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

FORM 8-K/A

(Amendment No. 1)

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): May 29, 2020

ALEXION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-27756**	**13-3648318**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

121 Seaport Boulevard, Boston, Massachusetts 02210

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (475) 230-2596

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))

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 $0.0001 per share	ALXN	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. ☐

EXPLANATORY NOTE

This Amendment No. 1 (this "Amendment") to the Current Report on Form 8-K originally filed by the Company with the U.S. Securities and Exchange Commission ("SEC") on May 29, 2020 (the "Original Form 8-K") is being filed by Alexion Pharmaceuticals, Inc. (the "Company") to include the Confidential Settlement and License Agreement (the "Settlement Agreement "), dated May 28, 2020, by and between the Company and Amgen Inc., which was not included with the Original Form 8-K. Except as set forth herein, this Amendment does not amend, modify or update the disclosure contained in the Original Form 8-K.

Item 9.01 Financial Statements and Exhibits

Exhibit Number	Description
10.1*	Confidential Settlement and License Agreement, dated as of May 28, 2020, by and between Alexion Pharmaceuticals, Inc., Alexion Pharma International Operations Unlimited Company and Amgen Inc.

* Certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

Signature

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.

Date: June 3, 2020

ALEXION PHARMACEUTICALS, INC.

By: /s/ Doug Barry
Name: Doug Barry
Title: Vice President, Corporate Law

CONFIDENTIAL
EXECUTION COPY

CONFIDENTIAL SETTLEMENT AND LICENSE AGREEMENT

This Confidential Settlement and License Agreement (this **Settlement Agreement**), is made effective as of May 28, 2020 (**Execution Date**), by and between Alexion Pharmaceuticals, Inc., a Delaware corporation having a place of business at 121 Seaport Blvd., Boston, Massachusetts 02210, and Alexion Pharma International Operations Unlimited Company, an Irish unlimited company having a place of business at College Business and Technology Park, Blanchardstown, Dublin 15, D15 R925 (collectively, **Alexion**); and Amgen Inc., a Delaware corporation having a place of business at One Amgen Center Drive, Thousand Oaks, California, 91320 (**Amgen**). Each of Alexion and Amgen is sometimes individually referred to herein as a **Party** and collectively referred to herein as the **Parties**.

WHEREAS Alexion is the holder of Biologic License Application No. 125166 (**BLA No. 125166**), which is approved by the U.S. Food and Drug Administration (**FDA**) for the manufacture of eculizumab (injection for intravenous use), which Alexion currently markets and sells under the tradename SOLIRIS®;

WHEREAS Alexion is the owner of United States Patent Nos. 9,732,149 (**'149 Patent**), 9,718,880 (**'880 Patent**), 9,725,504 (**'504 Patent**), 10,590,189 (**'189 Patent**), and other United States patents and patent applications related to eculizumab and various aspects of the eculizumab product that Alexion currently markets and sells under the tradename SOLIRIS®, including those additional patents and patent applications listed in Schedule A (collectively, **Eculizumab Patents**);

WHEREAS, Amgen is interested in researching and developing one or more experimental eculizumab products (each an **Amgen Eculizumab Product**), including the ABP 959 product that, as of the Execution Date, Amgen is investigating in clinical trials;

WHEREAS, the Parties are currently involved in *inter partes* review (**IPR**) proceedings Nos. IPR2019-00739, IPR2019-00740, and IPR2019-00741 (collectively, **Eculizumab IPRs**) before the United States Patent Trial and Appeal Board (**PTAB**), wherein Amgen has petitioned the PTAB for rulings that the claims of each of the ’149, ’880, and ’504 patents (collectively, **Eculizumab IPR Patents**) are unpatentable, and Alexion maintains that Amgen has failed to prove unpatentability of the Eculizumab IPR Patents;

WHEREAS, the ’189 Patent issued to Alexion on March 17, 2020, and is not at issue in the Eculizumab IPRs;

WHEREAS, Alexion and Amgen wish to resolve all current and potential patent disputes in the U.S. related to the Eculizumab IPRs, the Eculizumab Patents, and the Amgen Eculizumab Products without litigation, other proceedings, uncertainty, and expense; and

WHEREAS, no Party has received any consideration from the other Party for its entry into this Agreement other than that which is described in this Agreement.

