IDEAYA Biosciences, Inc. Reports First Quarter 2023 Financial Results and Provides Business Update

- Strong balance sheet of $351.2 million of cash, cash equivalents and marketable securities as of March 31, 2023 supplemented by $188.7 million estimated net proceeds from closing of underwritten public offering on April 27, 2023, anticipated to fund operations into 2027
- Initiating Phase 2/3 registrational trial in Q2 2023 of darovasertib and crizotinib combination in First-Line HLA-A2 negative MUM, with median PFS as primary endpoint for potential accelerated approval
- Reported compelling darovasertib program Phase 2 clinical efficacy, including in First-Line and Any-Line MUM, and additional clinical efficacy as neoadjuvant therapy in primary UM
- Targeting darovasertib clinical program updates in H2 2023
- IDE397 Phase 2 monotherapy expansion international site activation ongoing, including in Europe and Asia, to enhance patient enrollment in high priority MTAP-deletion tumors
- Compelling preclinical efficacy data (AACR 2023) supports anticipated clinical evaluation of IDE397 (MAT2A) and AMG 193 (PRMT5) combination targeting MTAP-deletion tumors
- Enrolled first cohort and accruing waitlist in Phase 1 trial evaluating IDE161 in patients having solid tumors with HRD, with planned strategic focus in ER+, Her2- breast cancer
- Anticipating IND submission for Pol Theta Helicase DC in Q2 2023 (potential $7 million milestone from GSK upon IND-effectiveness) and selection of Werner Helicase DC in 2023 (potential $3 million milestone from GSK in connection with IND-enabling studies)

SOUTH SAN FRANCISCO, Calif., May 9, 2023 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), a precision medicine oncology company committed to the discovery and development of targeted therapeutics, provided a business update and announced financial results for the first quarter ended March 31, 2023.

"This has been a transformational quarter for IDEAYA, with our lead clinical candidate, darovasertib, on-track to initiate a potential accelerated approval trial in first-line MUM this quarter, IDE397 in Phase 2 with ongoing international site activation to accelerate monotherapy expansion and compelling preclinical combination efficacy presented at AACR with Amgen's AMG 193 for treating MTAP-deletion solid tumors, and IDE161 first cohort enrolled in HRD solid tumors. Our preclinical pipeline and platform also continue to deliver potential first-in-class breakthrough therapies, including a Pol Theta Helicase IND targeted for this quarter and our Werner Helicase inhibitor development candidate nomination on track for this year," said Yujiro S. Hata, Chief Executive Officer, IDEAYA Biosciences."

"We observed compelling Phase 2 clinical efficacy of the darovasertib and crizotinib combination in First-Line, Any-Line and Hepatic-Only MUM, and encouraging clinical efficacy for darovasertib as a neoadjuvant therapy in primary uveal melanoma (UM), including one neoadjuvant UM patient who experienced an ~80% ocular tumor shrinkage after 4 months of treatment and was able to avoid enucleation, and an additional neoadjuvant UM patient on darovasertib that experienced a partial response after only one month of treatment. We are excited to launch the registrational trial in First-Line HLA-A2(-) MUM this quarter, with the opportunity to address a high unmet medical need. We look forward to sharing an additional clinical program update for darovasertib in 2023," said Dr. Darrin M. Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences.

IDEAYA is advancing darovasertib, its protein kinase C, or PKC, inhibitor, with a clinical strategy to broadly address uveal melanoma –in both primary and metastatic disease settings. The company reported updated clinical data from the ongoing Phase 2 expansion cohort evaluating darovasertib and crizotinib in MUM. These data demonstrated robust clinical efficacy in first-line MUM patients (e.g., 45% ORR, 90% DCR, 7 months median PFS) with a manageable safety profile and support the Company's plan to initiate a potential registration-enabling

Phase 2/3 clinical trial to evaluate the darovasertib and crizotinib combination in first-line HLA-A2(-) MUM in Q2 2023. As an independent clinical strategy, IDEAYA is also planning to enroll additional HLA-A2(+) patients in its ongoing Phase 2 clinical trial to address the HLA-A2(+) patient population in MUM.

