

IDEAYA Biosciences, Inc. Reports Second Quarter 2020 Financial Results and Provides Business Update

- **Established strategic partnership with GlaxoSmithKline on Synthetic Lethality programs MAT2A, Pol Theta and Werner Helicase**
- **Enhanced balance sheet through non-dilutive up-front cash payment and follow-on financing, extending cash runway into 2024**
- **IDE397, a potential best-in-class MAT2A inhibitor, on-track for an IND-filing in Q4 2020**
- **IDE196 demonstrated early clinical efficacy in GNAQ/11 skin melanoma; dosed first patient for IDE196/binimetinib clinical combination through Pfizer collaboration and supply agreement**

SOUTH SAN FRANCISCO, Calif., Aug. 12, 2020 [/PRNewswire/](#) -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), an oncology-focused precision medicine 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, 2020.

"This quarter was transformational for IDEAYA. We have cash runway into 2024, with quarter-end cash, cash equivalents and marketable securities of \$172.0 million supplemented by \$127.5 million aggregate gross proceeds received subsequently, including \$100 million non-dilutive upfront cash and \$20 million private placement equity investment from GSK. In addition, through our GSK strategic partnership and our Pfizer collaboration and supply agreement, we have established an attractive cost structure and retained significant future upside across our pipeline, while also creating opportunities for non-dilutive cash milestones of approximately \$3 billion across three programs with GSK. We also nominated MAT2A development candidate IDE397, initiated the IDE196 and binimetinib Phase 1 combination, and met the criteria for IDE196 Phase 2 expansion in skin melanoma. As we celebrate our five-year anniversary, we have built a strong foundation to create the industry leading Synthetic Lethality-focused precision medicine oncology company," said Yujiro S. Hata, Chief Executive Officer and President of IDEAYA Biosciences.

GlaxoSmithKline Strategic Partnership

IDEAYA and GSK entered into a strategic partnership in Synthetic Lethality focused on IDEAYA's MAT2A, Pol Theta, and Werner Helicase programs – each of which has a strong rationale for collaborating, including potential clinical combinations with GSK precision medicine therapeutics. The strategic partnership includes small molecule and protein degrader modalities.

IDEAYA retains all rights and interests in its other pipeline assets, including preclinical programs targeting PARG and a proprietary DNA Damage Target, as well as its clinical candidate IDE196 for patients having tumors harboring GNAQ or GNA11 hotspot mutations.

Program Updates

Key highlights for IDEAYA's pipeline programs include:

MAT2A

IDEAYA's lead synthetic lethality research program targets MAT2A for solid tumors with MTAP deletions, a patient population estimated to represent approximately 15% of solid tumors. IDEAYA continues to lead research and development on the MAT2A program through early clinical development. Subject to exercise of its option, GSK will lead later stage global clinical development. Highlights:

- Designated MAT2A inhibitor IDE397 as a development candidate;
- Demonstrated IDE397 *in vivo* dose-dependent efficacy and tumor regression (with >100% TGI, or tumor growth inhibition) as monotherapy in an endogenous non-small cell lung cancer MTAP-null PDX model;
- Initiated good laboratory practice (GLP)-compliant toxicology studies with IDE397 in two species;
- On track for IND submission to the FDA for IDE397 in the fourth quarter of 2020, subject to satisfactory completion of GLP toxicology studies;
- Plan to initiate a Phase 1 clinical trial for clinical evaluation of IDE397 as monotherapy in the first half of 2021, subject to effectiveness of the IND; and
- IDEAYA and GSK are evaluating a potential phase 1 combination clinical trial for IDEAYA's MAT2A inhibitor (IDE397) and GSK's Type I PRMT inhibitor (GSK3368715).

PARG

IDEAYA is advancing preclinical research for an inhibitor of poly (ADP-ribose) glycohydrolase, or PARG. PARG inhibitors have shown synthetic lethality with tumors harboring BRCA2 mutations, impaired base excision repair, or BER, and potentially other genetic and/or molecular signatures. Highlights:

- Demonstrated *in vivo* proof of concept in a relevant animal model having a replication stress genetic

signature;

- Validating a potential synthetic lethality biomarker for identifying tumor cells having sensitivity to a PARG inhibitor;
- Observed monotherapy PARG inhibitor *in vivo* efficacy in multiple PDX models, including tumor regression; and
- Targeting to identify a PARG inhibitor development candidate in 2021

Pol Theta

IDEAYA's Pol Theta program targets tumors with BRCA or other homologous recombination deficiency (HRD) mutations. IDEAYA and GSK will collaborate on ongoing preclinical research, including small molecules and protein degraders, and GSK will lead clinical development for the Pol Theta program.

