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

- Strong balance sheet of ~$324 million cash, cash equivalents and marketable securities as of June 30, 2022 is anticipated to fund planned operations into 2025
- Initiated IDE397 Phase 2 monotherapy expansion cohorts and Phase 1 combination dose escalation cohorts in solid tumors with MTAP deletion
- Entered into Clinical Trial Collaboration and Supply Agreement with Amgen to clinically evaluate IDE397 MAT2A inhibitor in combination with AMG 193, Amgen's investigational small molecule MTA-cooperative inhibitor of PRMT5, in MTAP-null solid tumors
- Retained worldwide rights to IDE397, following GSK waiver of its option to an exclusive license to further develop and commercialize IDE397
- Targeting interim Phase 2 clinical data update for darovasertib and crizotinib synthetic lethal combination in MUM in September 2022, including ORR, mPFS, mDOR, and AEs
- Tracking to submit an IND in Q4 2022 for PARG development candidate IDE161
- Selected potential first-in-class Pol Theta Helicase development candidate with GSK, and targeting Phase 1 initiation in H1 2023 for solid tumors with HRD

SOUTH SAN FRANCISCO, Calif., Aug. 15, 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 second quarter ended June 30, 2022.

"The IDE397 program is at a key inflection point, and as a wholly-owned program, is uniquely positioned for value accretion as we initiate monotherapy expansion and combination cohorts. Our clinical trial collaboration with Amgen enables clinical evaluation of IDE397 in combination with AMG 193, Amgen's investigational MTA-cooperative PRMT5 inhibitor, a potential first-in-class combination inhibiting two complementary synthetic lethal nodes within the MTAP pathway. The clinical ctDNA molecular response data from the IDE397 monotherapy dose escalation demonstrates target engagement and tumor pharmacodynamic modulation, and provides additional data on clinical activity," said Yujiro S. Hata, President and Chief Executive Officer, IDEAYA Biosciences.

"We look forward to providing the interim Phase 2 clinical data update for darovasertib and crizotinib synthetic

lethal combination in first-line and any-line MUM patients in September 2022. This clinical data update will include, confirmed ORR by RECIST, median PFS, median duration-of-response, and an adverse event summary. We will also provide an update on a potential registrational path in MUM, and share observations supporting clinical proof of concept for potential use of darovasertib in the (neo)adjuvant UM setting," continued Mr. Hata.

"We have a pipeline of potential first-in-class synthetic lethality therapeutics advancing toward the clinic. We are targeting an IND in Q4 2022 for IDE161, our PARG inhibitor, for patients having tumors with HRD. In collaboration with GSK, we are targeting first-in-human clinical evaluation in H1 2023 for our Pol Theta Helicase development candidate in combination with niraparib for patients having tumors with HRD, and our Werner Helicase program with GSK continues to be on track for development candidate nomination 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 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). Highlights:

- Patients are being identified by next generation sequencing (NGS) or by MTAP immunohistochemistry (IHC) assay with confirmatory NGS

- Initiated monotherapy expansion cohorts with enrollment open for NSCLC and esophagogastric tumors with MTAP deletion

- Initiated combination dose escalation cohorts with enrollment open for combinations with docetaxel in NSCLC, paclitaxel in esophagogastric cancer, and with pemetrexed in NSCLC and potentially other solid tumors

- Entered into Clinical Trial Collaboration and Supply Agreement with Amgen to clinically evaluate IDE397 MAT2A inhibitor in combination with AMG 193, Amgen's investigational small molecule MTA-cooperative inhibitor of PRMT5, in MTAP-null solid tumors

- Delivered IDE397 option data package to GSK comprising preclinical data and clinical data from the monotherapy dose escalation study of the Phase 1 clinical trial, including safety and tolerability data, pharmacokinetic and pharmacodynamic data

- Retained and fully own all right, title and interest in and to IDE397 and the MAT2A Program, following

receipt of notice from GSK waiving its rights to exercise its option to obtain an exclusive license to further develop and commercialize IDE397, as well as other IDEAYA compounds, if any, directly targeting MAT2A