IDEAYA reported clinical proof-of-concept (PoC) data for use of darovasertib as neoadjuvant therapy in primary, non-metastatic UM patients. These data (e.g., ocular tumor shrinkage in 6 of 6 patients) showed evidence of anti-tumor activity and support further clinical evaluation of darovasertib to determine its potential as a neoadjuvant and/or adjuvant therapy.

The company is planning to provide updates in the second half of 2023 on the darovasertib clinical program.

IDEAYA is collaborating with Amgen to evaluate IDE397, its methionine adenosyltransferase 2a, or MAT2A, inhibitor, in combination with AMG 193, the Amgen investigational MTA-cooperative PRMT5 inhibitor, in patients having tumors with methylthioadenosine phosphorylase, or MTAP, gene deletion. IDEAYA is separately evaluating IDE397 in Phase 2 monotherapy expansion cohorts with ongoing international clinical site activation, including in Europe and Asia to enhance patient enrollment in high priority MTAP-deletion tumors, and in Phase 1 monotherapy dose escalation cohorts in patients having tumors with MTAP deletion.

IDE161, the Company's poly (ADP-ribose) glycohydrolase, or PARG, inhibitor, is being evaluated in a Phase 1/2 clinical trial in patients having tumors with homologous recombination deficiency, or HRD. IDEAYA has enrolled its first cohort of patients into the dose escalation portion of the clinical trial and is accruing patients on a waitlist for subsequent cohorts. The company is planning for expansion cohorts in ER+, Her2- HRD breast cancer patients, HRD ovarian cancer patients and other HRD solid tumors.

The company's preclinical pipeline includes several potential first-in-class synthetic lethal therapeutics advancing toward the clinic. GSK is targeting an IND submission in the second quarter of 2023 for a GSK-sponsored Phase 1/2 clinical trial to evaluate the IDEAYA/GSK Pol Theta Helicase inhibitor development candidate (DC) in combination with niraparib for patients having tumors with HRD. The Werner Helicase program continues in collaboration with GSK toward a development candidate nomination in 2023.

Program Updates
Key highlights for IDEAYA's pipeline programs include:

Darovasertib – PKC Inhibitor in Tumors with GNAQ or GNA11 Mutations

Darovasertib is a potent, selective inhibitor of PKC which the company is developing for genetically defined cancers having GNAQ or GNA11 gene mutations. PKC is a protein kinase that functions downstream of the GTPases GNAQ and GNA11. IDEAYA is pursuing a clinical strategy for darovasertib to broadly address uveal melanoma, alternatively referred to as ocular melanoma, in both primary and metastatic disease.

IDEAYA owns or control all commercial rights in its darovasertib program, including in MUM and in primary UM, subject to certain economic obligations pursuant to its exclusive, worldwide license to darovasertib with Novartis.

Darovasertib / Crizotinib Combination Therapy in Metastatic Uveal Melanoma

IDEAYA reported data from its ongoing Phase 2 clinical trial, designated as IDE196-001, demonstrating compelling clinical efficacy of the darovasertib and crizotinib combination therapy in first-line and any-line MUM patients. The company is planning to initiate a potential registration-enabling Phase 2/3 clinical trial to evaluate the darovasertib and crizotinib combination in first-line HLA-A2(-) MUM. Highlights:

- Reported updated clinical data, including a safety and clinical efficacy profile, from the Phase 2 expansion cohort evaluating darovasertib and crizotinib in MUM. Reported data are based on 20 evaluable first-line

and 63 evaluable any-line patients enrolled as of September 22, 2022 in the darovasertib and crizotinib combination study at the expansion dose of 300 mg twice-a-day darovasertib and 200 mg twice-a-day crizotinib. Reported data are preliminary and based on investigator review from an unlocked database as of the data analyses cutoff date of March 8, 2023:

