
**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 17, 2018

CRISPR THERAPEUTICS AG

(Exact Name of Company as Specified in Charter)

Switzerland
(State or Other Jurisdiction
of Incorporation)

001-37923
(Commission
File Number)

Not Applicable
(IRS Employer
Identification No.)

**Baarerstrasse 14
6300 Zug
Switzerland
+41 (0)41 561 32 77**

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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 Instruction 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))

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 17, 2018, CRISPR Therapeutics AG (the “Company”) entered into a Research Collaboration Agreement (the “Agreement”) with ViaCyte, Inc. (“ViaCyte”). Pursuant to the Agreement, the Company and ViaCyte established a research plan (the “Research Plan”) for the purpose of designing and advancing allogeneic cell therapies derived from gene edited human stem cells for use in the treatment of diabetes type 1, diabetes type 2 and insulin dependent diabetes (together, the “Field”). The term of the research activities expires upon the earlier of (i) obtaining data from the research program that supports the initiation of good laboratory practice toxicology studies for a product candidate for use in the Field (a “POC”) or (ii) the fifth year anniversary of the Agreement, subject to specified extensions (the “Research Term”).

Under the Agreement, the Company and ViaCyte agreed to negotiate to reach agreement regarding the terms governing joint development and commercialization of a product candidate for use in the Field that is developed under the Research Plan during the Research Term for which a POC is established (such agreement the “Commercialization Agreement”). If POC has been established with respect a product candidate for use in the Field, the Commercialization Agreement will become immediately effective. If the parties are unable to finalize the terms of the Commercialization Agreement within a specified period, the parties will submit to the dispute resolution procedures outlined in the Agreement.

Licenses Granted

For purposes of carrying out the parties’ respective activities under the Research Plan, each party granted the other party a non-exclusive, royalty free, fully-paid, worldwide license to perform those activities during the Research Term. In addition, each party also granted the other party a non-exclusive license to research, develop, manufacture and commercialize products and product candidates for use in the Field (the “Commercialization License”). The Commercialization License is exercisable only upon the occurrence of certain termination events outlined in the Agreement including a termination due to the uncured material breach or insolvency of a party or a termination for convenience other than a termination for convenience by the Company within two years after the effective date of the Agreement. The Commercialization License is fully-paid and royalty free, other than as set forth in the Agreement, as summarized below.

Governance

Pursuant to the terms of the Agreement, the Company and ViaCyte will form a Joint Research Committee (the “JRC”) for the purpose of overseeing and coordinating the research activities. The JRC will be comprised of three representatives from each of the Company and ViaCyte and meet at least quarterly to review the progress of the research activities. All decisions by the JRC will be made by consensus. In the event the JRC is unable to reach consensus, the parties will follow the specified dispute resolutions procedures.

Expenses

Each party to the Agreement will be responsible for the costs incurred in connection with their respective activities set forth in the Research Plan. If the a POC is established and the Commercialization Agreement is executed, costs incurred under such agreement will be borne 60% by the Company and 40% by ViaCyte until the first commercial sale of a product for use in the Field (and the parties shall share such costs from and after such time), and the parties will share profits of any commercialized product equally.

Non-Competition

During the Research Term, neither party nor any of its affiliates may, alone or in conjunction with a third party, conduct discovery, research, development, manufacturing or commercialization activities with respect to any product which employs allogeneic cell therapy derived from gene edited human stem cell for use in the Field. In addition, in the event either of the parties acquire rights to a product that employs cell therapy for use in the Field (a “Distracting Product”) as a result of a merger, acquisition or combination with a third party, such acquiring party will either: (i) negotiate with the other party to include such Distracting Product within the Agreement, (ii) divest such Distracting Product within a specified period or (iii) cease all research and development activities related

to the Distracting Product within a specified period. The requirements relating to a Distracting Product in the previous sentence will not apply in the event of a Change of Control of a party (as defined in the Agreement), if the party and its third party acquirer establish specified procedures to segregate the development and research activities under the Agreement from that of the Distracting Product.

Consideration

In connection with entering into the Agreement, the Company agreed to issue, in two tranches, to ViaCyte an aggregate of (i) approximately \$15.0 million of its common shares (the "Shares"), subject to the adjustments set forth below, and (ii) aggregate cash payments of \$10,000 (the "Cash Consideration"). The Shares will be offered and sold pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-221491) filed by the Company with the U.S. Securities and Exchange Commission on November 9, 2017 and declared effective on December 4, 2017. All of the Shares will be valued using the closing price of the Company's common shares on the date of issuance as reported on the Nasdaq Global Market.

Five business days after effective date of the Agreement, the Company will (i) issue the first tranche of Shares equal to \$7.5 million of the Company's common shares (the "First Tranche Shares"), and (ii) \$5,000 of the Cash Consideration. The second tranche of Shares (the "Second Tranche Shares") and the remaining \$5,000 of the Cash Consideration will be issued and paid to ViaCyte on the first business day after the Company files its Quarterly Report on Form 10-Q for the three months ending September 30, 2018. The number of Second Tranche Shares to be issued will be equal to (i) \$15.0 million less (ii) the aggregate net proceeds received by ViaCyte in connection with selling all of the First Tranche Shares. Upon disposition of all the Shares in accordance with the terms of the Agreement, the Company will make a cash payment to ViaCyte if the net proceeds from the disposition of all Shares was less than \$15.0 million, or in the event the net proceeds exceeded \$15.0 million, ViaCyte will make a cash payment to the Company equal to any such excess.