Subject to such preclinical studies, we are targeting to file an IND for a Pol Theta inhibitor in 2021.

Highlights:

- Demonstrated *in vivo* efficacy with tumor regression in BRCA2 -/- xenograft model with IDEAYA Pol Theta inhibitor in combination with niraparib, a GSK PARP inhibitor

Werner Helicase

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

Expanding Synthetic Lethality Pipeline and Synthetic Lethality Platform

IDEAYA has initiated additional preclinical synthetic lethality research programs, including for a DNA Damage Target (DDT), for patients with solid tumors characterized by a proprietary biomarker or gene signature.

IDEAYA continues to build its Synthetic Lethality platform, investing in target identification, biomarker discovery and drug discovery, including small molecules and protein degraders, to create the industry leading Synthetic Lethality and DNA Damage based pipeline.

IDE196

IDEAYA continued to execute on its clinical trial, initiated in June 2019, to evaluate IDE196 in Metastatic Uveal Melanoma (MUM) and Non-MUM solid tumors harboring activating GNAQ/11 mutations. The clinical development strategy for IDE196 is focused on evaluating IDE196 combination therapy for the MUM indication, and evaluating IDE196 monotherapy in non-MUM GNAQ/11 hotspot mutation solid tumors, such as skin melanoma.

Combination Therapy

IDEAYA is enrolling MUM patients into a combination arm of the IDE196 Phase 1/2 clinical trial to evaluate safety and efficacy of IDE196 in combination with binimetinib, a MEK inhibitor. We may also evaluate IDE196 / binimetinib combination therapy in patients having other solid tumors with activating GNAQ/11 hotspot mutations, such as skin melanoma. The combination arm is being conducted under a clinical trial collaboration and supply agreement with Pfizer Inc., pursuant to which Pfizer supplies us with their MEK inhibitor, binimetinib; the companies established a Joint Development Committee with Pfizer to facilitate combination arm drug supply, trial initiation and ongoing development. Highlights:

- First-Patient-In (FPI) of a MUM patient for IDE196 / binimetinib combination arm of the IDE196 clinical trial in June 2020;
- Initiated dosing into a first cohort of the IDE196 / binimetinib dose escalation portion of combination arm; and
- Interim data from evaluation of IDE196 / binimetinib combination therapy anticipated in late 2021 to early 2022.

Monotherapy

IDEAYA is actively enrolling into the IDE196 monotherapy Phase 2 tissue-type agnostic basket arm in Non-MUM solid tumors having GNAQ or GNA11 hotspot mutations, including skin melanoma. Highlights:

- Clinical protocol criteria met for cohort expansion in cutaneous melanoma, or skin melanoma. Of 4 evaluable skin melanoma patients harboring GNAQ/11 hotspot mutations (out of 5 total enrolled; excluding 1 non-evaluable), a 100% Disease Control Rate was observed, and one confirmed partial

response (cPR) was determined by RECIST 1.1 guidelines;

- The skin melanoma patient with cPR observed an initial partial response (-31.1%) at 8 weeks, which was sustained at 20 weeks (-37%) with reduction in target liver lesion and inguinal lymph node. Treatment with IDE196 is ongoing as of August 1, 2020;
- Dosed first leiomyosarcoma patient in the Phase 2 GNAQ/11 basket arm, expanding the tissue-agnostic approach to additional solid tumors;
- Established a relationship with CARIS through which we are accessing their network of clinical trial sites into which we can enroll qualifying patients having tumors harboring GNAQ/11 hotspot mutations; and
- Interim data from the monotherapy arm of the Phase 2 basket trial anticipated in first half of 2021.

General

IDEAYA completed IDE196 tablet formulation and successfully introduced the tablet in the ongoing clinical trial, including the IDE196 / binimetinib combination arm and the GNAQ/11 basket arm.

IDEAYA completed 13-week GLP-compliant toxicology studies in two species, with receipt of submission-ready audited draft reports.

IDEAYA continues to monitor Covid-19 and its potential impact on clinical trials and timing of clinical data results. Covid-19 infection rates have increased recently in several states in which our clinical trial sites are located. As such, ongoing monitoring of enrolled patients, including obtaining patient computed tomography (CT) scans, may be impacted, and new patient enrollment into the Phase 2 expansion arm for IDE196 as a monotherapy in non-MUM solid tumors having GNAQ or GNA11 hotspot mutations may be delayed; the specific impacts are currently uncertain.

