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): April 16, 2021

CRISPR THERAPEUTICS AG
(Exact name of Registrant as Specified in Its Charter)

Switzerland	**001-37923**	**Not Applicable**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
Baarerstrasse 14 **6300 Zug, Switzerland**		**Not Applicable**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: +41 (0)41 561 32 77

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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 (see General Instructions A.2. below):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, nominal value CHF 0.03	CRSP	The NASDAQ Global 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

Amended and Restated Joint Development and Commercialization Agreement.

In December 2017, CRISPR Therapeutics AG, CRISPR Therapeutics Limited, CRISPR Therapeutics, Inc., and TRACR Hematology Ltd (together, "CRISPR") and Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Europe) Limited (together, "Vertex") entered into a Joint Development and Commercialization Agreement (the "Joint Development Agreement") pursuant to which the parties agreed to, among other things, co-develop and co-commercialize CTX001™ and other product candidates specified in the Joint Development Agreement.

On April 16, 2021, CRISPR and Vertex agreed to amend and restate the Joint Development Agreement and entered into an Amended and Restated Joint Development and Commercialization Agreement (the "A&R JDCA"), pursuant to which the parties agreed to, among other things, (a) adjust the governance structure for the collaboration and adjust the responsibilities of each party thereunder; (b) adjust the allocation of net profits and net losses between the parties with respect to CTX001 only; and (c) exclusively license (subject to CRISPR Entities' reserved rights to conduct certain activities) certain intellectual property rights to Vertex relating to the specified product candidates and products (including CTX001) that may be researched, developed, manufactured and commercialized under such agreement.

The A&R JDCA includes, among other things, provisions relating to the following:

Governance; Activities. CRISPR and Vertex will establish the following committees: (i) a joint oversight committee to provide high-level oversight and (ii) a transition committee to provide for forum planning, discussing and sharing information regarding certain transition activities until completion of such activities. Effective as of the closing of the transaction contemplated by the A&R JDCA, the previously established collaboration strategy team and all working groups established by such team will be disbanded. Each of the committees will contain an equal number of representatives from each of CRISPR and Vertex. The A&R JDCA provides that, subject to the terms and conditions of such agreement, Vertex will have the right to conduct all research, development, manufacturing and commercialization activities relating to the specified product candidates and products (including CTX001) throughout the world subject to CRISPR's reserved right to conduct certain activities. CRISPR continues to participate in certain aspects of such activities in an observer capacity unless and to the extent otherwise agreed to by the parties.

Financial Terms. In connection with the closing of the transaction contemplated by the A&R JDCA, CRISPR will receive a $900 million up-front payment from Vertex and a one-time $200 million milestone payment upon receipt by Vertex of the first marketing approval of the initial product candidate from the U.S. Food and Drug Administration or the European Commission. The net profits and net losses, as applicable, incurred under the A&R JDCA with respect to all product candidates and products specified in the A&R JDCA other than CTX001 shall be shared equally between CRISPR and Vertex. With respect to CTX001 only, the net profits and net losses, as applicable, incurred under the A&R JDCA through July 1, 2021 (or such applicable later date in the event HSR clearance has not been received by October 1, 2021) in connection with the initial shared product (i.e., CTX001) will be shared equally between CRISPR and Vertex, and beginning July 1, 2021 (or such applicable later date in the event HSR clearance has not been received by October 1, 2021), the net profits and net losses, as applicable, incurred under the A&R JDCA will be allocated 40% to CRISPR and 60% to Vertex.

Termination. Either party can terminate the A&R JDCA upon the other party's material breach, subject to specified notice and cure provisions, or, in the case of Vertex, in the event that CRISPR becomes subject to specified bankruptcy, winding up or similar circumstances. Either party may terminate the A&R JDCA in the event the other party commences or participates in any action or proceeding challenging the validity or enforceability of any patent that is licensed to such challenging party pursuant to the A&R JDCA. Vertex also has the right to terminate the A&R JDCA for convenience at any time after giving prior written notice.

