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

- Strong balance sheet of $511.1 million of cash, cash equivalents and marketable securities as of September 30, 2023, supplemented by $134.7 million estimated net proceeds from subsequent follow-on financing and $10.0 million receivable from GSK milestones
- Multiple patients dosed and international site activation and enrollment ongoing in Phase 2/3 potential registrational trial evaluating darovasertib and crizotinib combination in 1L HLA-A2-negative MUM, and proffered paper oral presentation at ESMO 2023
- Enrollment is ongoing in the Phase 1/2 study with IDE397 (MAT2A) and AMG 193 ($PRMT5^{MTA}$) in MTAP-deletion solid tumors
- Demonstrated eye preservation in 3 of 6 (50%) evaluable patients treated with darovasertib as neoadjuvant therapy for primary UM; observed PRs by RECIST 1.1 in 2 of 4 (50%) GNAQ/11 cutaneous melanoma patients on darovasertib and crizotinib
- Reported PRs by RECIST 1.1 and initiated IDE161 Ph1 expansion in HRD+ solid tumor types, and received Fast Track Designation for IDE161 in BRCA 1/2 ovarian and breast cancer
- IND clearance for GSK101 (IDE705) Pol Theta Helicase inhibitor ($7.0 million milestone), and selected Werner Helicase Inhibitor Development Candidate ($3.0 million milestone)
- Targeting multiple wholly-owned next generation development candidate nominations in 2024, including in MTAP-deletion, further advancing IDEAYA's multi-pronged strategy
- Hosting Investor R&D Day on December 4, 2023, with participation from GSK and KOL

SOUTH SAN FRANCISCO, Calif., Nov. 7, 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 third quarter ended September 30, 2023.

"We have advanced a diverse clinical pipeline of precision medicine oncology therapies targeting biomarker-defined solid tumor populations. Our innovative clinical pipeline has four potential first-in-class clinical programs, including darovasertib (PKC) in a Phase 2/3 potential registrational trial, IDE397 (MAT2A) in Phase 2, IDE161 (PARG) in Phase 1, and GSK101/IDE705 (Pol Theta Helicase) in Phase 1. We also selected a Werner Helicase Development Candidate in collaboration with GSK, for which an IND submission is planned for 2024. These programs represent five potential first-in-class programs, further validating our robust drug discovery platform and enhancing our industry leadership in precision medicine oncology," said Yujiro S. Hata, Chief Executive Officer, IDEAYA Biosciences.

"Darovasertib is being evaluated across the patient journey in uveal melanoma – including as a monotherapy in the neoadjuvant and adjuvant settings, and in combination with crizotinib in the metastatic setting. We also initiated a Phase 2 expansion in GNAQ/11 cutaneous melanoma based on multiple durable partial responses observed in our Phase 2 trial. With respect to IDE397, Phase 2 monotherapy expansion is ongoing in bladder and squamous NSCLC, and in collaboration with Amgen we are also testing IDE397 in combination with AMG193, the Amgen $PRMT5^{MTA}$ inhibitor, with a planned focus on NSCLC in the expansion phase. Lastly, in the IDE161 first-in-human study we have observed partial responses in the Phase 1 dose escalation, enabling the Phase 1 dose expansion in high priority HRD+ solid tumor types, including breast, ovarian, endometrial, and colorectal cancer," said Dr. Darrin 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, or UM, in both primary and metastatic disease settings. The company has initiated a potential registration-enabling Phase 2/3 clinical trial to evaluate the darovasertib and crizotinib combination in first-line Human Leukocyte Antigen- (HLA-) A2*02:01 negative serotype (HLA-A2(-)) metastatic UM (MUM). IDEAYA also initiated a company-sponsored Phase 2 clinical trial for evaluating single-agent darovasertib as neoadjuvant and adjuvant therapy in primary UM.