- Evaluable patients had a significant disease burden and were heavily pre-treated: baseline LDH was greater than the upper limit of normal in 60% of any-line and 50% of first-line patients; the largest metastatic lesion greater than 3.0 cm in 65% of any-line and 60% of first-line patients, and greater than 8.0 cm in 10% of any-line and 15% of first-line patients; patient metastases included both hepatic and extrahepatic loci in 64% of any-line and 50% of first-line patients; among any-line patients, 68% had received one or more prior lines of therapy and 43% had received two or more prior lines of therapy.
- In 20 evaluable first-line MUM patients at the expansion dose, the investigator-reviewed data by RECIST 1.1 included: (i) 45% overall response rate, or ORR, in first-line MUM: nine of 20 evaluable patients had a confirmed partial response, or PR; (ii) 90% disease control rate, or DCR, in first-line MUM: 18 of 20 evaluable patients showed disease control, including nine confirmed PRs, one unconfirmed PR and eight stable disease; and (iii) approximately seven months median progression free survival, or PFS in first-line MUM.
- In 63 evaluable any-line MUM patients at the expansion dose, the investigator-reviewed data by RECIST 1.1 included: (i) 30% ORR in any-line MUM: 19 of 63 evaluable patients had a confirmed PR; (ii) 87% DCR in any-line MUM: 55 of 63 evaluable patients showed disease control, including 19 confirmed PRs, four unconfirmed PRs and 2 stable disease; and (iii) approximately seven months median PFS in any-line MUM. Notably, the observed median PFS was enhanced from the median PFS of approximately five months as previously reported in September 2022 based on 35 evaluable any-line MUM patients.
- In a subset of 20 evaluable hepatic-only MUM patients, including first-line and pre-treated patients with only hepatic metastases, for whom the investigator-reviewed data by RECIST 1.1 included: (i) 35% ORR in hepatic-only MUM: seven of 20 evaluable patients had a confirmed PR; (ii) 100% DCR in hepatic-only MUM: 20 of 20 evaluable patients showed disease control, including seven confirmed PRs, one unconfirmed PR and 12 stable disease; and (iii) ~11 months median PFS in hepatic-only MUM. The reported Phase 2 data demonstrate clinical efficacy in both hepatic and well as extra-hepatic metastases.
- Observed clinical efficacy irrespective of HLA-A2 status, including in HLA-A2(-) and HLA-A2(+) serotypes.

- The darovasertib and crizotinib combination therapy continues to demonstrate a manageable adverse event profile in MUM patients (n=68) at the combination expansion doses, with a low rate of drug-related serious adverse events (SAEs), and a low rate of patients who discontinued treatment with either darovasertib or crizotinib due to a drug-related adverse event.

*Darovasertib—Potential Registration-Enabling Clinical Trial in First-Line HLA-A2*02:01 MUM*

IDEAYA is planning to initiate a potential registration-enabling Phase 2/3 clinical trial to evaluate darovasertib and crizotinib as a combination therapy in MUM. The protocol of the Phase 2/3 clinical trial design incorporates guidance and feedback following a Type C meeting with the FDA in March 2023. Highlights:

- Design: Integrated Phase 2/3 open-label study-in-study in first-line, or 1L, MUM patients with an HLA-A(-)serotype; median PFS as Phase 2 primary endpoint for potential accelerated approval; patients enrolled in Phase 2 will continue on treatment within the same study and will be considered, together with additional enrolled patients, to support overall survival, or OS as Phase 3 primary endpoint for potential approval.
- Phase 2: ~230 patients total, of which ~200 patients will be randomized on a 2:1 basis for treatment with the

darovasertib and crizotinib combination in the treatment arm or investigators choice in the control arm, selected from a combination of ipilimumab (ipi) and nivolumab (nivo), PD1-targeted monotherapy or dacarbazine, and of which ~30 will support a nested study to confirm the move forward combination dose for the integrated Phase 2/3 clinical trial; potential accelerated approval based on Phase 2 median PFS by blinded independent central review, or BICR, as a primary endpoint.
- Phase 3: ~120 additional patients with 2:1 randomization on the same basis as Phase 2, supplementing the ~200 patients enrolled in the Phase 2 and continuing on treatment at the selected treatment dose, to support data analysis for Phase 3 efficacy; potential approval based on Phase 3 median OS by BICR as a primary endpoint.

