IDEAYA Biosciences, Inc. Reports First Quarter 2022 Financial Results and Provides Business Update

- Strong balance sheet of ~$346 million cash, cash equivalents and marketable securities as of March 31, 2022 is anticipated to fund planned operations into 2025
- Targeting initiation of IDE397 Phase 1/2 monotherapy expansion and Phase 1 combination cohorts, and delivery of GSK option data package mid-year 2022
- Darovasertib and crizotinib Phase 1/2 clinical combination data update and regulatory guidance on potential registration-enabling trial anticipated mid-year 2022
- On-track to submit an IND in Q4 2022 for IDE161, a PARG development candidate, and to nominate a Pol Theta development candidate in Q2 2022

SOUTH SAN FRANCISCO, Calif., May 10, 2022 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), a synthetic lethality focused 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, 2022.

"The IDE397 Phase 1 dose escalation clinical data supports advancing the program to monotherapy expansions and clinical combinations in patients with MTAP deletion tumors. In addition, the darovasertib Phase 2 data is maturing to enable FDA discussions on potential registrational trial design in MUM, and we are preclinically exploring potential darovasertib expansion opportunities in additional cMET driven tumors," said Yujiro S. Hata, Chief Executive Officer and President of IDEAYA Biosciences.

"We are building a broad and deep pipeline of potential first-in-class synthetic lethality therapeutics. Several of our synthetic lethality programs are advancing toward the clinic, including our PARG inhibitor, IDE161, for which we are targeting an IND in Q4 2022, and our potential first-in-class Pol Theta helicase inhibitor, for which we are collaborating with GSK to select a development candidate in Q2 2022. Our potential first in class Werner helicase inhibitor is also progressing in collaboration with GSK; we are targeting development candidate selection in 2023," said Michael White, Senior Vice President and Chief Scientific Officer of IDEAYA Biosciences.

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

IDE397 (MAT2A)
IDEAYA is 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 leading early clinical development of IDE397. Subject to exercise of its option for an exclusive license, GlaxoSmithKline (GSK) will lead global clinical development. Highlights:

- Actively enrolling patients into dose-escalation cohorts of the Phase 1 clinical trial IDE397-001 (NCT04794699); as of May 1, 2022, the company has enrolled 21 MTAP-deletion patients into the dose escalation
- Patients are being identified by next generation sequencing (NGS) or by MTAP immunohistochemistry (IHC) assay with confirmatory NGS
- Evaluating IDE397 in patients with MTAP deletion across multiple solid tumor types, including non-small cell lung cancer, pancreatic cancer, thymic cancer, adenoid cystic carcinoma, esophagogastric cancer and bladder cancer
- Observed *in vivo* efficacy of IDE397 in combination with a MTAP-SL inhibitor in preclinical studies, including

a complete response (CR) in NSCLC MTAP-null CDX model
- Targeting IDE397 Phase 1/2 monotherapy cohort expansion and initiation of Phase 1 combination cohorts in the second or third quarter, or mid-year, 2022
- Targeting delivery of IDE397 option data package to GSK mid-year 2022, subject to initiation of expansion cohorts or establishing the MTD; the option data package will trigger an evaluation period for GSK to make an opt-in decision
- Subject to GSK election to opt-in, the company is entitled to receive a $50 million opt-in payment from GSK, ongoing development costs will be shared as 80% GSK / 20% IDEAYA, and IDEAYA is entitled to potential development and regulatory milestones aggregate up to $465 million; upon commercialization, IDEAYA is entitled to 50% of U.S. net profits and tiered royalties on global non-U.S. net sales ranging from high single digit to sub-teen double digit percentages, as well as certain commercial milestones of up to $475 million

PARG

IDEAYA is advancing preclinical research for an inhibitor of poly (ADP-ribose) glycohydrolase (PARG) in patients having tumors with a defined biomarker based on genetic mutations and/or molecular signature. PARG is a novel target in the same clinically validated biological pathway as poly (ADP-ribose) polymerase (PARP). IDEAYA owns or controls all commercial rights in its PARG program. Highlights:

- Ongoing IND-enabling studies for IDE161, a potential first-in-class PARG inhibitor development candidate for patients having tumors with homologous recombination deficiencies (HRD), including BRCA1 and BRCA2, and potentially other alterations
- Targeting IND for IDE161 in the fourth quarter of 2022

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 are collaborating on ongoing preclinical research, including small molecules and protein degraders, and GSK will lead clinical development for the Pol Theta program. Highlights:

- Targeting development candidate nomination and initiation of IND-enabling studies for a Pol Theta helicase inhibitor in the second quarter of 2022 in collaboration with GSK
- Potential for up to $20 million in aggregate milestone payments from GSK for advancing a Pol Theta Helicase inhibitor from preclinical to early Phase 1 clinical

Werner Helicase

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

- Targeting selection of a Werner Helicase development candidate in 2023
- Potential for up to $20 million in aggregate milestone payments from GlaxoSmithKline for advancing a Werner Helicase inhibitor from preclinical to early Phase 1 clinical

Other Synthetic Lethality Pipeline Programs

IDEAYA is advancing additional preclinical research programs to identify small molecule inhibitors for an MTAP-synthetic lethality target, as well as for multiple potential first-in-class synthetic lethality programs for patients with solid tumors characterized by proprietary biomarkers or gene signatures.

Darovasertib (IDE196)

IDEAYA continues to execute on its clinical trial strategy to evaluate darovasertib (IDE196), a potent and selective PKC inhibitor.

IDEAYA is evaluating darovasertib in combination with crizotinib, a cMET inhibitor, in metastatic uveal melanoma (MUM). The company is also clinically evaluating darovasertib as a combination with crizotinib in GNAQ/11 mutant skin melanoma in an ongoing arm of the current clinical trial, and in adjuvant primary uveal melanoma (UM) as monotherapy through an investigator sponsor clinical trial (IST). IDEAYA is also evaluating other potential darovasertib expansion opportunities, including in cMET driven tumors and in KRAS-mutation tumors.

Darovasertib / Crizotinib Combination Therapy
IDEAYA is continuing patient enrollment into the darovasertib / crizotinib combination arm of the Phase 1/2 clinical trial under clinical trial collaboration and supply agreements with Pfizer. Highlights:

- As of May 1, 2022, the company has enrolled 72 MUM patients into the darovasertib/crizotinib combination arm; the company is prioritizing enrollment into first-line MUM based on observed early clinical partial responses
- IDEAYA presented darovasertib and crizotinib clinical combination data in December 2021. The reported preliminary data, based on an unlocked database, showed robust clinical activity with manageable side effect profile
- In April 2022, the FDA designated darovasertib as an Orphan Drug in MUM under 21 C.F.R Part 316. Under an Orphan Drug designation, IDEAYA may be entitled to certain tax credits, exemption from user fees, and subject to FDA approval of a marketing application for darovasertib as a designated orphan-drug product, seven years of statutory marketing exclusivity
- The company is targeting a clinical data update for darovasertib and crizotinib combination in mid-year 2022, including tolerability and clinical efficacy. IDEAYA is also planning to seek FDA regulatory guidance in mid-year 2022 for potential registration-enabling trial design to evaluate darovasertib and crizotinib combination in MUM
- Collaborating with Pfizer under a clinical collaboration and supply agreement to support clinical evaluation of darovasertib and crizotinib combination in a potential registration-enabling clinical trial in MUM, subject to FDA feedback and guidance

Darovasertib Monotherapy
IDEAYA has completed enrollment into its ongoing Phase 1/2 clinical trial evaluating darovasertib as monotherapy in MUM patients.

IDEAYA is planning to initiate an Investigator Sponsored Trial, with St. Vincent's Hospital Sydney Limited to evaluate darovasertib as monotherapy in a neo-adjuvant / adjuvant setting in (non-metastatic) uveal melanoma (UM) patients.