IDEAYA is evaluating IDE397, its methionine adenosyltransferase 2a, or MAT2A, inhibitor, as monotherapy in a Phase 2 expansion cohort in patients having tumors with methylthioadenosine phosphorylase, or MTAP, deletion, including high-priority tumors such as squamous NSCLC and bladder cancer. Enrollment is ongoing in the Amgen-sponsored Phase 1/2 clinical trial evaluating IDE397 in combination with AMG 193, the Amgen investigational MTA-cooperative PRMT5 inhibitor, in patients having tumors with MTAP gene deletion.

IDEAYA is evaluating IDE161, its poly (ADP-ribose) glycohydrolase, or PARG, inhibitor in a Phase 1/2 clinical trial in patients having tumors with homologous recombination deficiency, or HRD. IDEAYA is enrolling patients into the Phase 1 monotherapy expansion in priority tumor types, including ER+, Her2- HRD+ breast cancer patients, HRD+ ovarian cancer patients and in patients having other solid tumors with HRD, such as HRD+ endometrial and colorectal cancer.

Investigational new drug, or IND, clearance by the U.S. FDA was achieved for GSK101 (IDE705), a Pol Theta Helicase inhibitor, triggering a $7.0 million milestone payment from GSK. Initiation of the first-in-human study is planned for the fourth quarter of 2023 to evaluate GSK101 in a GSK-sponsored Phase 1/2 clinical trial in combination with niraparib, GSK's commercial poly (ADP-ribose) polymerase, or PARP, inhibitor, for patients having tumors with HR mutations such as BRCA mutations, or with HRD.

IDEAYA, in collaboration with GSK, selected a Werner Helicase Inhibitor Development Candidate, or DC, and earned a $3.0 million milestone payment in October 2023 from GSK in connection with IND-enabling studies. Subject to IND-enabling studies, IND-submission is targeted in 2024 to enable clinical evaluation of the Werner Helicase Inhibitor DC in patients having tumors that are microsatellite instability, or MSI, high.

The company's preclinical pipeline includes several additional potential first-in-class precision medicine therapeutics.

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

*Registration-Enabling Clinical Trial in First-Line HLA-A2*02:01(-) Metastatic Uveal Melanoma*

Multiple patients have been dosed and international site activation and enrollment is ongoing into a potential registration-enabling Phase 2/3 clinical trial, designated as IDE196-002, to evaluate the darovasertib and crizotinib combination in first-line HLA-A2(-) MUM patients. The company has several clinical sites open and is targeting to open an aggregate of over 50 clinical sites across U.S., Europe and Australia to support this registrational study.

Phase 2 Clinical Trial Evaluating Darovasertib + Crizotinib Combination in MUM

In parallel, IDEAYA is continuing to evaluate darovasertib in its ongoing Phase 2 clinical trial, designated as IDE196-001, as a combination therapy with crizotinib in MUM. IDEAYA is the sponsor of this Phase 2 clinical trial and is collaborating with Pfizer on this Phase 2 clinical trial pursuant to the Clinical Trial Collaboration and Supply Agreement, or Pfizer Agreement. Highlights:

- A clinical update was presented by Dr. Merideth McKean, a clinical investigator, at the 2023 European Society for Medical Oncology's Congress (ESMO 2023), including clinical efficacy in HLA-A2(-)/(+) data subsets, clinical ctDNA data and updated duration of treatment from IDEAYA's Phase 2 clinical trial in MUM.
    - Phase 2 clinical data update was based on twenty (20) evaluable first-line and sixty-three (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; these data were preliminary and based on investigator review from an unlocked database as of the data analyses cutoff date of August 22, 2023.
    - Clinical efficacy was observed irrespective of HLA-A2 status, including in HLA-A2(-) and HLA-A2(+) serotypes. Observed an overall response rate, or ORR, of 42% in HLA-A2(-) and 60% in HLA-A2(+) first-line MUM patients by RECIST 1.1. A total of n=50 all-line MUM patients with known HLA-A2 status were among the n=63 patients evaluable for efficacy, including 31 HLA-A2(-) and 19 HLA-A2(+) patients. For HLA-A2(-) MUM patients, confirmed partial responses, or PRs, were observed in 9 of 31 (29% ORR) any-line and in 5 of 12 (42% ORR) first-line patients. For HLA-A2(+) MUM patents, confirmed PRs observed in 6 of 19 (32% ORR) any-line and in 3 of 5 (60% ORR) first-line patients.
    - With ~5.5 months of further follow-up from the previous March 8, 2023 cut-off date, we observed a median PFS of 7.1 months in first-line MUM, 6.8 months in any-line MUM, and 11.0 months in hepatic-only MUM. In addition, based on the two-year PFS analysis, over 20% (13 of 63 evaluable patients) of any-line patients on the darovasertib and crizotinib clinical combination are progression free at two-years, demonstrating a long tail effect.
    - Circulating tumor DNA, or ctDNA, molecular responses reported at ESMO 2023 were determined based on measured changes in mean allele frequency (MAF) on-treatment as compared to MAF levels at baseline for a subset of any-line MUM patients (n=32).
    - A reduction in MAF was observed in all but one patient – in 31 or 32 evaluable any-line MUM patients.
    - Patients whose ctDNA showed a reduction of greater than 50% MAF following treatment were characterized as having a ctDNA molecular response, or MR.
    - ctDNA MR was observed in 30 of 32 evaluable any-line MUM patients, reflecting a 94% ctDNA MR rate. The ctDNA molecular responses were deep and sustained, with approximately 80% of measured patients having >80% reduction in MAF. The ctDNA molecular responses correlated with observed efficacy, including confirmed PRs as determined by RECIST 1.1.
    - Treatment durations were observed for any-line (n=63) patients: approximately 50% of patients were treated for greater than six months, and approximately 30% of patients were treated for greater than one year.
    - The darovasertib and crizotinib combination therapy continued to demonstrate an overall manageable adverse event profile in MUM patients (n=68) at the combination expansion doses, with a low rate (10%) of drug-related serious adverse events, or SAEs, and limited Grade 4 and Grade 5 SAEs and discontinuations. Drug-related adverse events, or AEs, were predominantly Grade 1 or Grade 2. 31% of patients reported at least one Grade 3 AE; no patients observed a Grade 4 AE; and one patient observed a Grade 5 AE. Five patients (7%) discontinued treatment with darovasertib and crizotinib combination due to a drug-related AE.

*Prevalence of HLA-A2*02:01 Negative Serotype in MUM*

Data from darovasertib clinical trials in MUM demonstrate that approximately 70% of MUM patients with known human leukocyte antigen

(HLA)-A*02:01 (HLA-A2) status were HLA-A2(-).

As also reported at ESMO 2023 by Dr. McKean, the HLA-A2 status was known in subsets of patients enrolled in clinical trials evaluating darovasertib. Prevalence of HLA-A2(+) and HLA-A2(-) was shown:

- In a first data set of 149 MUM patients treated with darovasertib as monotherapy or in a combination arm of a clinical trial, 68% (102 of 149) of patients were HLA-A2(-) serotype and 32% of patients were HLA-A2(+) serotype.
- In a second data set of 118 MUM patients treated with the darovasertib and crizotinib combination, 69% (81 of 118) of patients were HLA-A2(-) serotype and 31% of patients were HLA-A2(+) serotype.

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 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:

- IDEAYA has dosed 7 patients as of November 1 2023, has clinical sites open and is actively recruiting additional patients into the 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 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.
- In October 2023, IDEAYA reported updated data from the ongoing Phase 1 investigator-sponsored trial, or IST, captioned as "Neoadjuvant / Adjuvant trial of Darovasertib in Ocular Melanoma" (NADOM) being led by principal investigator Professor Anthony Joshua, MBBS, PhD, FRACP, Head Department of Medical Oncology, Kinghorn Cancer Centre, St. Vincent's Hospital in Sydney with participating sites of Alfred Health and the Royal Victorian Eye and Ear Hospital in Melbourne. The study reported a preliminary interim update with a data cut-off as of July 17, 2023.
    - In total, 11 patients eligible to receive 6 months of neoadjuvant therapy had been enrolled as of October 2023 in the IST. Per current protocol, patients with planned enucleation who are enrolled in the study are treated to maximal benefit or up to 6 months with darovasertib monotherapy.
    - Seven patients were treated to maximal response or have ongoing treatment with darovasertib in the neo-adjuvant setting as of the data cut-off date. Six of these seven patients treated were considered evaluable based on evaluation with at least one ultrasound scan.
    - Two evaluable patients had a confirmed eye preservation (Eye Saved), based on conversion of their primary treatment from the planned enucleation to plaque brachytherapy. A third evaluable patient was confirmed as plaque-eligible and treatment of this patient is ongoing with darovasertib neo-adjuvant treatment until maximal benefit. These data reflect a 50% overall eye preservation rate for the six evaluable patients.
    - Of the evaluable patients (6 of 7), approximately 83% of patients had tumor shrinkage.
    - Two patients enrolled into the IST did not complete their treatment to maximal response. One of these patients had sub-retinal blood present at baseline and with lack of shrinkage and visual deterioration and the patient discontinued treatment after 6 weeks. A second of these patients had a Grade 3 drug-related AE of dermatitis and discontinued treatment before a first scan.
    - Enrollment into the IST is ongoing. Two out of four additional patients enrolled after the data cutoff date of July 17, 2023 are likely plaque eligible (22% ocular tumor shrinkage at 1-month and 20% ocular tumor shrinkage at 2-months) and are continuing darovasertib neoadjuvant therapy until maximal benefit. One patient is being enucleated. The status of the fourth patient was not reported.

Darovasertib – Expansion Opportunity in Cutaneous Melanoma

IDEAYA initiated a Phase 2 expansion arm in the clinical trial evaluating the darovasertib and crizotinib combination in GNAQ/11 metastatic cutaneous melanoma as a further expansion opportunity. In October 2023, the company reported that in a genetically defined GNAQ/GNA11 patient population with cutaneous melanoma, 3 cohorts of patients treated with darovasertib, either as monotherapy or in combination with either binimetinib or crizotinib, have shown preliminary clinical activity:

- Darovasertib Monotherapy Cutaneous Melanoma Cohort (n=8): 5 of 7 evaluable patients had tumor shrinkage (approximately 71%) with one patient having a PR and remaining on treatment over 10 months after previously receiving multiple prior lines of immunotherapy.
- Darovasertib plus Binimetinib Cutaneous Melanoma Cohort (n=2): 1 of 2 cutaneous melanoma patients with a PR demonstrated 50% tumor shrinkage and remained on treatment approximately 600 days after previously receiving multiple prior lines of immunotherapy.
- Darovasertib plus Crizotinib Cutaneous Melanoma Cohort (n=2): 1 of 2 cutaneous melanoma patients had tumor shrinkage of 60% with one patient having a PR and remaining on treatment (approximately 600 days) after previously receiving multiple prior lines of immunotherapy.

Darovasertib, as monotherapy or in combination with either binimetinib or crizotinib, has indicated a manageable adverse event profile in cutaneous melanoma patients with certain drug-related AEs being reported in certain cohorts. These preliminary clinical data support the Company's reported initiation of a Phase 2 expansion of the darovasertib and crizotinib combination in GNAQ/11 metastatic cutaneous melanoma. There are currently no FDA approved therapies in this genetically-defined GNAQ/11 cutaneous melanoma patient population.

The GNAQ/11 prevalence in cutaneous melanoma has been reported at approximately 5% in The Cancer Genome Atlas. The GNAQ/11 cutaneous melanoma estimated annual incidence is approximately 5,000 patients in the U.S. and 8,000 patients in the EU28, and the estimated total prevalence of GNAQ/11 cutaneous melanoma is approximately 70,000 patients in the U.S. and 110,000 patients in the EU28.

Based on several metastatic cancer patient databases, including Memorial Sloan Kettering Cancer Center Impact, we believe GNAQ/11 metastatic cutaneous melanoma has the potential to be another significant expansion opportunity for darovasertib, reflecting approximately double or more of the annual addressable metastatic patient population of metastatic uveal melanoma alone.

IDE397—MAT2A Inhibitor in Tumors with MTAP Deletion

IDEAYA is clinically evaluating IDE397, a potent and selective small molecule inhibitor targeting MAT2A in patients having solid tumors with 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, designated as IDE397-001 (NCT04794699).