Darovasertib as Neoadjuvant / Adjuvant Therapy in Primary Uveal Melanoma

IDEAYA is clinically evaluating the potential for darovasertib as neoadjuvant and/or adjuvant therapy, or (neo)adjuvant therapy, in primary, non-metastatic UM patients.

Preliminary clinical data in the neoadjuvant setting show evidence of anti-tumor activity and support further clinical evaluation of darovasertib to determine its potential as a neoadjuvant therapy or an adjuvant therapy. Clinical objectives as neoadjuvant therapy are to save the eye by avoiding enucleation and/or to reduce the tumor thickness in the eye, enabling treatment with less radiation to preserve vision. As an adjuvant therapy, a clinical goal is to potentially extend relapse free survival. Highlights:

- Reported additional clinical data demonstrating clinical activity for darovasertib as neoadjuvant therapy in primary UM, including tumor shrinkage in ocular tumor lesions. Data was reported from an ongoing IST evaluating darovasertib in (neo)adjuvant primary UM, from a compassionate use protocol in neoadjuvant UM and from patients having an ocular tumor lesion during their course of treatment in the Phase 1 and Phase 1/2 clinical trial evaluating darovasertib as monotherapy or in combination with crizotinib in MUM.
- Ocular tumor shrinkage was measured by various methods, including MRI, ultrasound, CT-scan or PET scan, with best tumor response measurement based on maximal percent reduction in measured apical height or Longest Basal Diameter. The reported investigator-reviewed data included:
    - Observed tumor shrinkage of primary ocular lesions in nine of nine (100%) UM or MUM patients treated as monotherapy or in combination with crizotinib, including in six of six primary UM patients treated with darovasertib (n=5) or in combination with crizotinib (n=1) as neoadjuvant therapy.
    - One neoadjuvant UM patient observed 31% ocular tumor shrinkage, reflecting a partial response at one month of treatment with darovasertib.
    - Another neoadjuvant UM patient observed ~80% ocular tumor shrinkage after four months of treatment with the darovasertib and crizotinib combination under a compassionate use protocol.
- In the compassionate use case, a primary UM patient who was already blind in one eye from vascular disease developed a large uveal melanoma lesion in his other eye with an associated cataract. The patient sought neoadjuvant treatment under a compassionate use protocol with a goal to avoid enucleation and potentially preserve vision in the affected eye. The patient, who remains on therapy as of April 20, 2023, was treated with the darovasertib and crizotinib combination. The reported investigator-reviewed data included:
    - The preliminary clinical data showed prompt responsiveness to treatment, including an observed progressive tumor shrinkage over each month of treatment—namely, ~30% after one month, ~50% after two months and ~70% after three months, and ~80% ocular tumor shrinkage after four months of treatment, in each case determined by measurement of apical height.
    - Ocular lesion size after one month of treatment was sufficiently reduced to approach the threshold for radiation therapy (e.g. plaque brachytherapy).
    - Avoided enucleation of the patient's affected eye having the uveal melanoma, which reflects an initial

case, and the company believes is a first-reported case of systemic neoadjuvant therapy resulting in eye preservation by avoiding enucleation.
    - Restored normal vision of the patients affected eye following the course of neoadjuvant treatment and treatment of the associated cataract, with a reported post-treatment vision score of 6/5 (measurement in meters: 6/6 m = 20/20 ft), reflecting a >20 fold improvement in vision, resulting in eye preservation by avoiding enucleation.

