
**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): **March 16, 2023**

Leap Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37990
(Commission
File Number)

27-4412575
(IRS Employer
Identification No.)

47 Thorndike Street, Suite B1-1
Cambridge, MA
(Address of principal executive offices)

02141
(Zip Code)

Registrant's telephone number, including area code: **(617) 714-0360**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K 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)).

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 Stock, par value \$0.001	LPTX	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.

On March 16, 2023, Leap Therapeutics, Inc. (the “Company”) and BeiGene, Ltd. (“BeiGene”) entered into a letter agreement (the “Letter Agreement”). Pursuant to the Letter Agreement, BeiGene and the Company have agreed that BeiGene’s option (the “Option”) under the previously disclosed Exclusive Option and License Agreement, dated as of January 3, 2020, between the Company and BeiGene (the “Option and License Agreement”) to obtain an exclusive license under certain of the Company’s intellectual property to develop and commercialize DKN-01, the Company’s anti-DKK1 monoclonal antibody, has expired in accordance with the terms of the Option and License Agreement.

The Letter Agreement also provides for (i) the Company and BeiGene to continue to collaborate on Part C of the Company’s ongoing randomized controlled trial of DKN-01 in combination with BeiGene’s anti-PD-1 antibody, tislelizumab, and chemotherapy in first-line gastric cancer patients (the “Distinguish Trial”) for so long as the Company and BeiGene require such collaboration to complete Part C of the Distinguish Trial in accordance with the protocol for the Distinguish Trial, (ii) BeiGene to continue to supply BeiGene’s anti-PD-1 antibody, tislelizumab, pursuant to that certain Clinical Manufacturing and Supply Agreement, dated as of April 23, 2020, by and between the Company and BeiGene (the “Supply Agreement”) for such period of time as is necessary to complete Part C of the Distinguish Trial in accordance with the protocol for the Distinguish Trial, (iii) the Company and BeiGene to continue to perform their respective obligations under the Option and License Agreement, the Supply Agreement, that certain Clinical Quality Agreement, dated as of May 3, 2020, by and between the Company and BeiGene (the “Quality Agreement”), and that certain First Amended and Restated Pharmacovigilance Agreement, dated as of October 12, 2022, by and between the Company and BeiGene (the “Pharmacovigilance Agreement”), in each case after giving effect to the amendments and modifications thereto effected and implemented by the Letter Agreement and only for such period of time as is necessary to complete Part C of the Distinguish Trial in accordance with the protocol for the Distinguish Trial, and (iv) certain amendments or modifications to the terms of the Option and License Agreement, the Supply Agreement, the Quality Agreement and the Pharmacovigilance Agreement to provide for the continuation of such agreements pursuant to, and in accordance with, terms that reflect the expiration of the Option and the continued clinical collaboration of the Company and BeiGene on Part C of the Distinguish Trial in accordance with the protocol for the Distinguish Trial.

The foregoing description of the Letter Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Letter Agreement attached hereto as Exhibit 10.1 to this Current Report on Form 8-K, which is incorporated herein by this reference.

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

On March 16, 2023, the Company filed with the Secretary of State of the State of Delaware the Certificate of Amendment to the Certificate of Designation of the Company’s Special Voting Stock (the “Certificate of Amendment”), which Certificate of Amendment is attached as Exhibit 3.1 to this Current Report on Form 8-K and incorporated herein by reference. The Certificate of Amendment amends the Certificate of Designation of the Company’s Special Voting Stock to provide for an increase in the percentage of outstanding shares of Common Stock of the Company that the sole holder of the Company’s Special Voting Stock, together with its affiliates and associates, must hold from 5% to 9.9% in order for such sole holder of the Company’s Special Voting Stock to have the right to designate one (1) individual as a director on the Board of Directors of the Company.

Item 5.07 Submission of Matters to a Vote of Security Holders.

(a) On March 16, 2023, the Company held a Special Meeting of the sole holder of Special Voting Stock of the Company (the “Special Meeting”). The Special Voting Stock of the Company is not registered under Section 12 of the Securities Exchange Act of 1934, as amended, and, as of March 6, 2023, the record date for the Special Meeting, there was only one share of Special Voting Stock authorized, issued and outstanding.