The IDE397 clinical development strategy is focused as monotherapy in select indications and on the IDE397 combination with AMG 193, 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:

- Enrollment is ongoing in the dose escalation portion of the Amgen-sponsored Phase 1/2 clinical trial evaluating IDE397 (MAT2A) and AMG 193 ($PRMT5^{MTA}$) combination in patients with MTAP-deletion solid tumors.
- Amgen-sponsored Phase 1/2 clinical trial (NCT 05975073) to evaluate the IDE397 and AMG 193 combination has an estimated planned enrollment of approximately 180 patients with solid tumors having MTAP deletion, with a planned expansion focus in NSCLC, to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of the combination.
- IDEAYA-sponsored IDE397 monotherapy Phase 2 expansion is enrolling patients with MTAP-deletion squamous NSCLC and bladder cancers.
- Preliminary clinical data for IDE397 in the Company's Phase 2 clinical trial shows responses in multiple MTAP-deletion high-priority tumor types based on experience across several patients in the early phase of the monotherapy dose expansion. These include an earlier-reported unconfirmed partial response which was subsequently confirmed (approximately 47% tumor reduction), and at the week-18 CT scan converted to a complete response (bladder cancer patient), and an additional observed approximately 33% tumor reduction in squamous NSCLC patient as measured by CT-PET. 8 patients have been dosed in the IDE397 monotherapy expansion in the priority tumor types, and 2 patients have not yet had a first tumor scan assessment, as of the October 13, 2023 cut-off date.
- We have observed relatively low rates of discontinuations and SAEs in the IDE397 monotherapy clinical evaluation as of the October 13, 2023 cut-off date.
- International site activation is ongoing in support of Phase 2 monotherapy expansion, including in Europe and Asia, to enhance patient enrollment in high priority MTAP-deletion tumor types of squamous NSCLC and bladder cancer.

IDE161—PARG Inhibitor in Tumors with Homologous Recombination Deficiency

IDEAYA is clinically evaluating its PARG inhibitor development candidate, IDE161, in a Phase 1/2 clinical trial, designated as IDE161-001, in patients having tumors with 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 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 IDE161 Phase 1 expansion based on multiple PRs by RECIST 1.1 and tumor shrinkage observed in multiple HRD solid tumor patients, including an endometrial cancer subject with a first imaging assessment of a partial response and an 87% reduction of the CA-125 marker, which was subsequently confirmed by RECIST 1.1 at the second scan.
- 7 patients treated at the expansion dose in the priority solid tumor types and 2 patients have not yet had a first tumor scan assessment as of the October 13, 2023 cut-off date.
- We have observed no drug related discontinuations or SAEs at the IDE161 expansion dose as of the October 13, 2023 cut-off date.
- Phase 1 expansion focus in ER+, Her2(-), HRD+ breast cancer representing approximately 10% to 14% of breast cancer, HRD+ ovarian cancer representing approximately 50% of ovarian cancer, and other solid tumors with HRD, including HRD+ endometrial cancer.
- Demonstrated IDE161 target engagement based on pharmacodynamic modulation of PAR, and achieved human exposures correlating to tumor regressions in preclinical models.
- Phase 1 dose optimization ongoing to confirm move forward Phase 2 expansion dose.
- Received Fast Track Designation from the U.S. FDA for IDE161 for adult, pretreated, advanced or metastatic BRCA 1/2m ovarian- and

HR+, Her2-, BRCA 1/2m breast- cancer patients, including specifically for:

  - Treatment of adult patients having advanced or metastatic hormone receptor positive, or HR+, Her2- breast cancer with germline or somatic BRCA 1/2 mutations who have progressed following treatment with at least one line of a hormonal therapy, a CDK4/6 inhibitor therapy and a PARP inhibitor therapy; and
  - Treatment of adult patients having advanced or metastatic ovarian cancer with germline or somatic BRCA 1/2 mutations who are platinum resistant and have received prior antiangiogenic and PARP inhibitor therapies.