NOW, THEREFORE, in consideration of the mutual execution of this Settlement Agreement and the promises and covenants made herein, the Parties agree as follows:

1. Definitions. Terms when used herein with initial capital letters shall have the meanings set forth below or as otherwise defined in this Settlement Agreement.

(a) **Affiliate** of a Party means any person or entity that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such Party, provided however, that in each case any such other person shall be considered to be an Affiliate only during the time period during which such control exists. As used in this definition, “control” of an entity means having (A) the direct or indirect power to either: (i) direct decisions of the board of directors or similar body governing the management and policies of such entity;

(ii) elect at least fifty percent (50%) of the members of the governing body of such entity; or (B) direct or indirect ownership of at least fifty percent (50%) of the shares of stock entitled to vote for the election of directors or other voting interest in such entity.

(b) **aBLA** means an abbreviated Biologic License Application pursuant to 42 U.S.C. § 262(k).

(c) **Alexion Eculizumab Product** means a product containing eculizumab sold by Alexion under a BLA, including SOLIRIS®.

(d) **Amgen Partner** means [* * * *].

(e) **Applicable Law** means all applicable provisions of constitutions, statutes, rules, regulations, ordinances, and orders of all Governmental Entities and all orders and decrees of all courts, tribunals and arbitrators.

(f) **BLA** means a Biologic License Application pursuant to 42 U.S.C. § 262(a).

(g) **FDA** means the United States Food and Drug Administration and any successor agency having the same functions.

(h) **Final Court Decision** means a decision by a U.S. federal district court, or by the United States Court of Appeals for the Federal Circuit (**Federal Circuit)** in an appeal from a U.S. federal district court, in either case from which no appeal (other than a petition for a writ of certiorari or other proceedings before the United States Supreme Court) has been or can be taken.

(i) **Final PTAB Decision** means a decision by the PTAB, or by the Federal Circuit in an appeal from the PTAB, in either case from which no appeal (other than a petition for a writ of certiorari or other proceedings before the United States Supreme Court) has been or can be taken.

(j) **Governmental Entity** means any (i) nation, state, county, city, town, village, district, or other jurisdiction of any nature, (ii) federal, state, local, municipal, foreign, or other government, (iii) governmental or quasi-governmental authority of any nature (including any governmental agency, branch, department, official, or entity and any court or other tribunal), (iv) multi-national organization or body, or (v) body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power of any nature.

(k) **Licensed Patents** means the Eculizumab Patents (including any patents that issue from the pending applications listed in Schedule A), including any patent and regulatory extensions thereof, all divisionals, continuations, continuations-in-part, reexaminations or reissues thereof, and any applications (and patents issuing therefrom) that claim priority to any of the Eculizumab Patents and/or any of its priority filings, [* * * *].

(l) **Net Sales** means the gross amounts invoiced in an arm's length transaction by Amgen or any if its Affiliates or distributors or licensees to a Third Party in respect of the sale of an Amgen Eculizumab Product in the United States less the following deductions, calculated in all instances in accordance with United States generally accepted accounting principles (US-GAAP):

(i)[* * * *];

(ii)[* * * *];

(iii)[* * * *];

(iv)[* * * *];

(v)[* * * *];

(vi)[* * * *];

(vii)[* * * *]; and

(viii)[* * * *]

All amounts shall be determined from the books and records of Amgen or any of its Affiliates maintained in accordance with United States generally accepted accounting principles consistently applied.

Provided, however, that where the Amgen Eculizumab Product is sold or supplied to a Third Party otherwise than in an arm's length transaction, the Net Sales of the Amgen Eculizumab Product is deemed to be the Net Sales amounts that would have been applied under this Settlement Agreement had the Amgen Eculizumab Product been sold or supplied to an independent arm's length Third Party. Any disposal or use of the Amgen Eculizumab Product for compassionate use, indigent patient programs or clinical trials, in each case when the Amgen Eculizumab Product is provided free of charge, will not be deemed a sale or disposition for calculating the Net Sales under this Settlement Agreement.

(m) **Royalty Term** means [* * * *].

(n) **SOLIRIS®** means the eculizumab product sold by Alexion under BLA No. 125166 or any replacement or substitute thereof, including all amendments and supplements to such BLAs.

