IDEAYA Biosciences, Inc. Reports Second Quarter 2019 Financial Results and Provides Business Update

SOUTH SAN FRANCISCO, Calif., Aug. 12, 2019 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics, provided a business update and announced financial results for the second quarter ended June 30, 2019.

"The initiation of our Phase 1/2 basket trial evaluating IDE196 in patients with solid tumors harboring GNAQ/11 mutations is an important step in the clinical development of IDE196. We are identifying and enrolling patients with solid tumors having likely pathogenic GNAQ/11 hotspot mutations that activate the PKC signaling pathway. We believe this pathway has clinical significance in metastatic uveal melanoma, cutaneous melanoma and other solid tumors," said Yujiro S. Hata, Chief Executive Officer and President at IDEAYA Biosciences.

IDEAYA continues to advance its MAT2A synthetic lethality program to treat patients having tumors with MTAP deletion. The company remains on track to select a MAT2A inhibitor as a development candidate for IND-enabling studies in Q4 2019. IDEAYA is also progressing a broad pipeline of additional synthetic lethality programs. These include Pol theta for patients having tumors with BRCA or other homologous recombination deficiency (HRD) mutations, and Werner (WRN) for patients having tumors with high microsatellite instability (MSI).

Key highlights for IDEAYA's research and development programs include:

Clinical Program IDE196

IDE196

- Initiated IDEAYA's Phase 1/2 tissue-type agnostic GNAQ / GNA11 basket trial in June 2019 entitled "*A phase 1/2 study of IDE196 in patients with solid tumors harboring GNAQ/11 mutations or PRKC fusions* (ClinicalTrials.gov Identifier: NCT03947385)
    - Dosed first patient in the Phase 1/2 basket trial with IDE196 in June 2019
    - Completed enrollment of first cohort in the Phase 1 dose escalation portion of the Phase 1/2 trial at sites in the U.S. and Australia, and anticipate dose selection for the Phase 2 portion of the trial by year-end 2019
    - Identified patients for potential enrollment in the Phase 1/2 basket trial with GNAQ/GNA11 hotspot mutations in solid tumors outside of uveal melanoma
    - Anticipate release of interim data from the Phase 1/2 basket trial in Q2/Q3 2020
- Continued the ongoing Phase 1 clinical trial, entitled "*A Phase I, multi-center, open-label, study of LXS196, an oral protein kinase C inhibitor, in patients with metastatic uveal melanoma*" (ClinicalTrials.gov Identifier: NCT02601378), being conducted by Novartis
    - As of August 10, 2019, five of 28 evaluable patients in the monotherapy BID cohort continue on therapy for more than two years, with four of these patients having a partial response or stable disease, and one patient experiencing disease progression from stable disease after approximately 22 months of treatment, and in each case, surpassing the historical median overall survival of approximately 10 months for metastatic uveal melanoma
- Targeting preliminary regulatory discussions with the U.S. Food and Drug Administration (FDA) in Q4 2019

on IDE196 regulatory path for potential approval in metastatic uveal melanoma
- Signed collaborative research agreement with AstraZeneca in August 2019 to evaluate preclinical combination of IDE196 and Osimertinib (Osi), an EGFR inhibitor

Synthetic Lethality Preclinical Pipeline

MAT2A

- On track to select development candidate for IND-enabling studies in Q4 2019
- Demonstrated *in vivo* efficacy in HCT116 MTAP null model with tumor growth inhibition (TGI) of ~60 to ~100% at dose range of 3 to 30 mg/kg once per day, and completed 7-day preclinical *in vivo* tolerability studies of several lead series compounds
- Biomarker evaluation in MTAP deletion

Pol theta

- *In vivo* characterization of lead series compounds
- Biomarker evaluation in BRCA/HRD

Synthetic Lethality Drug Discovery Platform

- Werner: Achieved <100 nanomolar IC_{50} potency in Werner helicase biochemical assay
- Dual CRISPR synthetic lethality target discovery: evaluating data sets in multiple cell lines for identification of novel synthetic lethality targets

"We continue to aggressively progress our programs, underscoring IDEAYA's commitment to build a leading precision medicine oncology company targeting defined patient populations. We are excited for the continued clinical advancement of IDE196 in our tissue-type agnostic basket trial, and to further advance our pipeline of synthetic lethality programs, an emerging new class of precision medicine," said Yujiro S. Hata, Chief Executive Officer and President at IDEAYA Biosciences.