Darovasertib – Other Potential Indications
IDEAYA is evaluating the potential for darovasertib in other oncology indications, including in cMET-driven tumors and in KRAS-mutation tumors. Highlights:

- Collaborating with Pfizer under a clinical collaboration and supply agreement for clinical evaluation of darovasertib and crizotinib combination therapy in cMET-driven tumors, such as NSCLC or HCC, subject to preclinical validation studies
- Evaluating darovasertib in combination with a KRAS inhibitor in preclinical studies in KRAS-driven solid tumors

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 $14.0 million and $18.2 million for the three months ended March 31, 2022 and December 31, 2021, respectively. As of March 31, 2022, the company had an accumulated deficit of $190.8 million.

As of March 31, 2022, IDEAYA had cash, cash equivalents and marketable securities of $346.2million. IDEAYA believes that its cash, cash equivalents and marketable securities will be sufficient to fund its planned operations into 2025. 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, 2022, IDEAYA had cash, cash equivalents and short-term marketable securities totaling $346.2 million. This compared to cash, cash equivalents and short-term and long-term marketable securities of $368.1 million at December 31, 2021. The decrease was primarily due to cash used in operations.

Collaboration revenue for the three months ended March 31, 2022 totaled $11.4 million compared to $3.0 million for the three months ended December 31, 2021. Collaboration revenue was recognized for the performance obligations satisfied through March 31, 2022 under the GSK Collaboration Agreement.

Research and development (R&D) expenses for the three months ended March 31, 2022 totaled $19.7 million compared to $16.1 million for the three months ended December 31, 2021. The increase was primarily due to higher personnel-related expenses, clinical trial expenses and consulting fees.

General and administrative (G&A) expenses for the three months ended March 31, 2022 totaled $5.9 million compared to $5.2 million for the three months ended December 31, 2021. The increase was primarily due to higher personnel-related expenses and consulting fees.

The net loss for the three months ended March 31, 2022 was $14.0 million compared to $18.2 million for the three months ended December 31, 2021. Total stock compensation expense for the three months ended March 31, 2022 was $2.6 million compared to $2.1 million for the three months ended December 31, 2021.

About IDEAYA Biosciences
IDEAYA is a synthetic lethality focused 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 monotherapy cohort expansion and combination cohort initiation in the IDE397 Phase 1 clinical trial, (iii) the timing of the delivery of the GSK option data package, (iii) the timing and content of an additional clinical data update for the darovasertib and crizotinib combination, (iv) the timing of submitting an IND for PARG inhibitor, IDE161, (v) the timing of identification of a development candidate and initiating IND-enabling studies for a Pol Theta inhibitor, (vi) the timing of identification of a development candidate for a Werner Helicase inhibitor, (vii) the potential receipt of GSK milestone payments, (viii) the timing of obtaining FDA guidance for

potential registration-enabling trial design to evaluate the darovasertib and crizotinib combination, (ix) the initiation of an IST to evaluate ID196 in a neo-adjuvant / adjuvant setting, (xi) and (x) 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, 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 recent Quarterly Report on Form 10-Q filed on May 10, 2022 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*)

(Unaudited)

	Three Months Ended	
	March 31, 2022	**December 31, 2021**
Collaboration revenue	$ 11,359	$ 2,963
Operating expenses:		
Research and development	19,656	16,109
General and administrative	5,923	5,223

Total operating expenses	25,579	21,332
Loss from operations	(14,220)	(18,369)
Interest income and other income, net	207	157
Net loss	(14,013)	(18,212)
Unrealized loss on marketable securities	(2,092)	(662)
Comprehensive loss	$ (16,105)	$ (18,874)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.36)	$ (0.47)
Weighted-average number of shares outstanding, basic and diluted	38,591,966	38,501,335

IDEAYA Biosciences, Inc.

Condensed Balance Sheet Data

(*in thousands*)

	March 31, 2022	**December 31, 2021**
	(Unaudited)	
Cash and cash equivalents and short-term and long-term marketable securities	$ 346,227	$ 368,063
Total assets	358,867	381,347
Total liabilities	70,200	79,833

Total liabilities and stockholders' equity	358,867	381,347

SOURCE IDEAYA Biosciences, Inc.

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https://media.ideayabio.com/2022-05-10-IDEAYA-Biosciences,-Inc-Reports-First-Quarter-2022-Financial-Results-and-Provides-Business-Update