - Encouraging Phase 1 expansion results of IDE397 in MTAP-deletion urothelial cancer (UC) and non-small cell lung cancer (NSCLC) patients were presented as a late-breaking oral presentation at the 36th EORTC-NCI-AACR Symposium (ENA 2024). Additional preclinical data on the anti-tumor activity of IDE397 and in combination with the PRMT5 inhibitors AMG 193 and BMS-986504 in MTAP-deleted tumors were presented as a poster.
    - Targeting Phase 1/2 expansion in the first quarter of 2025 and clinical data update for IDE397 in combination with Trodelvy® in MTAP-deletion UC in 2025. Entered into a Clinical Study Collaboration and Supply Agreement with Gilead to evaluate IDE397 in combination with Trodelvy® in MTAP-deletion NSCLC.
    - IDEAYA plans to enable wholly-owned IDE397 combination with IDE892 in patients with MTAP-deletion non-small cell lung cancer (NSCLC) in the second half of 2025. IDEAYA and Amgen mutually agreed to wind down the IDE397 and AMG 193 clinical combination study in February 2025, and will not pursue dose expansion.
- IDE849 (SHR-4849), a potential first-in-class Phase 1 DLL3 TOP1i antibody drug conjugate (ADC) targeting small cell lung cancer (SCLC) and neuroendocrine tumors (NETs).
    - IDEAYA entered into an exclusive global license agreement for IDE849 outside of Greater China with

Jiangsu Hengrui Pharmaceuticals Co., Ltd. (Hengrui Pharma) in December 2024.
  - IDE849 is currently being evaluated by Hengrui Pharma in an ongoing Phase 1 trial in China in SCLC patients. In preliminary results from the trial with a data cut-off date of December 10, 2024, 8 out of 11 evaluable patients achieved partial response by RECIST 1.1, resulting in an overall response rate of ~73% (including both confirmed and unconfirmed responses, all unconfirmed responses were pending further evaluation). As of the data cut-off date, treatment related adverse events (TRAEs) were predominantly Grade 1 or 2. The most common TRAEs observed were white blood cell count decreased, anemia, neutrophil count decreased, nausea and platelet count decreased. In January 2025, Hengrui Pharma selected expansion doses for the Phase 1 trial.
  - IDEAYA plans to submit a U.S. IND for the evaluation of IDE849 as a monotherapy in SCLC in the first half of 2025.
  - Targeting to initiate the evaluation in combination with IDE161 and in NETs in the second half of 2025.
  - Clinical data update targeted in 2025.

- IDE275 (GSK959), a potential first-in-class and best-in-class Phase 1 Werner Helicase inhibitor for the treatment of high microsatellite instability (MSI-High) tumors.
  - Received FDA IND clearance for a Phase 1 trial in MSI-High tumors and earned a $7.0 million milestone payment from GSK.
  - Data highlighting IDE275's differentiated potential best-in-class profile will be presented with GSK at a medical conference in the first half of 2025.

- IDE161, a potential first-in-class Phase 1 PARG inhibitor for the treatment of solid tumors.
  - Selected initial Phase 1/2 expansion dose for IDE161 monotherapy in endometrial cancer, based on AE profile and preliminary clinical efficacy observed. Phase 1 monotherapy dose optimization is ongoing to confirm a move-forward Phase 2 expansion dose.
  - First patient dosed in the Phase 1 trial evaluating IDE161 in combination with KEYTRUDA in patients with MSI-High and microsatellite stable (MSS) endometrial cancer. Targeting Phase 1 expansion in 2025.
  - Highlighted preclinical data of IDE161 and antibody drug conjugate (ADC) combination rationale at a poster presentation at ENA 2024.
  - Targeting clinical combination(s) of IDE161 with TOP1i ADCs in solid tumors in 2025.

- IDE705 (GSK101), a potential first-in-class Phase 1 Pol Theta Helicase Inhibitor in combination with PARP inhibitor for the treatment of HRD solid tumors.
  - Targeting Phase 2 expansion in HRD solid tumors, which would trigger a potential $10 million milestone payment from GSK.

- Announced three development candidates for the treatment of solid tumors:
  - IDE892, a potential best-in-class MTA-cooperative PRMT5 inhibitor to enable wholly-owned combination with IDE397. IND filing targeted for mid-year 2025.
  - IDE034, a potential first-in-class B7H3/PTK7 TOP1i bispecific ADC with combination potential with IDE161. IND filing targeted for the second half of 2025.
  - IDE251, a potential first-in-class KAT6/7 dual inhibitor development candidate with combination opportunities with multiple programs in the Company's pipeline. IND filing targeted for the second half of 2025.

Corporate Development

- Appointed Joshua Bleharski, Ph.D., as Chief Financial Officer. Dr. Bleharski to join IDEAYA from J.P. Morgan, serving most recently as Managing Director and Global Co-Head of Biopharma in the Healthcare Investment Banking group. Josh spent nearly 17 years at J.P. Morgan advising clients in the biopharma sector on capital markets transactions, corporate strategy and other investment banking services representing more than $65 billion of value for biotechnology companies worldwide.
- Appointed Stu Dorman as Chief Commercial Officer. Mr. Dorman brings over 20 years of global commercialization experience in oncology with prominent biopharmaceutical companies such as Gilead Sciences and Bristol Myers Squibb, where he led multiple commercial launches for products including Trodelvy and Opdivo.