Corporate Updates

IDEAYA completed an initial public offering in May 2019, raising $57.5 million of gross proceeds before deducting underwriting discounts, commissions and estimated offering expenses through the sale of 5,750,00 shares of common stock.

IDEAYA anticipates that existing cash, cash equivalents and short-term marketable securities of $120.2 million (as of June 30, 2019) will be sufficient to fund planned operations into the third quarter of 2021.

Financial Results

As of June 30, 2019, IDEAYA had cash, cash equivalents and short-term marketable securities totaling $120.2 million. This compared to cash, cash equivalents and short-term marketable securities of $90.0 million at December 31, 2018. The increase was primarily due to the receipt of $50.2 million in net proceeds from IDEAYA's initial public offering, which was completed in May 2019.

Research and development expenses for the three months ended June 30, 2019 totaled $8.9 million compared to $6.4 million for the same period in 2018. The increase was primarily due to costs incurred in connection with the initiation of IDEAYA's Phase 1/2 clinical trial to evaluate IDE196 in solid tumors, as well as an increase in personnel and consulting costs.

General and administrative expenses for the three months ended June 30, 2019 totaled $2.4 million compared to $1.1 million for the same period in 2018. The increase was primarily due to an increase in personnel costs and professional fees in connection with becoming a publicly traded company.

The net loss for the three months ended June 30, 2019 was $10.7 million compared to $7.0 million for the same period in 2018. Total stock compensation expense for the three months ended June 30, 2019 was $0.5 million compared to $0.2 million for the same period in 2018.

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) expected timing for dose selection for the Phase 2 portion of the IDE196 Phase 1/2 basket trial, release of interim data for the IDE196 Phase 1/2 basket trial, preliminary regulatory discussions with the FDA on the regulatory path for IDE196, selection of a MAT2A inhibitor development candidate for IND-enabling studies, and selection of a Pol theta inhibitor development candidate for IND-enabling studies, (ii) the extent to which IDEAYA's existing cash, cash equivalents and short-term marketable securities will fund its planned operations and (iii) IDEAYA's ability to select patients likely to benefit from IDEAYA's targeted therapies. 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 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, 2019 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*)
(***Unaudited***)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development	$ 8,859	$ 6,432	$ 16,855	$ 11,634
General and administrative	2,376	1,139	4,474	2,024
Total operating expenses	11,235	7,571	21,329	13,658
Loss from operations	(11,235)	(7,571)	(21,329)	(13,658)
Interest income	573	568	1,098	850
Other income (expense), net	6	8	6	76
Net loss	$ (10,656)	$ (6,995)	$ (20,225)	$ (12,732)
Change in unrealized gains (losses) on marketable securities	29	(6)	68	(32)
Comprehensive loss	$ (10,627)	$ (7,001)	$ (20,157)	$ (12,764)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.30)	$ (7.47)	$ (4.32)	$ (14.41)
Weighted average number of shares outstanding, basic and diluted	8,218,010	936,406	4,679,206	883,674

IDEAYA Biosciences, Inc.
Condensed Balance Sheet Data
(*in thousands, except share and per share amounts*)
(*Unaudited*)

	June 30, 2019	December 31, 2018 (1)
Cash and cash equivalents and short-term marketable securities	$ 120,163	$ 89,961
Total assets	133,358	96,541
Total liabilities	12,750	7,098
Total stockholders' equity (deficit) and redeemable convertible preferred stock	120,608	89,443

(1) Derived from the audited financial statements for the year ended December 31, 2018, included in the Company's Prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the U.S. Securities and Exchange Commission on May 24, 2019.

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