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

- IDE397, a potential best-in-class MAT2A inhibitor for patients with solid tumors having MTAP deletion, targeting an IND-filing in December 2020
- PARG and Pol Theta programs targeting Development Candidate in 2021
- Targeting IDE196 / binimetinib combination dose selection and expansion in Q1 2021
- Anticipate interim data in 2021 for each of IDE196/binimetinib combination arm and IDE196 monotherapy arm of Phase 1/2 GNAQ/11 basket trial

SOUTH SAN FRANCISCO, Calif., Nov. 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 third quarter ended September 30, 2020.

"We are advancing a broad pipeline of potential first-in-class synthetic lethality programs and executing on our IDE196 clinical strategy, including MEK and cMET combinations in MUM, and monotherapy development in skin melanoma and additional non-MUM GNAQ/11 solid tumors. Our synthetic lethality pipeline includes three programs recently partnered with GSK targeting MAT2A, Pol Theta and Werner Helicase, as well as three wholly-owned or controlled programs targeting PARG, DNA Damage Target 1 (DDT1) and DNA Damage Target 2 (DDT2). We are continuing to invest in our synthetic lethality platform, including through our strategic partnerships with the Broad Institute and UCSD, and enhancing our internal research capabilities to extend our leadership in synthetic lethality," said Yujiro S. Hata, Chief Executive Officer and President of IDEAYA Biosciences.

Program Updates

Key highlights for IDEAYA's pipeline programs include:

IDE397 (MAT2A)

IDEAYA is developing IDE397, a potent and selective small molecule inhibitor targeting 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:

- Evaluating efficacy of monotherapy IDE397 in over forty patient-derived xenograft (PDX) models with homozygous MTAP deletions in solid tumors;
- Completed in-life phase of good laboratory practice (GLP)-compliant toxicology studies with IDE397 in two species;
- Targeting IND submission for IDE397 in December 2020, subject to satisfactory completion of GLP toxicology studies and completion of chemistry, manufacturing and control, or CMC, certification requirements;
- 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 IDE397 and GSK's Type I PRMT inhibitor, GSK3368715.

PARG

IDEAYA is advancing preclinical research for an inhibitor of PARG. PARG inhibitors have shown synthetic lethality with tumors harboring homologous recombination deficiency (HRD) mutations and potentially other genetic and/or molecular signatures. Highlights:

- Demonstrated monotherapy PARG inhibitor *in vivo* efficacy in multiple PDX models
- Entered into a strategic collaboration with the Broad Institute of MIT and Harvard, pursuant to which in a PARG program initiative, IDEAYA and Broad Institute will evaluate paralog CRISPR knockdown in selected cell lines in conjunction with pharmacological inhibition of PARG to inform patient selection and combination strategies in ovarian and breast cancer; and
- Targeting to identify a PARG inhibitor development candidate in 2021.

Pol Theta

IDEAYA's Pol Theta program targets tumors with BRCA or other HRD mutations. 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:

- Demonstrated *in vivo* efficacy with tumor regression in BRCA2 -/- xenograft model with IDEAYA Pol Theta inhibitor in combination with niraparib, a GSK PARP inhibitor; and
- Targeting selection of a Pol Theta inhibitor development candidate in 2021.

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.

DNA Damage Targets

IDEAYA has initiated multiple preclinical synthetic lethality research programs, designated as DDT1 and DDT2, to identify small molecule inhibitors for DNA Damage Targets (DDT's) for patients with solid tumors characterized by a proprietary biomarker or gene signature.

Synthetic Lethality Platform

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 and sustain an industry leading synthetic lethality pipeline. Highlights:

- Synthetic lethality research platform integrates computational and functional capabilities to identify synthetic lethal pairs in defined patient populations; the platform includes parallel data sets with orthogonal content based on screens of curated, genetically defined model cells, including IDEAYA-proprietary libraries and data sets such as PAGEO™ and DECIPHER™, partnership data sets such as DepMap and Foundation Insights™, and multiple public databases.
- PAGEO™ Paralogous Gene Evaluation in Ovarian Cancer – Broad Institute
    - Entered into a strategic collaboration with the Broad Institute of MIT and Harvard focused on synthetic lethality target and biomarker discovery
    - Collaboration will use large-scale CRISPR paralog screening platform developed at the laboratory of William R. Sellers, M.D., Core Institute Member, Broad Institute, to evaluate functionally redundant paralogous genes across ovarian cancer subtypes and to generate novel target and biomarker hypotheses
    - Dr. Sellers, who also serves on IDEAYA Scientific Advisory Board, is the principal investigator for the strategic collaboration
- DECIPHER™ Dual CRISPER Synthetic Lethality Library – UCSD
    - Constructed DECIPHER Dual CRISPR library for synthetic lethality target and biomarker discovery in collaboration with the University of California, San Diego
    - Bioinformatics analysis and validation ongoing for DECIPHER 1.0 library, focused on DNA Damage Repair targets across various tumor suppressor genes and oncogenes selected based on their known prevalence and role in solid tumors
- DepMap (Cancer Dependency Map) – Broad Institute
    - Joined the DepMap (Cancer Dependency Map) consortium led by the Broad Institute, through which we have access to a comprehensive data set of genome-wide cell-based synthetic lethality screens conducted by the Broad and other contributing institutes, including pre-publication access to new data releases

IDE196 (PKC)

IDEAYA continues to execute on its clinical trial strategy to evaluate IDE196 combination therapies in Metastatic Uveal Melanoma (MUM) and to evaluate IDE196 monotherapy in Non-MUM solid tumors harboring activating GNAQ/11 mutations. Interim data for each of the IDE196 / binimetinib combination arm for MUM and the IDE196 monotherapy arm of the Phase 1/2 basket trial is anticipated in 2021.