ViaCyte may not sell more than 50,000 Shares in any single trading day.

In lieu of issuing the First Tranche Shares or Second Tranche Shares, the Company may, in its sole discretion, opt to pay ViaCyte an amount of cash equal to the value of the First Tranche Shares or Second Tranche Shares, as applicable, by giving notice to ViaCyte by 7 pm (ET) on the day before the applicable date the Company is required to issuance such shares.

Note Financing

Pursuant to the terms of the Agreement, if ViaCyte has not consummated a bona fide preferred stock financing by January 15, 2019 resulting in ViaCyte receiving (or providing that ViaCyte will receive) at least \$25.0 million in total proceeds, then ViaCyte has the option, exercisable in its sole discretion, to obtain a \$10.0 million financing from the Company in the form of a promissory convertible note issuable to the Company (the "Convertible Note"). If issued, the Convertible Note will be automatically convertible into shares of ViaCyte's capital stock upon an equity financing by ViaCyte which has gross proceeds in excess of \$25.0 million (excluding the conversion of the Convertible Note), at a conversion price equal to the price per share paid by the investors in the financing. ViaCyte's option to exercise the financing option and require the Company to purchase the Convertible Note expires on February 1, 2019.

Termination

Unless earlier terminated, the Agreement will expire upon the earlier of the expiration of the Research Term or the date that the Commercialization Agreement becomes effective. Either party can terminate the Agreement for convenience or uncured material breach, upon notice of a specified period. Either party may also terminate the Agreement upon notice if the other challenges the enforceability, validity, or scope of any patent rights belonging to the other party (a "Patent Challenge"), unless the challenging party withdraws or causes the challenge to be withdrawn within a specified period. The Agreement may be terminated by either party upon the insolvency of the other party.

In the event either party is acquired by specified third parties the Agreement may be terminated, at the election of the non-acquired party, upon the closing of such acquisition.

If (i) a party terminates the Agreement due to an uncured material breach by the other party, a Patent Challenge by the other party that is not otherwise withdrawn, the insolvency of the other party or (ii) either party terminates the Agreement for convenience other than the Company if the Company terminates the Agreement for convenience within the first two years after the effective date of the Agreement (the terminating party described in clause (i) and the non-terminating party described in clause (ii) are collectively referred to as the “Continuing Party”), then the Continuing Party may either elect (other than for terminations arising from, relating to or otherwise in connection with fraud or willful misconduct) the (1) remedies set forth in the Agreement or (2) pursue remedies under applicable law. Under the Agreement, the Continuing Party has the right to cause the other party to transfer such data, reports, inventory or other materials and information necessary for the research, development, commercialization and manufacturing of the products and product candidates for use in the Field (whether conceived, discovered or advanced under the Research Plan or in continued research and development by or on behalf of the Continuing Party after termination of the Agreement, and the Commercial License granted to the Continuing Party under the Agreement shall be in full force and effect. If the Continuing Party commercializes any such products or product candidates, then it will be required to pay (i) research, development and commercialization milestone payments, not to exceed \$25.0 million in the aggregate and (ii) a single-digit royalty to the other party upon commercialization of such products. The amount of the milestone payments and royalties will be finally determined by taking into consideration the status of the Research Plan at the time of termination, the reason for the termination and the amount of funding provided by the Company to ViaCyte pursuant to the terms of the Agreement.

Item 8.01 Other Events.

On September 17, 2018, the Company issued a press release announcing the entry into the Agreement. A copy of the press release is attached hereto as Exhibits 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

The following exhibit shall be deemed to be furnished, and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by CRISPR Therapeutics AG on September 17, 2018



CRISPR Therapeutics and ViaCyte Announce Strategic Collaboration to Develop Gene-Edited Stem Cell-Derived Therapy for Diabetes

- *Aims to develop an immune-evasive stem cell therapy as a potentially curative treatment for diabetes -*
- *Parties will collaborate through commercialization and share costs and profits worldwide -*

ZUG, Switzerland and CAMBRIDGE, Mass., and SAN DIEGO, September 17, 2018 — CRISPR Therapeutics (NASDAQ: CRSP), a biopharmaceutical company focused on developing transformative gene-based medicines for serious diseases, and ViaCyte, Inc., a privately held regenerative medicine company, today announced a collaboration focused on the discovery, development, and commercialization of gene-edited allogeneic stem cell therapies for the treatment of diabetes.