- IDEAYA initiated a company-sponsored Phase 2 clinical trial designated as IDE196-009 to evaluate darovasertib as neoadjuvant treatment of UM prior to primary interventional treatment of enucleation or radiation therapy, and also as adjuvant therapy following the primary treatment. The clinical protocol includes neoadjuvant treatment with darovasertib to maximum benefit up to six months, primary treatment, then up to six months of follow-up adjuvant therapy.

    - Neoadjuvant – Enucleation Cohort: UM patients with large tumors will be treated with darovasertib until maximum benefit or six months, at which time they will undergo a primary interventional treatment. The neoadjuvant endpoint for this large-sized tumor cohort is eye preservation. For example, a patient who would otherwise have undergone enucleation would instead be eligible for radiation treatment.
    - Neoadjuvant – Radiation (e.g., Brachytherapy) Cohort: UM patients with small or medium tumors will be treated with darovasertib until maximum benefit or six months, at which time they will undergo radiation therapy. The neoadjuvant endpoints for this small or medium-sized tumor cohort include (i) reducing the radiation dose that the patient receives, relative to the radiation dose they would have otherwise received without the neoadjuvant treatment and (ii) functional vison preservation.
    - Adjuvant – In the adjuvant setting, each of the two neoadjuvant cohorts will be treated with darovasertib for up to six months as follow-up adjuvant therapy after the primary interventional treatment. The adjuvant endpoints for this portion of the clinical trial include relapse free survival and useful vision.

- IDEAYA is additionally supporting evaluation of darovasertib as (neo)adjuvant therapy in primary UM in an ongoing IST captioned as "Neoadjuvant / Adjuvant trial of Darovasertib in Ocular Melanoma" (NADOM) and led by St. Vincent's Hospital in Sydney with the participation of Alfred Health and the Royal Victorian Eye and Ear Hospital in Melbourne.

*Darovasertib—Strategy for HLA-A2*02:01 Positive MUM*

Based on preliminary analyses of darovasertib clinical data from the monotherapy and combination arms of the clinical trial, and based on the darovasertib mechanism of action, darovasertib clinical activity is independent of Human Leukocyte Antigen, or HLA, serotype in UM, MUM and other GNAQ/11-mutation cancers.

Accordingly, IDEAYA is planning its clinical strategy to separately address MUM patients with an HLA-A*02:01 positive serotype. The company is planning to enroll additional HLA-A2(+) patients into its ongoing Phase 2 clinical trial evaluating the darovasertib and crizotinib combination treatment. Clinical efficacy data from the subset of HLA-A2(+) patients in this Phase 2 clinical trial could support publication and potential inclusion in NCCN Clinical Practice Guidelines in Oncology.

Darovasertib Orphan Drug Designation in UM and Fast Track Designation in MUM

In April 2022, the FDA designated darovasertib as an Orphan Drug in UM, including primary and metastatic disease under 21 C.F.R Part 316. Under an Orphan Drug designation, darovasertib may be entitled to certain tax credits for qualifying clinical trial expenses, exemption from certain user fees and, subject to FDA approval of a new drug application, or NDA, for darovasertib in UM, seven years of statutory marketing exclusivity. As an FDA-designated Orphan Drug, darovasertib may also be excluded from certain mandatory price negotiation provisions of the 2022 Inflation Reduction Act.

In November 2022, the FDA granted Fast Track designation to IDEAYA's development program investigating darovasertib in combination with crizotinib in adult patients being treated for MUM. The Fast Track designation makes IDEAYA's darovasertib and crizotinib development program eligible for various expedited regulatory review processes, including generally more frequent FDA interactions, such as meetings and written communications, potential eligibility for rolling review of a future NDA and potential accelerated approval and priority review of an NDA.

IDE397—MAT2A Inhibitor in Tumors with MTAP Deletion

IDEAYA is clinically evaluating IDE397, a potent and selective small molecule inhibitor targeting methionine adenosyltransferase 2a (MAT2A), in patients having solid tumors with methylthioadenosine phosphorylase (MTAP) deletion, a patient population estimated to represent approximately 15% of solid tumors. IDEAYA is continuing clinical development of IDE397 in its Phase 1/2 clinical trial, IDE397-001 (NCT04794699).