- Targeting IDE161 clinical program updates in the fourth quarter of 2023.

GSK101 (IDE705) – Pol Theta Helicase Inhibitor in Tumors with HR Mutations

GSK101 (IDE705) is targeting Pol Theta Helicase for solid tumors with homologous recombination, or HR mutations, such as BRCA, or HRD. IDEAYA and GSK collaborated on preclinical research and, following selection of GSK101 as the development candidate, GSK is leading clinical development for the Pol Theta program. Highlights:

- Obtained IND clearance from U.S. FDA to enable GSK-sponsored Phase 1/2 clinical trial to evaluate GSK101 in combination with niraparib, the GSK small molecule inhibitor of PARP, for patients having solid tumors with HR mutations, such as BRCA or other HR mutations, or with HRD.
- Targeting first-in-human studies for GSK101 in the fourth quarter of 2023.
- Earned $7.0 million milestone payment from GSK based on IND clearance, with potential to receive additional $10.0 million upon initiation of Phase 1 clinical dose expansion, as well as potential further aggregate later-stage development and regulatory milestones of up to $465.0 million.
- GSK is the sponsor of the Phase 1/2 clinical trial and will lead clinical development for the Pol Theta program pursuant to its global, exclusive license from IDEAYA. GSK is responsible for all research and development costs for the program.

WRN Inhibitor 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 MSI, and GSK will lead clinical development for the Werner Helicase program. Highlights:

- Selected a Werner Helicase Inhibitor DC in collaboration with GSK.
- Targeting an IND in 2024 to enable first-in-human clinical evaluation of Werner Helicase Inhibitor DC for patients having tumors with MSI-High.
- Earned $3.0 million milestone from GSK in connection with IND-enabling studies with potential for up to an additional $17.0 million aggregate milestones through early Phase 1, as well as potential further aggregate later-stage development and regulatory milestones of up to $465.0 million.
- Subject to IND submission and clearance, GSK will lead clinical development for the Werner Helicase program pursuant to its global, exclusive license to develop and commercialize the Werner Helicase Inhibitor DC. GSK is responsible for 80% of global research and development costs and IDEAYA is responsible for 20% of such costs.

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. These research programs have the potential for discovery and development of first-in-class or best-in-class therapeutics with multiple wholly-owned development candidate nominations targeted in 2024, including to treat MTAP-deletion solid tumors.

IDEAYA Investor R&D Day

The IDEAYA Investor R&D Day will include participation from GSK and a key opinion leader that will showcase scientific insights and clinical development opportunities across IDEAYA's synthetic lethality pipeline, including IDE397 (MAT2A) in Phase 2, IDE161 (PARG) in Phase 1, GSK101/IDE705 (Pol Theta Helicase) in Phase 1, and the Werner Helicase program for which an IND submission is planned for 2024. In addition, IDEAYA will highlight its next generation initiatives in MTAP-deletion, including a wholly-owned program where a development candidate nomination is targeted in 2024, further advancing IDEAYA's multi-pronged strategy.

Corporate Updates

IDEAYA's net losses were $27.4 million and $27.9 million for the three months ended September 30, 2023 and June 30, 2023, respectively. As of September 30, 2023, the company had an accumulated deficit of $314.4 million.

As of September 30, 2023, IDEAYA had cash, cash equivalents and marketable securities of $511.1 million. These funds were supplemented by $134.7 million in estimated net proceeds from a follow-on financing on October 27, 2023, and $10.0 million in milestones achieved from the GSK collaboration. The $10.0 million in GSK milestones includes $7.0 million earned upon IND clearance from the Pol Theta Program in August 2023, which was subsequently received in October 2023, and $3.0 million earned in connection with the IND-enabling studies from the

Werner Helicase program in October 2023.

On October 27, 2023, subsequent to the reporting period for the quarter ended September 30, 2023, the company completed an underwritten public follow-on offering. The offering consisted of 5,797,872 shares of our common stock at an offering price to the public of $23.50 per share, including 797,872 shares of common stock upon the exercise in full of the overallotment option by the underwriters, and pre-funded warrants to purchase 319,150 shares of common stock at a public offering price of $23.4999 per pre-funded warrant before underwriting discounts and commissions. Pursuant to the offering, we received net proceeds of approximately $134.7 million, after deducting underwriting discounts and commissions and other offering expenses.