Decades of clinical data with islet transplants indicate that beta-cell replacement approaches may offer curative benefit to patients with insulin-requiring diabetes. ViaCyte has pioneered the approach of generating pancreatic-lineage cells from stem cells and delivering them safely and efficiently to patients. PEC-Direct, ViaCyte’s lead product candidate currently being evaluated in the clinic, uses a non-immunoprotective delivery device that permits direct vascularization of the cell therapy. This approach has the potential to deliver durable benefit; however, because the patient’s immune system will identify these cells as foreign, PEC-Direct will require long-term immunosuppression to avoid rejection. As a result, PEC-Direct is being developed as a therapy for the subset of patients with type 1 diabetes at high risk for acute complications.

CRISPR gene editing offers the potential to protect the transplanted cells from the patient’s immune system by ex-vivo editing immune-modulatory genes within the stem cell line used to produce the pancreatic-lineage cells. The speed, specificity, and multiplexing efficiency of the CRISPR system make it ideally suited to this task. CRISPR Therapeutics is pursuing a similar approach for its allogeneic CAR-T programs and has established significant expertise in immune-evasive gene editing. The combination of ViaCyte’s stem cell capabilities and CRISPR’s gene editing capabilities has the potential to enable a beta-cell replacement product that may deliver durable benefit to patients without triggering an immune reaction.

“We believe the combination of regenerative medicine and gene editing has the potential to offer durable, curative therapies to patients in many different diseases, including common chronic disorders like insulin-requiring diabetes. ViaCyte is a pioneer in the regenerative medicine field, and has built a compelling clinical program, robust manufacturing capabilities, and assembled a strong intellectual property position. Partnering with ViaCyte will allow us to accelerate our efforts in regenerative medicine, an area that we believe will provide a variety of longer-term opportunities for our company,” commented Samarth Kulkarni, Ph.D., Chief Executive Officer of CRISPR Therapeutics.



Under the terms of the agreement, CRISPR and ViaCyte will jointly seek to develop an immune-evasive stem cell line as a first step on the path to an allogeneic stem-cell derived product. Upon successful completion of these studies and identification of a product candidate, the parties will jointly assume responsibility for further development and commercialization worldwide. Upon execution of the agreement ViaCyte will receive \$15 million from CRISPR, which at CRISPR's election may be paid in either cash or CRISPR stock. ViaCyte also has the option, under certain circumstances, to receive an additional \$10 million from CRISPR in the form of a convertible promissory note.

“Creating an immune-evasive gene-edited version of our technology would enable us to address a larger patient population than we could with a product requiring immunosuppression. CRISPR Therapeutics is the ideal partner for this program given their leading gene editing technology and expertise and focus on immune-evasive editing. We are thrilled to have the opportunity to partner with CRISPR Therapeutics on what we believe could be a transformational therapy for patients with insulin-requiring diabetes,” commented Paul Laikind, Ph.D., Chief Executive Officer and President of ViaCyte. “We also believe that this approach may have many other applications which we and CRISPR may explore in the future.”

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 and rare diseases. To accelerate and expand its efforts, CRISPR Therapeutics has established strategic collaborations with leading companies including Bayer AG and Vertex Pharmaceuticals. 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 London, United Kingdom. For more information, please visit www.crisprtx.com.

About ViaCyte

ViaCyte is a privately-held regenerative medicine company developing novel cell replacement therapies as potential long-term diabetes treatments to achieve glucose control targets and reduce the risk of hypoglycemia and diabetes-related complications. ViaCyte's product candidates are based on the derivation of pancreatic progenitor cells from stem cells, which are then implanted in durable and retrievable cell delivery devices. Once implanted and matured, these cells are designed to secrete insulin and other pancreatic hormones in response to blood glucose levels. ViaCyte has two product candidates in clinical-stage development. The PEC-Direct™ product candidate delivers the pancreatic progenitor cells in a non-immunoprotective device and is being developed for type 1 diabetes patients who have hypoglycemia unawareness, extreme glycemic lability, and/or recurrent severe hypoglycemic episodes. The PEC-Encap™ (also known as VC-01) product candidate delivers the same pancreatic progenitor cells in an immunoprotective device and is being developed for all patients with diabetes, type 1 and type 2, who use insulin. ViaCyte is also seeking to develop immune-evasive 'universal donor' stem cell lines, from its proprietary CyT49 cell line, which are expected to further broaden the availability of cell therapy for diabetes and other potential indications. ViaCyte is headquartered in San Diego, California. ViaCyte is funded in part by the California Institute for Regenerative Medicine (CIRM) and JDRF. For more information, please visit www.viacyte.com.



CRISPR Forward-Looking Statement

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the timing of filing of clinical trial applications and INDs, any approvals thereof and timing of commencement of clinical trials, the intellectual property coverage and positions of CRISPR Therapeutics, its licensors and third parties, the sufficiency of CRISPR Therapeutics' cash resources and the therapeutic value, development, and commercial potential of CRISPR/Cas9 gene editing technologies and therapies. 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, the 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: uncertainties regarding the intellectual property protection for our technology and intellectual property belonging to third parties; uncertainties inherent in the initiation and completion of preclinical studies for CRISPR Therapeutics' product candidates; availability and timing of results from preclinical studies; whether results from a preclinical trial will be predictive of future results of the future trials; expectations for regulatory approvals to conduct trials or to market products; 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 (SEC), 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.

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