- Wholly-owned Phase 2 clinical asset, IDE397 provides company with additional strategic optionality as monotherapy and combination therapies advance
- Strategic rationale of the IDE397 collaboration with GSK became less compelling for IDEAYA following GSK termination of its internal PRMT5 and Type 1 PRMT clinical programs, each of which was contemplated as a potential combination partner with IDE397 when the partnership was formed in June 2020
- IDEAYA is sufficiently capitalized to execute the IDE397 Phase 2 clinical program

- Demonstrated IDE397 clinical tumor pharmacodynamic modulation based on ctDNA Molecular Responses observed in thirteen evaluable patients with liquid biopsy samples available at baseline and after first treatment cycle, including:
  - 31% (n=4 of 13) of evaluable patients treated with IDE397 across all dose escalation Cohorts 1 thru 6 observed ctDNA molecular responses
  - 75% (n=3 of 5) of evaluable patients treated with IDE397 at higher doses in Cohorts 5 and 6 observed ctDNA molecular responses
  - 100% (n=2 of 2) of evaluable NSCLC patients observed ctDNA molecular responses

Darovasertib (PKC)

IDEAYA continues to advance its Phase 1/2 clinical trial evaluating darovasertib (IDE196), a potent and selective PKC inhibitor, 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 (neo)adjuvant uveal melanoma (UM) as monotherapy through an investigator sponsor clinical trial (IST).

IDEAYA is planning to initiate a company-sponsored clinical trial to evaluate darovasertib in (neo)adjuvant uveal melanoma. The company is also evaluating other potential darovasertib expansion opportunities, including in cMET driven tumors and in KRAS-mutation tumors.

Darovasertib / Crizotinib Combination Therapy in Metastatic Uveal Melanoma (MUM)

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:

- IDEAYA presented preliminary darovasertib and crizotinib clinical combination data in December 2021. The reported preliminary data, based on an unlocked database, showed robust clinical activity, including 31% ORR (n=4 of 13 evaluable) in heavily pre-treated MUM patents, with manageable side effect profile

- Historical % ORR and median PFS by other therapies in MUM have been low, including ranging from 0% to 5% ORR and 2 to 3 months median PFS

- Prioritizing enrollment of additional first-line MUM patients based on observed early clinical partial responses

- Targeting interim Phase 2 clinical results for darovasertib and crizotinib synthetic lethal combination in first-line and any-line MUM patients in September 2022, including:

    - clinical efficacy in MUM based on confirmed overall response rate by RECIST, median progression-free survival, median duration of response and adverse event summary

    - potential registrational path for darovasertib and crizotinib combination in MUM

    - clinical proof of concept for potential use of darovasertib in (neo) adjuvant UM

- In April 2022, the FDA designated darovasertib as an Orphan Drug in Uveal Melanoma, including 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 – (Neo)Adjuvant Uveal Melanoma (UM)

IDEAYA is evaluating the potential for darovasertib in neoadjuvant and/or adjuvant uveal melanoma. Highlights:

- (Neo)adjuvant UM represents a significant expansion opportunity – with a potential annual incidence of approximately 6,400 patients aggregate in US and Europe

- IDEAYA has initiated an Investigator Sponsored Trial with St. Vincent's Hospital Sydney Limited to evaluate darovasertib as monotherapy in a neo-adjuvant and/or adjuvant setting in uveal melanoma patients

Darovasertib – Other Potential Indications

IDEAYA is evaluating the potential for darovasertib in other oncology indications, including in cMET-driven

tumors and RAS-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; targeting initiation of a Phase 1/2 clinical trial in the first quarter of 2023

- Evaluating darovasertib in combination with a KRAS inhibitor in preclinical studies in KRAS-driven solid tumors

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

- Considering potential development approaches based on observed activity of IDE161 in PARPi resistant and/or platinum-resistant tumors, differentiated sensitivity relative to PARP inhibitors, and improved preliminary safety profile relative to PARP inhibitors

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:

- Selected a potential first-in-class Pol Theta Helicase development candidate in collaboration with GSK

- Observed complete responses in preclinical combination studies of Pol Theta Helicase DC with niraparib in multiple in vivo PDX and CDX HRD models

- Targeting first-in-human clinical evaluation of Pol Theta Helicase DC combination with niraparib in H1 2023 for patients having tumors with HRD

- IDEAYA is eligible to receive future development and regulatory milestones of up to $485 million aggregate from GSK:

- Preclinical and clinical milestones of up to $20 million in aggregate for advancing a Pol Theta Helicase inhibitor from preclinical to early Phase 1 clinical, including up to $10 million aggregate through IND effectiveness

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.