Financial Results

As of December 31, 2024, IDEAYA had cash, cash equivalents and marketable securities of approximately $1.1 billion, compared to $632.6 million as of December 31, 2023. The increase was primarily driven from $379.9 million in net proceeds from the sale of common stock shares through at-the-market financings during the year, $283.8 million from an underwritten public offering of common stock and pre-funded warrants to purchase common stock completed in July 2024, partially offset by net cash used in operations. IDEAYA believes that these funds will be sufficient to fund its planned operations into at least 2028.

Subsequent to the reporting period for the year ended December 31, 2024, the Company generated net proceeds of approximately $25.1 million from the sale of shares of its common stock through at-the-market (ATM) offerings in January 2025.

Collaboration revenue for the three months ended December 31, 2024 totaled $7.0 million compared to $3.9 million for the three months ended December 31, 2023. Collaboration revenue was recognized for a $7.0 million milestone payment from GSK that was earned for the IND clearance of IDE275 (GSK959) in October 2024.

Research and development (R&D) expenses for the three months ended December 31, 2024, totaled $140.2 million compared to $38.8 million for the three months ended December 31, 2023. The increase was primarily due to a $75.0 million upfront payment under the license agreement for IDE849 with Hengrui Pharma, higher clinical trial expenses to support the portfolio growth and personnel-related expenses.

General and administrative (G&A) expenses for the three months ended December 31, 2024 totaled $11.0 million compared to $7.1 million for the three months ended December 31, 2023. The increase was primarily due to higher personnel-related expenses, higher consulting and legal fees.

The net loss for the three months ended December 31, 2024, was $130.3 million compared to the net loss of $34.0 million for the three months ended December 31, 2023. Total stock compensation expense for the three months ended December 31, 2024, was $9.5 million compared to $4.8 million for the same period in 2023.

The net loss for the year ended December 31, 2024 was $274.5 million compared to $113.0 million for the same period in 2023. Total stock compensation expense for the year ended December 31, 2024, was $34.7 million compared to $18.5 million for the same period in 2023.

About IDEAYA Biosciences

IDEAYA is a precision medicine oncology company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. IDEAYA's approach integrates capabilities in identifying and validating translational biomarkers with drug discovery to select patient populations most likely to benefit from its targeted therapies. IDEAYA is applying its research and drug discovery capabilities to synthetic lethality – which represents an emerging class of precision medicine targets.

IDEAYA's updated 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 and clinical trial data readouts; (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 and potential of registration-enabling trial and readouts for darovasertib in 1L HLA-A2 negative MUM; (vi) the timing of the initiation of Phase 3 trial for darovasertib; (vii) the timing and potential for accelerated FDA approval of darovasertib in MUM; (viii) the timing of expansion in IDE397 and Trodelvy combination trial in MTAP-deletion UC and indication in NSCLC; (ix) the timing of combination trial of IDE397 and IDE892 in patients with MTAP-deletion NSCLC; (x) the potential of a Phase 2 expansion monotherapy dose for IDE161; (xi) the timing of initiating IDE161 and DLL3 TOP1i ADC combination trial; (xii) the timing of IDE161 expansion with KEYTRUDA and combinations with TOP1i ADCs in solid tumors; (xiii) timing of INDs for IDE892, IDE034, IDE251, and IDE849; (xiv) timing of data presentation for IDE275 at medical conference; and (xv) 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 20, 2024 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	Year Ended
	December 31,	**December 31,**

	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Collaboration revenue	$ 7,000	$ 3,923	$ 7,000	$ 23,385
Operating expenses:				
Research and development	140,183	38,770	294,673	129,508
General and administrative	10,955	7,068	39,302	28,306
Total operating expenses	151,138	45,838	333,975	157,814
Loss from operations	(144,138)	(41,915)	(326,975)	(134,429)
Interest income and other income, net	13,826	7,960	52,498	21,468
Net loss	(130,312)	(33,955)	(274,477)	(112,961)
Unrealized gains (losses) on marketable securities	(3,024)	1,312	250	3,433
Comprehensive loss	$ (133,336)	$ (32,643)	$ (274,227)	$ (109,528)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.49)	$ (0.52)	$ (3.36)	$ (1.96)
Weighted-average number of shares outstanding, basic and diluted	87,340,758	65,246,361	81,678,069	57,519,929

IDEAYA Biosciences, Inc.
Condensed Balance Sheet Data
(*in thousands*)

	December 31, 2024	December 31, 2023
	(Unaudited)	
Cash and cash equivalents and short-term and long-term marketable securities	$ 1,082,151	$ 632,606
Total assets	1,124,091	649,316
Total liabilities	64,944	28,226
Total liabilities and stockholders' equity	1,124,091	649,316

SOURCE IDEAYA Biosciences, Inc.

https://media.ideayabio.com/2025-02-13-IDEAYA-Biosciences,-Inc-Reports-Fourth-Quarter-and-Full-Year-2024-Financial-Results-and-Provides-Business-Update