The IDE397 clinical development strategy is focused as monotherapy in select indications and on the IDE397 combination with AMG193, the Amgen investigational MTA-cooperative PRMT5 inhibitor.

IDEAYA owns all right, title and interest in and to IDE397 and the MAT2A program, including all worldwide commercial rights thereto. Highlights:

- Initiated and enrolling patients into monotherapy expansion cohorts, with a focus on squamous cell NSCLC, esophagogastric cancer, and bladder cancer, consistent with preclinical efficacy and translational data; continuing to enroll patients in parallel into the monotherapy dose escalation portion of the clinical trial.
- International site activation ongoing in support of monotherapy expansion, including in Europe and Asia, to enhance patient enrollment in high priority MTAP-deletion tumors
- Data from preclinical efficacy studies completed in collaboration with Amgen support clinical evaluation of IDE397 in combination with AMG 193, the Amgen investigational MTA-cooperative PRMT5 inhibitor, in patients having solid tumors with MTAP deletion. Clinical investigation of the IDE397 and AMG 193 combination is anticipated to be conducted under an Amgen-sponsored clinical trial pursuant to a Clinical Trial Collaboration and Supply Agreement with Amgen (Amgen CTCSA).
- Presented preclinical efficacy data and supporting data at the 2023 Annual Meeting of the American Association for Cancer Research, or AACR 2023:
    - Preclinical data for the IDE397 and AMG 193 combination in a NSCLC MTAP-null CDX model showed complete responses following approximately 30 days of combination treatment, at doses below the maximally efficacious preclinical dose for each of IDE397 and AMG 193. The complete responses were durable from approximately study-day 40 to study-day 100. The IDE397 and AMG 193 combination was well tolerated, with no observed body weight loss through the approximate 30 days of combination treatment.
    - Preclinical efficacy data at AACR 2023 showing deep and durable anti-tumor efficacy and PD responses for IDE397 in combination with representative MTA-cooperative PRMT5 inhibitors in NSCLC MTAP-null CDX models, and for one representative compound, also in a pancreatic MTAP-null CDX model.
    - Results of gene expression analysis of hallmark pathways, alternative splicing analysis and retained intron analysis collectively demonstrate that combined pharmacological inhibition of MAT2A and PRMT5 deepens the biological response through maximal pathway suppression. The enhanced combination effect was observed selectively in MTAP-null relative to MTAP wild-type models.

IDE161—PARG Inhibitor in Tumors with Homologous Recombination Deficiency

IDEAYA is clinically evaluating its poly (ADP-ribose) glycohydrolase (PARG) inhibitor development candidate,

IDE161, in a Phase 1/2 clinical trial, IDE161-001, in patients having tumors with a defined biomarker based on genetic mutations and/or molecular signature.

IDE161 is a clinical-stage small molecule inhibitor of PARG being evaluated in a Phase 1/2 clinical trial designated as IDE161-001 for patients having tumors with homologous recombination deficiencies (HRD), including BRCA1 and BRCA2, and potentially other alterations, in solid tumors such as breast cancer or ovarian cancer. PARG is a novel, mechanistically distinct target in the same clinically validated biological pathway as poly (ADP-ribose) polymerase (PARP).

IDEAYA owns or controls all commercial rights to IDE161 and its PARG program, subject to certain economic obligations pursuant to its exclusive, worldwide license with Cancer Research UK and University of Manchester. Highlights:

- Initiated and enrolled the first cohort and accruing patients on a waitlist for subsequent cohorts of the dose escalation portion of the Phase 1/2 clinical trial in patients having solid tumors with HRD; the dose escalation protocol includes an initial starting dose of IDE161 of approximately one-half of the projected human efficacious dose, based on preclinical studies.
- Planned expansion cohorts will include ER+, Her2- HRD breast cancer patients, which represent approximately 10% to 14% of breast cancer patients, as well as HRD ovarian cancer patients, and a basket expansion cohort of other solid tumors with HRD.

