ALDER BIOPHARMACEUTICALS INC
Form 8-K
November 21, 2016

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): November 18, 2016

Alder BioPharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36431**	**90-0134860**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

11804 North Creek Parkway South

Bothell, WA	**98011**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (425) 205-2900

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))

Item 1.01 Entry into a Material Definitive Agreement

Lease Amendment

On November 18, 2016, Alder BioPharmaceuticals, Inc. (Alder) entered into a Fifth Amendment to Lease (the Fifth Amendment) with KBS North Creek LLC, as successor-in-interest to RREEF American REIT II Corp. KK, to amend certain provisions of the Lease by and between Alder and RREEF American REIT II Corp. KK, dated August 5, 2005, as previously amended (the Original Lease).

The Fifth Amendment (i) extends the term of the Original Lease by an additional 60 months through July 31, 2023, (ii) expands the premises covered by the Original Lease, beginning on or about February 1, 2017, (iii) provides Alder with an option for future expansion, and (iv) changes the rental rate, which together with the term extension, results in incremental rent obligations of an aggregate of $7.8 million for the duration of the Original Lease, as amended by the Fifth Amendment.

The foregoing description of the Fifth Amendment is a summary, is not complete, and is qualified in its entirety by the terms and conditions of the actual Fifth Amendment, which is attached hereto as Exhibit 10.1 and incorporated herein by reference.

Item 8.01 Other Events.

Decision in Opposition Proceeding in European Patent Office

Alder is reporting an outcome in its opposition to Labrys Biologics Inc. s (owned by Teva Pharmaceutical Industries Ltd.) European Patent No. 1957106 B1. The patent at issue, granted in October 2013, originally contained claims relating to calcitonin gene-related peptide (CGRP) antagonist antibodies and the use of such CGRP antagonist antibodies in human therapy for the prevention or treatment of CGRP-associated vasomotor symptoms such as migraine and hot flush. The opposition to the patent was filed in July 2014 by both Alder and Eli Lilly and Company. The opposition asserts that the patent be revoked in its entirety because the patent s broad claims do not meet the requirements for patentability under the European Patent Convention. In an oral proceeding held in Munich, Germany on November 18, 2016, the Opposition Division (OD) of the European Patent Office (EPO) issued a ruling revoking all claims in the patent relating to CGRP antagonist antibodies and maintaining but narrowing claims relating to the use of CGRP antagonist antibodies in human therapy to the prevention or treatment of headache such as migraine and cluster headache. The written decision consistent with the oral ruling is expected within a few weeks.

The initial decision by the EPO affirms Alder s right to continue clinical development of ALD403, Alder s drug candidate for the prevention of migraine, and has no impact on Alder s plan to submit a Biologics License Application (BLA) for ALD403 with the U.S. Food and Drug Administration (FDA) in the second half of 2018 and to commercialize ALD403 in the United States. The OD s decision is subject to appeal to the EPO s Technical Board of Appeal by the parties to the proceeding. Alder plans to pursue an appeal based on its continued firm belief that the patent claims that were maintained and narrowed were nevertheless improperly granted by the EPO and upheld by the OD, and should be revoked in its entirety on appeal for the reasons set forth in the opposition. The OD decision has no binding effect on the U.S. Patent and Trademark Office s patentability determination of claims in granted or pending Labrys patent applications in the United States which correspond to the opposed European patent or impact on Alder s ability to take action seeking to invalidate such granted or pending U.S. applications.

For the reasons set forth in Alder s opposition, Alder continues to firmly believe the patent should be revoked in its entirety. However, Alder cannot predict the specific timing or outcome of events or matters discussed in this Current Report on Form 8-K, or the impact of the November 18, 2016 decision on Alder s business. Because of the inherent uncertainty in intellectual property legal proceedings, the opposition proceeding and appeal may not ultimately be

resolved in Alder s favor regardless of Alder s perception of the merits. If Alder loses such a proceeding or appeal, Alder may not be able to engage in commercialization and related activities for ALD403 for the treatment of migraine in the European countries that are members of the European Patent Organisation without obtaining a license. However, such license may not be available on commercially reasonable terms or at all, and if granted may be non-exclusive, thereby giving Alder s competitors freedom to operate in these countries. If Alder is found to infringe the patent in these European countries, Alder could be forced, including by court order, to cease commercialization and related activities for ALD403 in such countries and possibly be found liable for monetary damages and attorneys fees.

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements relating to: Alder s plan to appeal the referenced decision of the OD; Alder s belief that the referenced patent should be revoked in its entirety and Alder s belief in the merits of the opposition; future developments in the opposition of the referenced patent and Alder s expectations with respect thereto; Alder s expectation that the OD s decision will not interfere with the continued clinical development of ALD403 or Alder s plan to submit a BLA for ALD403 with the FDA in the second half of 2018; Alder s belief that the OD decision has no impact Alder s ability to take action seeking to invalidate granted or pending Labrys U.S. patent applications; and the potential future impact on Alder and its business as a result of the opposition and appeal. Words such as expect, can, plans, continues, believe, predict, could, or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. The forward-looking statements in this Current Report on Form 8-K are based upon Alder s current plans, assumptions, beliefs, expectations, estimates and projections, and involve substantial risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements due to these risks and uncertainties as well as other factors, which include, without limitation: the inherent uncertainty in legal proceedings involving intellectual property and the possibility that such proceedings may result in outcomes that are unfavorable to Alder; the timing, scope and costs of legal proceedings involving intellectual property; Alder s ability to obtain and protect intellectual property rights, and operate without infringing on the intellectual property rights of others; the potential failure of ALD403 to demonstrate safety and efficacy in clinical testing; Alder s ability to conduct clinical trials and studies of ALD403 sufficient to achieve a positive completion; the availability of data at the expected times; the clinical, therapeutic and commercial value of ALD403; risks and uncertainties related to regulatory application, review and approval processes and Alder s compliance with applicable legal and regulatory requirements; risks and uncertainties relating to the manufacture of ALD403; the uncertain timing and level of expenses associated with the development of ALD403; the sufficiency of Alder s capital and other resources; market competition; changes in economic and business conditions; and other factors discussed under the caption Risk Factors in Alder s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2016, which was filed with the Securities and Exchange Commission (SEC) on October 27, 2016, and is available on the SEC s website at www.sec.gov. Additional information will also be set forth in Alder s other reports and filings it will make with the SEC from time to time. The forward-looking statements made in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K. Alder expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Alder s expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1	Fifth Amendment to Lease by and between KBS North Creek LLC, as successor-in-interest to RREEF American REIT II Corp. KK, and Alder Biopharmaceuticals, Inc. dated as of November 18, 2016.

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.

Alder BioPharmaceuticals, Inc.

Dated: November 21, 2016

By: /s/ James B. Bucher
James B. Bucher
Senior Vice President and General Counsel

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