(b) At the Special Meeting, the sole stockholder of the Company’s Special Voting Stock approved the proposal to amend the Certificate of Designation of the Company’s Special Voting Stock set forth below. The tabulation of votes for the proposal is as follows:

Proposal 1 – Approval of Amendment to the Certificate of Designation of the Company’s Special Voting Stock.

	<u>For</u>	<u>Against</u>	<u>Abstain</u>
To consider and vote upon a proposal to amend the Certificate of Designation of Special Voting Stock of the Company as set forth in the Certificate of Amendment.	1	0	0

Item 8.01. Other Events

On March 16, 2023, the Company issued a press release entitled “Leap Therapeutics Provides Update on BeiGene Option Agreement for DKN-01.”

The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference; provided, however that information on or connected to our website referenced in the Company’s press release is expressly not incorporated by reference into or intended to be filed as a part of this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

Exhibit Number	Description
3.1	Certificate of Amendment to the Certificate of Designation of Special Voting Stock
10.1*	Continuing Clinical Collaboration Letter Agreement
99.1	Press Release dated March 16, 2023
104	Cover Page Interactive Data File

*Certain of the schedules and exhibits to this exhibit have been omitted pursuant to Regulation S-K Item 601(a)(5). The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

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.

LEAP THERAPEUTICS, INC.

Dated: March 16, 2023

By: /s/ Douglas E. Onsi

Name: Douglas E. Onsi

Title: Chief Executive Officer and President

CERTIFICATE OF AMENDMENT
TO
CERTIFICATE OF DESIGNATION OF
SPECIAL VOTING STOCK
OF
LEAP THERAPEUTICS, INC.

Leap Therapeutics, Inc., a corporation organized under and existing under the laws of the State of Delaware (the "Corporation"), certifies that:

FIRST: The name of the Corporation is Leap Therapeutics, Inc. The Corporation was originally incorporated pursuant to the General Corporation Law of the State of Delaware (the "Delaware General Corporation Law") on January 3, 2011 under the name "Dekkun Corporation."

SECOND: The Certificate of Designation of Special Voting Stock of the Corporation was filed with the Secretary of State of the State of Delaware on January 7, 2020 (the "Certificate of Designation").

THIRD: Section 5(b) of the Certificate of Designation is hereby amended by deleting the reference to "5%" in the second line of such Section 5(b) and replacing such reference with a reference to "9.9%".

FOURTH: The amendment to the Certificate of Designation, which amendment is set forth in Article Third above, has been duly adopted in accordance with Section 242 of the Delaware General Corporation Law.

LEAP THERAPEUTICS, INC.

By: /s/ Douglas E. Onsi

Name: Douglas E. Onsi

Title: Chief Executive Officer



March 16, 2023

BeiGene, Ltd.
c/o Mourant Ozannes Corporate Services (Cayman) Limited
94 Solaris Avenue
Camana Bay
PO Box 1348
Grand Cayman, KY1-1108
Cayman Islands
Attention: Chairman and Chief Executive Officer

RE: Termination of Option and License; Continued Clinical Collaboration

Ladies and Gentlemen,

Reference is hereby made to (i) that certain Exclusive Option and License Agreement, dated as of January 3, 2020 (the "**Option and License Agreement**"), by and between Leap Therapeutics, Inc., a Delaware corporation ("**Leap**"), and BeiGene, Ltd., a Cayman Island exempted company incorporated with limited liability ("**BeiGene**"), (ii) that certain Clinical Manufacturing and Supply Agreement, dated as of April 23, 2020, by and between Leap and BeiGene, as amended, modified or supplemented from time to time prior to the date hereof (the "**Supply Agreement**"), (iii) that certain Clinical Quality Agreement, dated as of May 3, 2020, by and between Leap and BeiGene, as amended, modified or supplemented from time to time prior to the date hereof (the "**Quality Agreement**"), and (iv) that certain First Amended and Restated Pharmacovigilance Agreement, dated as of October 12, 2022, by and between Leap and BeiGene, as amended, modified or supplemented from time to time prior to the date hereof (the "**Pharmacovigilance Agreement**"). The Option and License Agreement, the Supply Agreement, the Quality Agreement and the Pharmacovigilance Agreement may hereinafter be referred to, collectively, as the "**Clinical Collaboration Agreements**" and each individually as a "**Clinical Collaboration Agreement**." Leap and BeiGene may hereinafter be referred to, collectively, as the "**Parties**", and each individually as a "**Party**." Capitalized terms used in this letter agreement (the "**Letter Agreement**") without definition shall have the meaning ascribed to such terms in the Option and License Agreement.