IDEAYA's updated corporate presentation is available on its website, at its Investor Relations page: https://ir.ideayabio.com/.

Financial Results

As of September 30, 2023, IDEAYA had cash, cash equivalents and short-term marketable securities totaling $511.1 million. This compared to cash, cash equivalents and short-term and long-term marketable securities of $510.1 million as of June 30, 2023.

The increase was attributable to net proceeds of $26.3 million from the sale of shares of our common stock under the at-the-market offerings pursuant to the June 2023 Sales Agreement with Jefferies as sales agent.

Collaboration revenue for the three months ended September 30, 2023, totaled $8.0 million compared to $3.5 million for the three months ended June 30, 2023. Collaboration revenue was recognized for the performance obligations satisfied through September 30, 2023, under the GSK Collaboration Agreement and the Pol Theta program's IND effectiveness milestone achievement.

Research and development (R&D) expenses for the three months ended September 30, 2023, totaled $33.7 million compared to $29.2 million for the three months ended June 30, 2023. The increase was primarily due to higher clinical trial expenses.

General and administrative (G&A) expenses for the three months ended September 30, 2023, totaled $7.9 million compared to $7.1 million for the three months ended June 30, 2023. The increase was primarily due to higher consulting fees and personnel-related expenses.

The net loss for the three months ended September 30, 2023, was $27.4 million compared to the net loss of $27.9 million for the three months ended June 30, 2023. Total stock compensation expense for the three months ended September 30, 2023, was $5.3 million compared to $4.7 million for the three months ended June 30, 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.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to (i) the timing of designation of next generation development candidates, (ii) the timing, content and participants in the Investor R&D Day and content of a darovasertib clinical program update, (iii) the timing of IND submission for the Werner Helicase inhibitor DC, (iv) the clinical focus the IDE397 and AMG 193 combination clinical trial, (v) the number of clinical trial sites in the darovasertib and crizotinib combination potential registration-enabling Phase 2/3 clinical trial, (vi) the potential therapeutic benefits of IDEAYA therapeutics, (vii) the translation of preliminary clinical trial results into future clinical trial results, (vii) the estimate of patient populations, (viii) the timing and content of clinical program updates, (ix) the timing of first-in-human studies for GSK101, and (x) the receipt of development and regulatory milestones. 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 November 7, 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		Nine Months Ended	
	September 30, 2023	June 30, 2023	September 30, 2023	September 30, 2022
	(Unaudited)		(Unaudited)	
Collaboration revenue	$ 8,038	$ 3,544	$ 19,463	$ 46,909
Operating expenses:				
Research and development	33,701	29,178	90,738	64,823
General and administrative	7,863	7,075	21,237	18,145
Total operating expenses	41,564	36,253	111,975	82,968
Loss from operations	(33,526)	(32,709)	(92,512)	(36,059)
Interest income and other income, net	6,086	4,783	13,506	1,605
Net loss	(27,440)	(27,926)	(79,006)	(34,454)
Unrealized gains (losses) on marketable securities	429	226	2,121	(3,290)
Comprehensive loss	$ (27,011)	$ (27,700)	$ (76,885)	$ (37,744)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.46)	$ (0.50)	$ (1.44)	$ (0.88)
Weighted-average number of shares outstanding, basic and diluted	59,999,449	56,251,130	54,916,150	39,191,098

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

	September 30, 2023	December 31, 2022
	(Unaudited)	

Cash and cash equivalents and short-term and long-term marketable securities	$	511,145	$	373,146
Total assets		532,942		387,969
Total liabilities		24,893		38,514
Total liabilities and stockholders' equity		532,942		387,969

SOURCE IDEAYA Biosciences, Inc.

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https://media.ideayabio.com/2023-11-07-IDEAYA-Biosciences,-Inc-Reports-Third-Quarter-2023-Financial-Results-and-Provides-Business-Update