(o) **Third Party** means any person or entity other than the Parties and their respective Affiliates.

(p) **Third Party Eculizumab Product** means a pharmaceutical product comprising eculizumab for which marketing approval was sought by a Third Party by means of a BLA filed pursuant to 42 U.S.C. § 262(a), or by means of an aBLA filed pursuant to 42 U.S.C. § 262(k) for which SOLIRIS® or another Alexion Eculizumab Product is the reference product.

(q) **United States** or **U.S.** means the United States of America and its territories, districts, commonwealths and possessions, including without limitation, the Commonwealth of Puerto Rico and the District of Columbia.

2. Dismissal.

(a) In consideration of the mutual benefits of entering into this Settlement Agreement, within three (3) business days of the Execution Date, the Parties shall request authorization from the PTAB to file a Joint Motion to Terminate Proceeding in the Eculizumab IPRs; and promptly upon receiving authorization from the PTAB, the Parties shall file (i) a Joint Motion to Terminate Proceeding in the form attached as Annex A to this Settlement Agreement, requesting that the PTAB terminate the Eculizumab IPRs in their entirety without costs or fees, and (ii) a Joint Motion to File Settlement Agreement as Business Confidential Information in the form attached as Annex B to this Settlement Agreement.

(b) Nothing herein shall prevent or impair the right of Alexion or Amgen to bring a proceeding in court for a breach of, or to enforce any requirement or provision of, this Settlement Agreement or any representation, warranty, or covenant herein.

(c) [* * * *].

3. Compromise. Each Party acknowledges and agrees that this Settlement Agreement is a compromise of existing and potential disputed claims. [* * * *]

4. License, Release, and Covenant.

(a) Alexion, on its own behalf and behalf of its Affiliates, hereby grants Amgen and its Affiliates a non-exclusive, [* * * *], royalty-free, [* * * *] license under the Licensed Patents to make, have made, use, import, have imported, sell, have sold, offer for sale, have offered for sale, distribute, and have distributed in or for the United States, commencing on the License Effective Date, the Amgen Eculizumab Products. [* * * *]

(b) The "License Effective Date" shall be the earliest to occur of:

(i)March 1, 2025;

(ii)[* * * *] or

(iii)[* * * *]

(c) Release. In consideration of the mutual benefits of entering into this Settlement Agreement, as of the Execution Date, each of Alexion and Amgen hereby fully, finally and forever releases, relinquishes, acquits, and discharges, and will cause its Affiliates, directors, officers, and employees, representatives, administrators and attorneys, agents, assigns, predecessors, successors, and all other persons or entities claiming by, through, and under them (along with Alexion, the **Alexion Releasors**; and along with Amgen, the **Amgen Releasors**, respectively) to fully, finally, and forever release, relinquish, acquit, and discharge, the other Party and its Affiliates, administrators, shareholders, directors, officers, employees, representatives, predecessors, successors, sublicensees, agents, and assigns, and with respect to Amgen, the Amgen Partners (the **Amgen Releasees**, and the **Alexion Releasees**, respectively) from any and all claims, demands, damages, liabilities, obligations, and causes of action accruing prior to the Execution Date (including without limitation, costs, expenses, and attorneys' fees, and those capable of being asserted in any complaint and amendments thereto) arising out of,

related to, or in connection with [* * * *], whether known or unknown, and in each case arising before the Execution Date. It is expressly understood and agreed that the Parties hereby waive any statutes or common law doctrines under which a general release would not extend to claims which the party releasing such claim does not know or suspect to exist in his favor at the time of executing the release, including but not limited to any and all rights and benefits conferred by § 1542 of the California Civil Code (if and to the extent applicable). Alexion, on behalf of itself and any Affiliates, represents, warrants, and covenants that it has not heretofore assigned or transferred, and will not assign or otherwise transfer, to any Person any matters released in this Section 4(c), and Alexion agrees to indemnify and hold harmless Amgen from and against all such released matters arising from any such alleged or actual assignment or transfer. This Settlement Agreement may be pleaded as a full and complete defense to, and used as a basis for injunction against, any proceeding that may be instituted, prosecuted, or attempted in breach of the Release stated in this Section 4(c).

(d) Covenant Not to Sue.