For and in consideration of the mutual agreements set forth below in this Letter Agreement, and for other good and valid consideration, the receipt and sufficiency of which is hereby acknowledged, each of Leap and BeiGene, intending to be legally bound, hereby agree as follows:

1. Expiration of BeiGene's Option and Right to License. Leap and BeiGene hereby agree that BeiGene's rights under the Option and License Agreement to exercise the Option, to effect and implement the grant of the License, and to practice, use, exploit and exercise its rights under the License, have expired in accordance with Section 2.1 of the Option and License Agreement.

2. Continued Clinical Collaboration. Leap and BeiGene hereby agree that, notwithstanding the expiration the Option, as mentioned in Section 1 above, the Parties have agreed to continue to collaborate only to the extent that Part C of Leap's ongoing randomized controlled trial of DKN-01 in combination with the BeiGene Drug (i.e. BeiGene's anti-PD-1 antibody, tislelizumab) and chemotherapy in first-line gastric cancer patients (the "Distinguish Trial") may be completed, in accordance with the Distinguish Trial protocol attached hereto as Appendix A (the "**Part C Protocol**"). BeiGene hereby agrees to continue to supply the BeiGene Drug pursuant to the Supply Agreement for only that time period necessary to complete the Part C Protocol. Furthermore, the Parties hereby agree to continue to perform their respective obligations under the Clinical Collaboration Agreements, as amended, modified or supplemented pursuant to this Letter Agreement or any other written agreements, entered into by the Parties from time to time, for only that time period necessary to complete the Part C Protocol.

3. Continuing Effectiveness of Option and License Agreement; Amendments or Modifications Thereto. Leap and BeiGene hereby agree that, notwithstanding the expiration of the Option as set forth in Section 1 of this Letter Agreement, the Option and License Agreement shall remain in full force and effect for so long as the Parties require collaboration to complete the Part C Protocol and subject to the amendments and modifications set forth below in this Section 3. Leap and BeiGene hereby agree to amend or modify the Option and License Agreement as follows, effective immediately:

(a) Any reference in the Option and License Agreement to the term "**Agreement**" shall be deemed to be a reference to the Option and License Agreement, as amended and modified from time to time, including, without limitation, pursuant to this Letter Agreement.

(b) Article 5, Article 7, Article 8, Article 9, Article 14 (other than Section 14.1), Sections 2.3, 2.5, 2.7, 4.1, 6.2(a), 6.2(b), 6.3, 6.6 (second sentence only), 11.1, 12.4(b), 12.4(d), 12.5(b), 12.5(d), 15.2(e) (second sentence only) and 15.4 of the Option and License Agreement are hereby deleted in their entirety.

(c) All references to the JCC in the Option and License Agreement as well as all provisions related to or with respect to the JCC in the Option and License Agreement are hereby deleted in their entirety.

(d) Section 3.2(f) of the Option and License Agreement is hereby deleted in its entirety. Leap and BeiGene hereby agree that, effective as of the date of this Letter Agreement, the JDC shall be a forum to facilitate discussion and the exchange of information and ideas between the Parties and shall not have any decision-making authority or responsibility.

(e) All references to the Global Development Plan or any Territory Development Plan in the Option and License Agreement are hereby eliminated in their entirety and the Parties respective rights and obligations under the Option and License Agreement in connection with the Global Development Plan or any Territory Development Plan are hereby terminated.