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 $22.1 million and $14.0 million for the three months ended June 30, 2022 and March 31, 2022, respectively. As of June 30, 2022, the company had an accumulated deficit of $212.8 million.

As of June 30, 2022, IDEAYA had cash, cash equivalents and marketable securities of $323.8 million. 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 June 30, 2022, IDEAYA had cash, cash equivalents and short-term marketable securities totaling $323.8 million. This compared to cash, cash equivalents and short-term and long-term marketable securities of $346.2

million at March 31, 2022. The decrease was primarily due to cash used in operations.

Collaboration revenue for the three months ended June 30, 2022 totaled $5.9 million compared to $11.4 million for the three months ended March 31, 2022. Collaboration revenue was recognized for the performance obligations satisfied through June 30, 2022 under the GSK Collaboration Agreement.

Research and development (R&D) expenses for the three months ended June 30, 2022 totaled $22.8 million compared to $19.7 million for the three months ended March 31, 2022. The increase was primarily due to higher personnel-related expenses, clinical trial expenses and outside services.

General and administrative (G&A) expenses for the three months ended June 30, 2022 totaled $5.6 million compared to $5.9 million for the three months ended March 31, 2022. The decrease was primarily due to lower personnel-related expenses and outside services.

The net loss for the three months ended June 30, 2022 was $22.1 million compared to $14.0 million for the three months ended March 31, 2022. Total stock compensation expense for the three months ended June 30, 2022 was $3.0 million compared to $2.6 million for the three months ended March 31, 2022.

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 and content of an additional clinical data update for the darovasertib and crizotinib combination, (iii) the timing of submitting an IND for PARG inhibitor, IDE161, (iv) the timing of identification of initiating first-in-human clinical evaluation of Pol Theta inhibitor with niraparib, (v) the initiation of an IST to evaluate ID196 in a neo-adjuvant / adjuvant setting, (vi) the timing of initiation of a Phase 1/2 darovasertib and crizotinib clinical trial in cMET-driven tumors, (vii) the timing of identification of a development candidate for a Werner Helicase inhibitor, and (viii) 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 August 15, 2022 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

IDEAYA Biosciences, Inc.

Condensed Statements of Operations and Comprehensive Loss

(*in thousands, except share and per share amounts*)

(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2022	**March 31, 2022**	**June 30, 2022**	**June 30, 2021**
Collaboration revenue	$ 5,851	$ 11,359	$ 17,210	$ 16,003
Operating expenses:				
Research and development	22,796	19,656	42,451	26,546
General and administrative	5,554	5,923	11,478	9,643
Total operating expenses	28,350	25,579	53,929	36,189
Loss from operations	(22,499)	(14,220)	(36,719)	(20,186)
Interest income and other income, net	443	207	650	218
Net loss	(22,056)	(14,013)	(36,069)	(19,968)
Unrealized loss on marketable securities	(825)	(2,092)	(2,917)	(11)
Comprehensive loss	$ (22,881)	$ (16,105)	$ (38,986)	$ (19,979)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.57)	$ (0.36)	$ (0.93)	$ (0.62)
Weighted-average number of shares outstanding, basic and diluted	38,660,971	38,591,966	38,626,659	32,321,481

IDEAYA Biosciences, Inc.

Condensed Balance Sheet Data

(*in thousands*)

	June 30, 2022	December 31, 2021
	(Unaudited)	
Cash and cash equivalents and short-term and long-term marketable securities	$ 323,791	$ 368,063
Total assets	338,007	381,347
Total liabilities	68,686	79,833
Total liabilities and stockholders' equity	338,007	381,347

SOURCE IDEAYA Biosciences, Inc.

For further information: IDEAYA Biosciences, Paul Stone, Senior Vice President and Chief Financial Officer, investor@ideayabio.com

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https://media.ideayabio.com/2022-08-15-IDEAYA-Biosciences,-Inc-Reports-Second-Quarter-2022-Financial-Results-and-Provides-Business-Update