Corporate Updates

IDEAYA anticipates that existing cash, cash equivalents, and short-term and long-term marketable securities of \$172.0 million as of June 30, 2020, together with the additional aggregate gross proceeds of \$127.5 million received from GSK as up-front cash payment and from equity investments subsequent to June 30, 2020, will be sufficient to fund planned operations into 2024, and through potential achievement of multiple preclinical and clinical milestones across multiple programs.

Our updated corporate presentation is available on our website, in the Presentations section of our Investor Relations page. See: <https://ir.ideayabio.com/news-events/presentations>.

Financial Results

As of June 30, 2020, IDEAYA had cash, cash equivalents, and short-term and long-term marketable securities totaling \$172.0 million. This compared to cash, cash equivalents and short-term marketable securities of \$100.5 million at December 31, 2019. The increase was primarily due to \$93.6 million in net proceeds from IDEAYA's follow-on public offering through June 30, 2020.

Research and development (R&D) expenses for the three months ended June 30, 2020 totaled \$8.6 million compared to \$8.9 million for the same period in 2019. The decrease was primarily due to a decrease in R&D headcount and laboratory supply costs, offset by an increase in costs related to our IDE196 clinical trial and the advancement of IDE397 through preclinical studies.

General and administrative (G&A) expenses for the three months ended June 30, 2020 totaled \$4.0 million compared to \$2.4 million for the same period in 2019. The increase was primarily due to an increase in G&A headcount costs, director and officer insurance policy premiums, costs related to our shelf registration statement filing on Form S-3, and an increase in legal expenses.

The net loss for the three months ended June 30, 2020 was \$12.4 million compared to \$10.7 million for the same period in 2019. Total stock compensation expense for the three months ended June 30, 2020 was \$0.8 million compared to \$0.5 million for the same period in 2019.

About IDEAYA Biosciences

IDEAYA is an oncology-focused precision medicine 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 small molecule drug discovery to select patient populations most likely to benefit from the targeted therapies IDEAYA is developing. IDEAYA is applying these capabilities across multiple classes of precision medicine, including direct targeting of oncogenic pathways and 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 potential to receive cash payments under the GSK collaboration, (iii) the timing of filing of an IND and initiation of a Phase 1 clinical trial for IDE397, (iv) the timing of identification of a development candidate for a PARG inhibitor, (v) the timing of filing of an IND for a Pol Theta inhibitor, (vi) the potential to evaluate IDE196 / binimetinib combination in other solid tumor types, (vii) the timing of release of interim data for the IDE196 / binimetinib combination, and (viii) the timing of release of interim monotherapy data for the IDE196 Phase 1/2 basket trial. 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, 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 12, 2020 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

IDEAYA Biosciences, Inc.

Condensed S tatements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Operating expenses				
Research and development	\$ 8,596	\$ 8,859	\$ 17,622	\$ 16,855
General and administrative	3,994	2,376	7,446	4,474
Total operating expenses	12,590	11,235	25,068	21,329
Loss from operations	(12,590)	(11,235)	(25,068)	(21,329)
Interest income and other income (expense), net	199	579	634	1,104
Net loss	\$ (12,391)	\$ (10,656)	\$ (24,434)	\$ (20,225)
Change in unrealized gains (losses) on marketable securities	57	29	(8)	68
Comprehensive loss	\$ (12,334)	\$ (10,627)	\$ (24,442)	\$ (20,157)
Net loss per				

share				
attributable to				
common				
stockholders,				
basic and				
diluted	\$ (0.59)	\$ (1.30)	\$ (1.18)	\$ (4.32)
Weighted				
average number				
of shares				
outstanding,				
basic and				
diluted	21,001,730	8,218,010	20,626,139	4,679,206

IDEAYA Biosciences, Inc.

Condensed Balance Sheet Data

(in thousands)

	June 30,	December 31,
	2020	2019
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Cash and cash equivalents and short-term and long-term		
marketable securities	\$ 171,959	\$ 100,482
Total assets	184,510	113,001
Total liabilities	12,452	12,601
Total liabilities and stockholders' equity	184,510	113,001

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SOURCE IDEAYA Biosciences, Inc.

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<https://media.ideayabio.com/2020-08-12-IDEAYA-Biosciences-Inc-Reports-Second-Quarter-2020-Financial-Results-and-Provides-Business-Update>