(f) Section 15.1 of the Option and License Agreement is hereby amended and modified in its entirety to provide solely that the Option and License Agreement shall be effective as of the Effective Date and shall continue in effect until the Part C Protocol is completed, pursuant to, and in accordance with, any of the provisions of Section 15.2 (as amended hereby), and following the completion of the Part C Protocol, the Option and License Agreement shall terminate in its entirety, if not earlier terminated in accordance with those provisions set forth in Section 15.2 (as amended hereby).

(g) Section 15.5 of the Option and License Agreement is hereby amended and modified to remove or eliminate from such Section 15.5 any Section or provision of the Option and License Agreement referenced in such Section 15.5 that has been deleted pursuant to any of the provisions of this Letter Agreement.

(h) Any numbered section, paragraph, clause, sub-section, sub-paragraph or sub-clause that is deleted or eliminated from the Option and License Agreement pursuant to any of the foregoing provisions of this Letter Agreement shall be deemed and treated as if the text (but not the numbering) of such numbered section, paragraph, clause, sub-section, sub-paragraph or sub-clause had been deleted and replaced by the text “[**Intentionally Deleted**]” so as to not require any renumbering of any other sections, paragraphs, clauses, sub-sections, sub-paragraphs or sub-clauses not deleted.

4. Continuing Effectiveness of Each Other Clinical Collaboration Agreement. Leap and BeiGene hereby agree that, notwithstanding the termination pursuant to Section 1 of this Letter Agreement of the Option and BeiGene’s rights with respect to the Option and License Agreement, each of the Supply Agreement, the Quality Agreement and the Pharmacovigilance Agreement (collectively, the “Other Clinical Collaboration Agreements” and individually a “Clinical Collaboration Agreement”) shall remain in full force and effect, subject to the amendments and modifications thereto set forth in this Section 4, for purposes of facilitating the Parties’ continued clinical collaboration pursuant to Section 2 of this Letter Agreement. Leap and BeiGene hereby agree to amend or modify the Other Clinical Collaboration Agreements as follows, effective immediately:

(a) Any reference in each Other Clinical Collaboration Agreement to the term “Agreement” shall be deemed to be a reference to such Other Clinical Collaboration Agreement, as amended, including, without limitation, pursuant to this Letter Agreement.

(b) Any reference in each Other Clinical Collaboration Agreement to the term “Option and License Agreement” shall be deemed to be a reference to the Option and License Agreement, as amended, including, without limitation, pursuant to this Letter Agreement.

5. Ratification. Except to the extent amended or modified pursuant to this Letter Agreement, each of the Clinical Collaboration Agreements and all of its terms are hereby ratified and confirmed.

6. Miscellaneous.

(a) This Letter Agreement may be amended only by a written instrument executed in one or more counterparts by the Parties.

(b) The provisions of Article 16 of the Option and License Agreement shall apply to this Letter Agreement, mutatis mutandis.

(c) This Letter Agreement may be executed in counterparts, all of which together shall for all purposes constitute one agreement binding on each of the parties hereto notwithstanding that each such party shall not have signed the same counterpart.

If the foregoing correctly reflects our agreement and understanding, please so confirm by signing in the space provided for your signature below in this Letter Agreement.

Sincerely,

LEAP THERAPEUTICS, INC.

By: /s/ Douglas E. Onsi

Name: Douglas E. Onsi

Title: Chief Executive Officer

ACKNOWLEDGED AND ACCEPTED:

BEIGENE, LTD.

By: /s/ Chan Lee

Name: Chan Lee

Title: Senior Vice President, General Counsel & Corporate Secretary



Leap Therapeutics Provides Update on BeiGene Option Agreement for DKN-01

DisTinGuish Trial of DKN-01 plus tislelizumab and chemotherapy to continue as a clinical collaboration

Cambridge, MA – March 16, 2023 – Leap Therapeutics, Inc. (Nasdaq:LPTX), a biotechnology company focused on developing targeted and immuno-oncology therapeutics, today announced that BeiGene’s option under the Exclusive Option and License Agreement between Leap and BeiGene granting rights in certain Asian territories to DKN-01, Leap’s anti-DKK1 monoclonal antibody, has expired in accordance with the terms of the agreement. Leap and BeiGene will continue to collaborate on the ongoing Part C of the DisTinGuish trial, a randomized controlled trial of DKN-01 in combination with BeiGene’s anti-PD-1 antibody, tislelizumab, and chemotherapy in first-line gastric cancer patients, as a clinical collaboration with BeiGene supplying tislelizumab. Enrollment in the 160-patient study is expected to be completed in late 2023.