If circumstances arise pursuant to which a party would have the right to terminate the A&R JDCA on account of an uncured material breach, such party may elect to keep the A&R JDCA in effect and cause such breaching party to be treated as if it had exercised its opt-out rights with respect to the products associated with such uncured material breach (described below) and the royalties payable to the breaching party would be reduced by a specified percentage.

Opt-Out Rights. Either party may opt out of the development of a product candidate under the A&R JDCA after predetermined points in the development of the product candidate, on a candidate-by-candidate basis. In the event of such opt-out, the party opting-out will no longer share in the net profits and net losses associated with such product candidate and, instead, the opting-out party will be entitled to high single to mid-teen percentage royalties on the net sales of such product, if commercialized.

The closing of the transaction contemplated by the A&R JDCA is subject to certain conditions including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and any other required antitrust clearance.

The foregoing description of the A&R JDCA is only a brief description of the terms of such agreement, does not purport to be a complete description of the rights and obligations of the parties thereunder, and is qualified in its entirety by such agreement, which will be filed with the Securities and Exchange Commission as an exhibit to CRISPR's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 if not earlier.

Item 7.01. Regulation FD Disclosure.

On April 20, 2021, CRISPR issued a press release announcing, among other things, the entry into the A&R JDCA. A copy of the press release is attached hereto as Exhibits 99.1.

The information in this Item 7.01 of Form 8-K, including the accompanying Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liability of such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Description
99.1	Press release issued by CRISPR Therapeutics AG and Vertex Pharmaceuticals Incorporated, dated April 20, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

CRISPR THERAPEUTICS AG

Date: April 20, 2021

By: /s/ Samarth Kulkarni
Samarth Kulkarni, Ph.D.
Chief Executive Officer

Exhibit 99.1

Vertex Pharmaceuticals and CRISPR Therapeutics Amend Collaboration for Development, Manufacturing and Commercialization of CTX001™ in Sickle Cell Disease and Beta Thalassemia

- Under terms of amended agreement, Vertex to lead worldwide development, manufacturing and commercialization of CTX001-

- Revised agreement provides Vertex with 60% and CRISPR with 40% of program economics-

- CRISPR to receive $900 million upfront payment with potential for additional $200 million milestone payment upon CTX001 regulatory approval -

BOSTON, Mass., CAMBRIDGE, Mass., and ZUG, Switzerland, April 20, 2021 – Vertex Pharmaceuticals Incorporated (NASDAQ: VRTX) and CRISPR Therapeutics (NASDAQ: CRSP) today announced that the companies have amended their collaboration agreement to develop, manufacture and commercialize CTX001, an investigational CRISPR/Cas9-based gene editing therapy that is being developed as a potentially curative therapy for sickle cell disease (SCD) and transfusion-dependent beta-thalassemia (TDT). With this revised agreement, Vertex will deploy the breadth of its established global capabilities and proven experience in manufacturing, development, regulatory, and commercialization to maximize the potential for CTX001 to transform the lives of tens of thousands of patients in the U.S., Europe and other countries. CRISPR Therapeutics will continue to support the development of CTX001 and invest in further innovation to maximize its potential.

Under the terms of the amended agreement, Vertex will lead global development, manufacturing and commercialization of CTX001 with support from CRISPR Therapeutics. Vertex will be responsible for 60% of program costs and will receive 60% of profits from future sales of CTX001 worldwide, representing a 10% increase in program economics compared to the previous agreement. CRISPR will be responsible for 40% of costs and will receive 40% of profits. Additionally, CRISPR will receive a $900 million upfront payment, with potential for a $200 million payment upon the first regulatory approval of CTX001.

“Cell and genetic therapies are key to our strategy of developing transformative therapies for serious diseases, and this agreement is an important next step in cementing our leadership in these modalities as we bring forward our broad gene and cell-based therapeutics portfolio. As we take the lead on CTX001, we want to acknowledge the foundational contributions by the team at CRISPR Therapeutics,” said Jeffrey Leiden, M.D., Ph.D., Executive Chairman of Vertex. “Our increased investment in our partnership with CRISPR is based on the compelling clinical profile of CTX001, which shows its potential to be a durable cure for patients with SCD and TDT, and

the rapid progress that we and our partners at CRISPR have made toward registration and commercialization. We see a significant commercial opportunity for CTX001, and we believe we will be able to further enhance that opportunity by fully leveraging the breadth of Vertex's capabilities – including our established and proven R&D and commercialization expertise in serious diseases – to bring CTX001 to more patients around the world, more quickly."

