

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): September 23, 2020

IDEAYA Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38915
(Commission
File Number)

47-4268251
(IRS Employer
Identification Number)

7000 Shoreline Court, Suite 350
South San Francisco, California 94080
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 443-6209

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0001 par value per share	IDYA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

On September 24, 2020, IDEAYA Biosciences, Inc. (the “Company”) announced that, effective as of September 23, 2020, it had entered into an amendment (the “Amendment”) of the Clinical Trial Collaboration and Supply Agreement (the “Agreement”), dated March 11, 2020, with Pfizer Inc. (“Pfizer”). Pursuant to the Amendment, the Company and Pfizer will collaborate on a portion of the Company’s Phase 1/2 study in Metastatic Uveal Melanoma (MUM) and other solid tumors harboring activating GNAQ or GNA11 hotspot mutations, in each case pertaining to the clinical evaluation of the Company’s IDE196 compound in combination with Pfizer’s cMET inhibitor, crizotinib (the “IDE196/Crizotinib Combination Study”). The IDE196/Crizotinib Combination Study is in addition to the clinical evaluation of the Company’s IDE196 compound in combination with Pfizer’s MEK inhibitor, binimetinib (the “IDE196/Binimetinib Combination Study”) already initiated under the Agreement. Pursuant to the Amendment, the Company is the sponsor of the IDE196/Crizotinib Combination Study and the Company will provide the Company’s IDE196 compound and will pay for the costs of the IDE196/Crizotinib Combination Study. Pfizer will provide crizotinib for the IDE196/Crizotinib Combination Study at no cost to the Company. The Company and Pfizer will jointly own clinical data and all inventions relating to the combined use of IDE196 and crizotinib from the IDE196/Crizotinib Combination Study. The Company and Pfizer have formed a joint development committee responsible for coordinating all regulatory and other activities under the Agreement, including for both the IDE196/Crizotinib Combination Study and the IDE196/Binimetinib Combination Study. If the clinical data from the IDE196/Crizotinib Combination Study and/or the IDE196/Binimetinib Combination Study is positive, the Company and Pfizer will enter into good faith negotiations to determine a regulatory submission strategy for the compounds.

The foregoing is only a summary description of the terms of the Amendment, does not purpose to be complete and is qualified in its entirety by reference to the Amendment, which will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the fiscal quarter ending September 30, 2020.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated September 24, 2020

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IDEAYA BIOSCIENCES, INC.

Date: September 24, 2020

By: /s/ Yujiro Hata
Yujiro Hata
President and Chief Executive Officer

IDEAYA and Pfizer Expand Clinical Trial Collaboration and Supply Agreement to Evaluate Clinical Combination of IDE196 and Crizotinib in Solid Tumors Harboring GNAQ or GNA11 Mutations

South San Francisco, CA, September 24, 2020 – IDEAYA Biosciences, Inc. (NASDAQ: IDYA), an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics to treat cancer, today announced that it has expanded its clinical trial collaboration and supply agreement with Pfizer Inc. (NYSE: PFE) for an IDEAYA sponsored clinical combination study of IDE196, a Protein Kinase C (PKC) inhibitor, and crizotinib, a cMET inhibitor to which Pfizer has exclusive worldwide rights. The study will evaluate IDE196 and crizotinib combination therapy in patients with solid tumors having GNAQ or GNA11 mutations (GNAQ/11), including metastatic uveal melanoma (MUM), skin melanoma, lung cancer and colorectal cancer.

Evaluating MUM patient clinical samples, IDEAYA identified cMET expression or activation as a potentially valuable biomarker that may guide IDE196 clinical treatment in this indication. IDEAYA also demonstrated preclinical synergy in MUM with the combination of IDE196 and crizotinib, which further supports the potential biomarker on cMET expression.

“We are excited to expand our agreement with Pfizer to evaluate the clinical combination of IDE196 and crizotinib in MUM and other solid tumors with GNAQ or GNA11 mutations,” said Mick O’Quigley, Vice President, Head of Development Operations, IDEAYA Biosciences. “Through our translational research we have identified cMET expression as a potential biomarker, and we are excited to explore this rational combination between IDE196 and crizotinib clinically,” said Mark Lackner, Ph.D., Senior Vice President, Head of Biology and Translational Sciences.

IDEAYA’s clinical development plan in MUM for IDE196 is based on combination therapies, including with binimetinib, a MEK inhibitor, and crizotinib, a cMET inhibitor, enabled through our clinical trial collaboration and drug supply agreement with Pfizer. The company announced First-Patient-In (FPI) for the IDE196 and binimetinib clinical combination in June 2020 and is targeting FPI for the crizotinib clinical trial combination in late 2020 to early 2021. IDEAYA is also evaluating IDE196 as monotherapy in an ongoing GNAQ/11 non-MUM basket trial in additional solid tumor types, including in skin melanoma, where the company announced Phase 2 expansion.

IDEAYA and Pfizer have established a Joint Development Committee (JDC), and there will be joint decision making and data sharing of the clinical trial results between the parties. IDEAYA will sponsor the study and Pfizer will provide the crizotinib drug supply. If there is clinical data from the collaboration studies that could be used to obtain regulatory approvals or label

changes, IDEAYA and Pfizer will enter into good faith negotiations to determine a regulatory submission strategy.

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 clinical potential of crizotinib in combination with IDE196, including whether the combination will enhance the response rate, and the depth and durability of clinical benefit and (ii) the timing of initiation of the combination clinical trial of IDE196 plus crizotinib in late 2021 to early 2022. 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, 2020 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

Investor and Media Contact

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