Combination Therapies

IDEAYA expanded the scope of its clinical trial and supply agreement with Pfizer to evaluate IDE196 and crizotinib, a cMET inhibitor, as a combination therapy in patients having tumors harboring activating GNAQ or GNA11 hotspot mutations. This extends the prior relationship to evaluate IDE196 and binimetinib, a MEK inhibitor, as a combination therapy in such patients. Highlights:

- Pfizer will supply IDEAYA with their cMET inhibitor, crizotinib, in addition to their MEK inhibitor, binimetinib, to support the IDEAYA-sponsored clinical combination trials
- Targeting initiation of the IDE196/crizotinib study in late 2020 to early 2021
- Continuing enrollment into the IDE196 / binimetinib combination arm under the clinical trial collaboration and supply agreement with Pfizer and targeting combination expansion in Q1 2021;

Monotherapy

IDEAYA is actively enrolling patients 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 and other tumor types. Highlights:

- As of November 1, 2020, enrolled a total of 7 patients with GNAQ/11-mutated non-MUM solid tumors into the Phase 2 monotherapy arm, including 6 patients with skin melanoma; and
- Ongoing enrollment for Phase 2 cohort expansion in skin melanoma.

General

IDEAYA completed 13-week GLP-compliant toxicology studies for IDE196 in two species.

IDEAYA continues to monitor Covid-19 and its potential impact on clinical trials and timing of clinical data results. 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 $288.8 million as of September 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 September 30, 2020, IDEAYA had cash, cash equivalents, and short-term and long-term marketable securities totaling $288.8 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 $100.7 million in net proceeds from IDEAYA's follow-on public offering, $100.0 million from the upfront payment received from GSK, and $20.0 million in net proceeds from the private placement with GSK received through September 30, 2020.

Collaboration revenue for the three months ended September 30, 2020 totaled $9.0 million compared to zero for the same period in 2019. Collaboration revenue was recognized for the performance obligations satisfied through September 30, 2020 under the GSK Collaboration Agreement.

Research and development (R&D) expenses for the three months ended September 30, 2020 totaled $10.0 million compared to $8.9 million for the same period in 2019. The increase was primarily due to the Phase 1/2 clinical trial to evaluate IDE196 in solid tumors, and the advancement of our lead product candidates through preclinical studies and regulatory support activity, offset by a decrease in laboratory supplies and payroll expense.

General and administrative (G&A) expenses for the three months ended September 30, 2020 totaled $3.9 million compared to $2.7 million for the same period in 2019. The increase was primarily due to an increase in G&A headcount costs and an increase in consulting expenses.

The net loss for the three months ended September 30, 2020 was $4.9 million compared to $11.0 million for the same period in 2019. Total stock compensation expense for the three months ended September 30, 2020 was $1.0 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 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 filing of an IND and initiation of a Phase 1 clinical trial for IDE397, (ii) the timing of identification of a development candidate for a PARG in inhibitor, (iii) the timing of identification of a development candidate for a Pol Theta inhibitor, (iv) the timing of release of interim data for the IDE196/binimetinib combination arm of the Phase 1/2 GNAQ/11 basket trial, (v) the timing of release of interim data for the IDE196 monotherapy arm of the Phase 1/2 GNAQ/11 basket trial, (vi) the extent to which IDEAYA's existing cash, cash equivalents, and marketable securities will fund its planned operations, and (vii) the timing of initiation of the IDE196/crizotinib study. 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 November 12, 2020 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*)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Collaboration revenue	$ 8,967	$ —	$ 8,967	$ —
Total revenue	8,967	—	8,967	—
Operating expenses				
Research and development	10,024	8,923	27,647	25,778
General and administrative	3,939	2,700	11,384	7,174
Total operating expenses	13,963	11,623	39,031	32,952

Loss from operations	(4,996)	(11,623)	(30,064)	(32,952)
Interest income and other income (expense), net	70	654	704	1,758
Net loss	$ (4,926)	$ (10,969)	$ (29,360)	$ (31,194)
Change in unrealized gains (losses) on marketable securities	(22)	41	(30)	109
Comprehensive loss	$ (4,948)	$ (10,928)	$ (29,390)	$ (31,085)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.17)	$ (0.54)	$ (1.26)	$ (3.15)
Weighted average number of shares outstanding, basic and diluted	28,396,670	20,158,223	23,235,218	9,895,574

IDEAYA Biosciences, Inc.

Condensed Balance Sheet Data

(*in thousands*)

	September 30, 2020	December 31, 2019
Cash and cash equivalents and short-term and long-term marketable securities	$ 288,841	$ 100,482
Total assets	301,384	113,001
Total liabilities	105,955	12,601
Total liabilities and stockholders' equity	301,384	113,001

SOURCE IDEAYA Biosciences, Inc.

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

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https://media.ideayabio.com/2020-11-12-IDEAYA-Biosciences-Inc-Reports-Third-Quarter-2020-Financial-Results-and-Provides-Business-Update