"Working with Vertex, we have made tremendous progress with CTX001, the first CRISPR/Cas9-based therapy to demonstrate proof of concept in the clinic and together we have broken new ground in the treatment of genetic diseases. We have now dosed more than 30 patients with CTX001, with longest follow-up beyond two years, and we are on track to complete enrollment in both clinical trials this year," said Samarth Kulkarni, Ph.D., Chief Executive Officer of CRISPR Therapeutics. "Given the transformative results and momentum that we have generated with this program, we are adopting a new operating model to enable a globally coordinated launch of CTX001, leveraging Vertex's best-in-class global capabilities and leadership in development, manufacturing, and commercialization to enable this medicine to reach all patients that can benefit from it as quickly as possible. We remain deeply committed to the Sickle Cell and Thalassemia patient communities and look forward to continued success in our partnership with Vertex."

The transaction is subject to customary closing conditions and clearances, including clearance under the Hart-Scott Rodino Antitrust Improvements Act.

About CTX001
CTX001 is an investigational, autologous, *ex vivo* CRISPR/Cas9 gene-edited therapy that is being evaluated for patients suffering from TDT or severe SCD, in which a patient's hematopoietic stem cells are edited to produce high levels of fetal hemoglobin (HbF; hemoglobin F) in red blood cells. HbF is a form of the oxygen-carrying hemoglobin that is naturally present at birth, which then switches to the adult form of hemoglobin. The elevation of HbF by CTX001 has the potential to alleviate transfusion requirements for patients with TDT and reduce painful and debilitating sickle crises for patients with SCD.

Based on progress in this program to date, CTX001 has been granted Regenerative Medicine Advanced Therapy (RMAT), Fast Track, Orphan Drug, and Rare Pediatric Disease designations from the U.S. Food and Drug Administration (FDA) for both TDT and SCD. CTX001 has also been granted Orphan Drug Designation from the European Commission for both TDT and SCD, as well as Priority Medicines (PRIME) designation from the European Medicines Agency (EMA) for SCD.

Among gene-editing approaches being investigated/evaluated for TDT and SCD, CTX001 is the furthest advanced in clinical development.

About the CRISPR-Vertex Collaboration
CRISPR Therapeutics and Vertex entered into a strategic research collaboration in 2015 focused on the use of CRISPR/Cas9 to discover and develop potential new treatments aimed at the underlying genetic causes of human disease. CTX001 represents the first potential treatment to emerge from the joint research program.

About Vertex
Vertex is a global biotechnology company that invests in scientific innovation to create transformative medicines for people with serious diseases. The company has multiple approved medicines that treat the underlying cause of cystic fibrosis (CF) — a rare, life-threatening genetic disease — and has several ongoing clinical and research programs in CF. Beyond CF, Vertex has a robust pipeline of investigational small molecule medicines in other serious diseases where it has deep insight into causal human biology, including pain, alpha-1 antitrypsin deficiency and APOL1-mediated kidney diseases. In addition, Vertex has a rapidly expanding pipeline of genetic and cell therapies for diseases such as sickle cell disease, beta thalassemia, Duchenne muscular dystrophy and type 1 diabetes mellitus.

Founded in 1989 in Cambridge, Mass., Vertex's global headquarters is now located in Boston's Innovation District and its international headquarters is in London. Additionally, the company has research and development sites and commercial offices in North America, Europe, Australia and Latin America. Vertex is consistently recognized as one of the industry's top places to work, including 11 consecutive years on Science magazine's Top Employers list and a best place to work for LGBTQ equality by the Human Rights Campaign. For company updates and to learn more about Vertex's history of innovation, visit www.vrtx.com or follow us on Facebook, Twitter, LinkedIn, YouTube and Instagram.