Pol Theta Helicase Inhibitor Development Candidate in Tumors with HRD

Pol Theta

IDEAYA's DNA Polymerase Theta, (Pol Theta) program targets tumors with BRCA or other homologous recombination (HR) mutations or homologous recombination deficiency (HRD). IDEAYA and GSK collaborated on preclinical research and, following selection of the development candidate, GSK will lead clinical development for the Pol Theta program. Highlights:

- Selected a potential first-in-class Pol Theta Helicase inhibitor development candidate (DC) in collaboration with GSK.
- Observed tumor regressions in preclinical combination studies of Pol Theta Helicase DC with niraparib in multiple in vivo PDX and CDX HRD models.
- Targeting a GSK-sponsored IND submission in Q2 2023 to evaluate Pol Theta Helicase inhibitor DC combination with niraparib for patients having tumors with HRD.
- IDEAYA is eligible to receive total development and regulatory milestones of up to $485 million aggregate from GSK, with up to $20 million in aggregate for advancing a Pol Theta Helicase inhibitor from preclinical to early Phase 1 clinical. These include up to $10 million aggregate through IND effectiveness, of which IDEAYA received a $3.0 million milestone payment for achievement of the first preclinical development milestone in connection with IND-enabling studies to support evaluation of Pol Theta Helicase Inhibitor DC, and has the potential to receive up to an additional $7.0 million for advancing the Pol Theta Helicase Inhibitor DC through IND effectiveness.

WRN Inhibitors in Tumors with High Microsatellite Instability

IDEAYA and GSK are collaborating on ongoing preclinical research for an inhibitor targeting Werner Helicase for tumors with high microsatellite instability (MSI), and GSK will lead clinical development for the Werner Helicase program. Highlights:

- Targeting selection of a Werner Helicase development candidate in 2023, in collaboration with GSK, with potential for $3 million milestone in connection with IND-enabling studies; and

- IDEAYA is eligible to receive future development and regulatory milestones of up to $485 million aggregate from GSK, with potential for up to $20 million in aggregate for advancing a Werner Helicase inhibitor from preclinical to early Phase 1 clinical. These include up to $10 million aggregate through IND effectiveness – $3 million in connection with IND-enabling studies and up to an additional $7 million through IND effectiveness.

Next-Generation Precision Medicine Pipeline Programs

IDEAYA has initiated early preclinical research programs focused on pharmacological inhibition of several new targets, or NTs, for patients with solid tumors characterized by defined biomarkers based on genetic mutations and/or molecular signatures. The company believes these research programs have the potential for discovery and development of first-in-class or best-in-class therapeutics. IDEAYA owns or controls all commercial rights in its next generation NT programs.

General
IDEAYA continues to monitor COVID-19 and its potential impact on clinical trials and timing of clinical data results. Initiation of clinical trial sites, patient enrollment and ongoing monitoring of enrolled patients, including obtaining patient computed tomography (CT) scans, may be impacted for IDEAYA clinical trials evaluating IDE397 and darovasertib; the specific impacts are currently uncertain.

Corporate Updates
IDEAYA's net losses were $23.6 million and $24.2 million for the three months ended March 31, 2023 and December 31, 2022, respectively. As of March 31, 2023, the company had an accumulated deficit of $259.0 million.

As of March 31, 2023, IDEAYA had cash, cash equivalents and marketable securities of $351.2 million.

On April 27, 2023, and subsequent to its reported financial statements for the quarter ending March 31, 2023, IDEAYA announced the closing of an underwritten public offering. The offering included 8,858,121 shares of common stock (including 1,418,920 shares of common stock from the exercise in full of the underwriters' option to purchase such additional shares) at a public offering price of $18.50 per share, as well as pre-funded warrants to purchase 2,020,270 shares of common stock at a public offering price of $18.4999 per underlying share, in each case before underwriting discounts and commissions. Gross proceeds from the offering, before deducting underwriting discounts and commissions and other offering expenses payable by IDEAYA, were approximately $201.3 million.