(i)The Alexion Releasors covenant that no Alexion Releasor will commence or cause to be commenced against any of the Amgen Releasees any action or other proceeding based upon any claim which has been released in Section 4(c) and will not challenge or seek to challenge the validity or enforceability of any portion of the release contained in Section 4(c).

(ii)The Amgen Releasors covenant that no Amgen Releasor will commence or cause to be commenced against any of the Alexion Releasees any action or other proceeding based upon any claim which has been released in Section 4(c) and will not challenge or seek to challenge the validity or enforceability of any portion of the release contained in Section 4(c).

(iii)With respect to the Amgen Eculizumab Products only, each of the Alexion Releasors covenant not to sue, assert any claim or counterclaim, or otherwise participate in or assist in any action or proceeding against any of the Amgen Releasees, or support or encourage any Third Party to sue any Amgen Releasee, for infringement of any Licensed Patent [* * * *] based on (a) the making, using, selling, offering for sale, or distributing in or for the United States, or making or having made only for importation, distribution, use, sale or offering for sale into or for the United States of the Amgen Eculizumab Products as of and following the License Effective Date, (b) any of the activities allowed under Section 6(b) of this Settlement Agreement, or (c) in the event of a launch of an Amgen Eculizumab Product as contemplated in Section 5 herein. Alexion shall impose this covenant not to sue on any Third Party to which Alexion and each of its Affiliates may later assign, license, or otherwise transfer or grant any patent rights that are the subject of this covenant to the extent that such assignment, license, or other transfer or grant includes the right to enforce the subject patent rights. Notwithstanding the foregoing, Alexion and its Affiliates maintain the right to bring an action for infringement of any of the Licensed Patents against any of the Amgen Releasees in the event of material breach by Amgen or its Affiliates of this Settlement Agreement.

(e) [* * * *]

(f) Alexion hereby irrevocably and unconditionally consents to Amgen seeking immediate entry of a temporary restraining order or preliminary injunction to enforce either of Sections 4(a) or 4(d) of this Settlement Agreement. For the avoidance of doubt, Alexion's consent to Amgen seeking such equitable relief does not relieve Amgen of it burden of proving it is entitled to such relief. Alexion irrevocably and unconditionally consents to personal jurisdiction and venue in the United States District Court for the District of Delaware for the purpose of enforcing this Settlement Agreement and those provisions.

(g) [* * * *]

5. At-Risk Launch Rights

[* * * *]

6. Restrictions on Marketing/Sales.

(a) In return for Alexion's grant of a license, except as provided in Sections 5 and 6(b) and also excepting those actions which are exempt from patent infringement under 35 U.S.C. § 271(e)(1) or are not legally considered to be acts of patent infringement under 35 U.S.C. § 271, neither Amgen nor its Affiliates or any Amgen Partner shall market, sell or offer to sell, directly or indirectly, the Amgen Eculizumab Products in the United States prior to the License Effective Date. [* * * *].

(b) [* * * *]. For the avoidance of doubt, the performance of any of the activities in the time periods expressly provided for in the preceding sentences by Amgen, its Affiliates, the Amgen Partners, or any of the other Amgen Releasees shall not be construed as the sale, use, distribution, or commercial launch of the Amgen Eculizumab Products prior to the License Effective Date or a breach of this Settlement Agreement. Also, for the avoidance of doubt, the Amgen Releasees may disclose the License Effective Date during the course of any of the activities expressly provided for in the preceding sentences without compliance with the confidentiality restrictions set forth in Section 10 of this Settlement Agreement. Further, for the avoidance of doubt, prior to the License Effective Date, the Amgen Releasees may engage in all other activities with respect to preparing for the launch of the Amgen Eculizumab Products that are not acts considered to be, or are exempt from, patent infringement under U.S. law.

7. Agreement. This Settlement Agreement constitutes the complete agreement of the Parties with respect to the subject matter hereof and supersedes and replaces any prior negotiations, mediations, proposed agreements or agreements, whether written or oral. This Settlement Agreement may be modified only by a writing signed by all Parties.

8. Assignment. [* * * *]

9. Attorneys' Fees and Costs. Each party shall bear its own attorneys' fees and costs incurred in connection with the Eculizumab IPRs and in connection with the preparation, execution, and performance of this Settlement Agreement.

10. Confidential Information.

(a) Treatment of Confidential Information.