Vertex Special Note Regarding Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, including, without limitation, statements made by Dr. Leiden and Dr. Kulkarni in this press release, and statements regarding: (i) the status and clinical progress of the CTX001 clinical program; (ii) the expected therapeutic benefits of CTX001, including the potential for CTX001 to transform the lives of patients; (iii) the potential closing of the transaction; (iv) future activities of the parties pursuant to the amended collaboration, (v) the potential benefits of the amended collaboration, and (vi) the commercial potential of CTX001. While Vertex believes the forward-looking statements contained in this press release are accurate, these forward-looking statements represent the company's beliefs only as of the date of this press release and there are a number of risks and uncertainties that could cause

actual events or results to differ materially from those expressed or implied by such forward-looking statements. Those risks and uncertainties include, among other things, that the transaction is subject to certain conditions, including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, that data from a limited number of patients may not be indicative of final clinical trial results, that Vertex may not realize the potential benefits of the amended collaboration, and that data from the company's development programs, including the CTX001 program, may not support registration or further development of its potential medicines in a timely manner, or at all, due to safety, efficacy or other reasons, and other risks listed under the heading "Risk Factors" in Vertex's annual report filed with the Securities and Exchange Commission and available through the company's website at www.vrtx.com and on the SEC's website at www.sec.gov. You should not place undue reliance on these statements. Vertex disclaims any obligation to update the information contained in this press release as new information becomes available.

About CRISPR Therapeutics

CRISPR Therapeutics is a leading gene editing company focused on developing transformative gene-based medicines for serious diseases using its proprietary CRISPR/Cas9 platform. CRISPR/Cas9 is a revolutionary gene editing technology that allows for precise, directed changes to genomic DNA. CRISPR Therapeutics has established a portfolio of therapeutic programs across a broad range of disease areas including hemoglobinopathies, oncology, regenerative medicine and rare diseases. To accelerate and expand its efforts, CRISPR Therapeutics has established strategic collaborations with leading companies including Bayer, Vertex Pharmaceuticals and ViaCyte, Inc. CRISPR Therapeutics AG is headquartered in Zug, Switzerland, with its wholly-owned U.S. subsidiary, CRISPR Therapeutics, Inc., and R&D operations based in Cambridge, Massachusetts, and business offices in San Francisco, California and London, United Kingdom. For more information, please visit www.crisprtx.com.

CRISPR Therapeutics Forward-Looking Statement

This press release may contain a number of "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements made by Dr. Kulkarni and Dr. Leiden in this press release, as well as statements regarding CRISPR Therapeutics' expectations about any or all of the following: (i) the status and clinical progress of the CTX001 clinical program and development timelines for product candidates under development by CRISPR Therapeutics and its collaborators; (ii) the timing of the potential closing

of the transaction, future activities of the parties pursuant to the collaboration and the potential benefits of CRISPR Therapeutics' collaboration with Vertex; and (iii) the therapeutic value, development, and commercial potential of CRISPR/Cas9 gene editing technologies and therapies. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects" and similar expressions are intended to identify forward-looking statements. You are cautioned that forward-looking statements are inherently uncertain. Although CRISPR Therapeutics believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: the transaction is subject to certain conditions, including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, CRISPR Therapeutics may not realize the potential benefits of the collaboration, the potential that clinical trial results may not be favorable; uncertainties about regulatory approvals and that future competitive or other market factors may adversely affect the commercial potential for CRISPR Therapeutics' product candidates; the potential impacts due to the coronavirus pandemic such as (x) delays in regulatory review, manufacturing and supply chain interruptions and (y) the timing and progress of clinical trials; uncertainties regarding the intellectual property protection for CRISPR Therapeutics' technology and intellectual property belonging to third parties, and the outcome of proceedings (such as an interference, an opposition or a similar proceeding) involving all or any portion of such intellectual property; and those risks and uncertainties described under the heading "Risk Factors" in CRISPR Therapeutics' most recent annual report on Form 10-K and in any other subsequent filings made by CRISPR Therapeutics with the U.S. Securities and Exchange Commission, which are available on the SEC's website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. CRISPR Therapeutics disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by law.

(VRTX-GEN)

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