Following the closing of the underwritten public offering, IDEAYA's cash, cash equivalents and marketable securities of $351.2 million as of March 31, 2023, supplemented by $188.7 million of estimated net proceeds from the financing, is anticipated to fund its planned operations into 2027. These funds will support the company's efforts through potential achievement of multiple preclinical and clinical milestones across multiple programs.

Our updated corporate presentation is available on our website, at our Investor Relations page: https://ir.ideayabio.com/.

Financial Results
As of March 31, 2023, IDEAYA had cash, cash equivalents and short-term marketable securities totaling $351.2 million. This compared to cash, cash equivalents and short-term and long-term marketable securities of $373.1 million as of December 31, 2022. The decrease was attributable to net cash used in operations offset by net proceeds of $2.5 million from the sale of shares of IDEAYA common stock under an at-the-market offering program during the period from January 1, 2023 to March 31, 2023.

Collaboration revenue for the three months ended March 31, 2023 totaled $7.9 million compared to $4.0 million for the three months ended December 31, 2022. Collaboration revenue was recognized for the performance obligations satisfied through March 31, 2023 under the GSK Collaboration Agreement.

Research and development (R&D) expenses for the three months ended March 31, 2023 totaled $27.9 million compared to $24.7 million for the three months ended December 31, 2022. The increase was primarily due to higher clinical trials, external research and personnel-related expenses.

General and administrative (G&A) expenses for the three months ended March 31, 2023 totaled $6.3 million compared to $5.8 million for the three months ended December 31, 2022. The increase was primarily due to higher personnel-related expenses to support our growth.

The net loss for the three months ended March 31, 2023 was $23.6 million compared to the net loss of $24.2 million for the three months ended December 31, 2022. Total stock compensation expense for the three months ended March 31, 2023 was $3.7 million compared to $3.0 million for the three months ended December 31, 2022.

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.

Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to (i) the extent to which IDEAYA's existing cash, cash equivalents, and marketable securities will fund its planned operations, (ii) the timing of initiation of the Phase 2/3 registrational trial for the darovasertib and crizotinib combination, (iii) the timing of a darovasertib clinical program update, (iv) the clinical focus for the IDE161 Phase 1 trial, (v) the timing of IND submission for Pol Theta Helicase DC, (vi) the timing of selection of a development candidate for a Werner Helicase inhibitor, (vii) the receipt of development and regulatory milestones, (viii) the potential of preclinical research programs, and (ix) the impact of COVID-19. 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, the effects on IDEAYA's business of the worldwide COVID-19 pandemic, the ongoing military conflict between Russia and Ukraine, banking sector volatility, 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 Quarterly Report on Form 10-Q dated May 9, 2023 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	
	March 31, 2023	**December 31,2022**
	(Unaudited)	
Collaboration revenue	$ 7,880	$ 4,022
Operating expenses:		
Research and development	27,859	24,714
General and administrative	6,300	5,752
Total operating expenses	34,159	30,466
Loss from operations	(26,279)	(26,444)
Interest income and other income, net	2,639	2,243
Net loss	(23,640)	(24,201)
Unrealized gains on marketable securities	1,466	1,131
Comprehensive loss	$ (22,174)	$ (23,070)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.49)	$ (0.50)
Weighted-average number of shares outstanding, basic and diluted	48,370,074	48,132,003

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

	March 31, 2023	December 31, 2022
	(Unaudited)	
Cash and cash equivalents and short-term and long-term marketable securities	$ 351,210	$ 373,146
Total assets	364,746	387,969
Total liabilities	30,936	38,514
Total liabilities and stockholders' equity	364,746	387,969

SOURCE IDEAYA Biosciences, Inc.

https://media.ideayabio.com/2023-05-09-IDEAYA-Biosciences,-Inc-Reports-First-Quarter-2023-Financial-Results-and-Provides-Business-Update