“We look forward to continuing to collaborate with BeiGene to execute on our first randomized controlled trial for DKN-01 in first-line gastric cancer patients,” said Douglas E. Onsi, President and Chief Executive Officer of Leap. “With global rights to DKN-01 and a cash runway that was enhanced into mid-2025 by our recent acquisition of Flame Biosciences, we will look to identify a new strategic partner as we generate new clinical data from our ongoing studies in first-line gastric cancer patients, second-line colorectal cancer patients, and an investigator-sponsored study in endometrial cancer patients. We will also continue the development of the newly-acquired Claudin18.2 programs as part of our focus on biomarker-targeted antibody therapies for cancer patients, particularly those with GI cancers.”

About Leap Therapeutics

Leap Therapeutics (Nasdaq: LPTX) is focused on developing targeted and immuno-oncology therapeutics. Leap’s most advanced clinical candidate, DKN-01, is a humanized monoclonal antibody targeting the Dickkopf-1 (DKK1) protein. DKN-01 is being developed in patients with esophagogastric, gynecologic, and colorectal cancers. FL-301, is a humanized monoclonal antibody targeting Claudin18.2, being developed in patients with gastric and pancreatic cancer. Leap also has preclinical antibody programs targeting Claudin18.2/CD137 and GDF15. For more information about Leap Therapeutics, visit <http://www.leaptx.com> or view our public filings with the SEC that are available via EDGAR at <http://www.sec.gov> or via <https://investors.leaptx.com/>.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements within the meaning of the federal securities laws. Such statements are based upon current plans, estimates and expectations of the management of Leap that are subject to various risks and uncertainties that could cause actual results to differ materially from such statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as “anticipate,” “expect,” “project,” “intend,” “believe,” “may,” “will,” “should,” “plan,” “could,” “continue,” “target,” “contemplate,” “estimate,” “forecast,” “guidance,” “predict,” “possible,” “potential,” “pursue,” “likely,” and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, including statements regarding the continuation over time of our clinical collaboration with BeiGene on the ongoing Part C of the DisTinGuish trial, with BeiGene continuing to supply tislelizumab; the enhancement of our cash runway into mid-2025; our future development plans in connection with our newly-acquired Claudin18.2 programs; the potential, safety, efficacy, and regulatory and clinical progress of Leap’s product candidates, including the anticipated timing for enrollment of clinical trials and release of clinical trial data and outcomes of such trials; the ability to enter into a new strategic partnership for DKN-01 or any of Leap’s other programs; and any assumptions underlying any of the foregoing, are forward-looking statements. Important factors that could cause actual results to differ materially from Leap’s plans, estimates or expectations could include, but are not limited to: (i) Leap’s ability to successfully execute its clinical trials and the cost of such clinical trials; (ii) Leap’s ability to successfully enter into new strategic partnerships for DKN-01 or any of its other programs; (iii) whether any Leap clinical trials and products will receive approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; (iii) exposure to inflation, currency rate and interest rate fluctuations, as well as fluctuations in the market price of Leap’s traded securities; (iv) that the initiation, conduct, and completion of clinical trials, laboratory operations, manufacturing campaigns, and other studies may be delayed, adversely affected, or impacted by COVID-19, global conflict or supply chain related issues; (v) the results of Leap’s clinical trials and pre-clinical studies; and (vi) Leap’s ability to comply with the continued listing requirements of the Nasdaq Global Market. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or Implied) are made about the accuracy of any such forward-looking statements. Leap may not actually achieve the forecasts disclosed in such forward-looking statements, and you should not place undue reliance on such forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption “Risk Factors” in Leap’s most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in its subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither Leap, nor any of its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing Leap’s views as of any date subsequent to the date hereof.

CONTACT:

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