(i)During the term of this Settlement Agreement (as defined in Section 13 below) and continuing thereafter, each Party shall keep confidential and not disclose to others or use for any purpose, other than as authorized by this Settlement Agreement, all Confidential Information which was provided to it by any other Party or its Affiliates or their respective employees or representatives pursuant to this Settlement Agreement. This Settlement Agreement does not constitute the conveyance of ownership with respect to or a license to any Confidential Information, except as otherwise provided in this Settlement Agreement.

(ii)For purposes of this Settlement Agreement, the term **Confidential Information** means the terms of this Settlement Agreement and any information furnished in connection with this Settlement Agreement, including without limitation any and all know-how, trade secrets, formulae, data, inventions, technology and other information, including manufacturing techniques, processes, trade and financial information, related to the manufacture, use, sale or marketing of any products that are the subject of this Settlement Agreement, currently in the possession of, or developed during the term of the Settlement Agreement by the Parties or any of their respective Affiliates. The restrictions of this Section 10 shall not apply to any Confidential Information which (i) is already known to the recipient at the time of disclosure, as reasonably documented by written records; (ii) is or later becomes public knowledge through no fault of the recipient; (iii) is received from a Third Party having the lawful right to disclose the information; or (iv) is independently developed by employees of the recipient without access to the disclosing Party's Confidential Information.

(b) Permitted Disclosure.

(i)For purposes of this Settlement Agreement, the existence of this Settlement Agreement and the Parties' agreement to seek termination of the Eculizumab IPRs pursuant to Section 2(a) above shall not be considered Confidential Information. [* * * *]. Confidential Information may only be disclosed pursuant to Sections 10(b)(ii), 10(b)(iii), and 10(d) of this Settlement Agreement.

(ii)A Party may disclose Confidential Information relating to this Settlement Agreement or Confidential Information of another Party to (a) its Affiliates, and to its and their directors, employees, attorneys, advisors, consultants, representatives, and agents, and in the case of Amgen, to the Amgen Partners and other Amgen Releasees and to their directors, employees, attorneys, advisors, consultants, representatives, and agents, in each case to those who have a specific need to know such Confidential Information and who are bound by a like obligation of confidentiality and restriction on use; (b) any bona fide actual or prospective collaborators, underwriters, investors, lenders or other financing sources in each case to those who have a specific need to know such Confidential Information and who are bound by a like obligation to keep such information confidential and restriction on use, and only to the extent reasonably necessary to enable such actual or prospective collaborators, underwriters, investors, lenders or other financing sources to determine their interest in collaborating with, underwriting or making an investment in, or otherwise providing financing to, the Party making the disclosure of the Confidential Information; (c) any Third Party in connection with a potential or actual merger, reorganization, change of control or sale of all or substantially all of the applicable business or assets of such Party to which this Settlement Agreement relates, in accordance with confidentiality terms at least as restrictive as the terms hereof; and (d)

the extent such disclosure is required to comply with Applicable Law (including the regulations of the United States Securities and Exchange Commission or the rules of any stock exchange or listing entity) or to defend or prosecute litigation, provided, however, that the Party intending to make a disclosure to comply with Applicable Law complies with Section 10(d).

(iii)If a Governmental Entity directs or recommends to Amgen that Amgen transfer any BLA or aBLA for the Amgen Eculizumab Products to a Third Party, Amgen may disclose a copy of this Settlement Agreement to a Third Party in connection with such a possible transfer so long as the Third Party agrees to confidential treatment of this Settlement Agreement.

(c) Publicity. No public announcement or, except as contemplated under Sections 6(b), 10(b)(ii), 10(b)(iii), and 10(d), other disclosure to Third Parties concerning the terms of this Settlement Agreement shall be made, either directly or indirectly, by any Party.

(d) Disclosure to Government or in Discovery. Specific terms or conditions of this Settlement Agreement may be disclosed if, in the opinion of a Party's counsel, this Settlement Agreement or such terms or conditions thereof are required to be disclosed (i) in order to comply with Applicable Law, including disclosures to Governmental Entities or other regulatory agencies, or the rules of any stock exchange or listing entity, or (ii) pursuant to a discovery demand; subpoena; order of a court, administrative body or arbitrator; or administrative guidance. Each Party agrees that it shall cooperate fully with the other Parties with respect to all disclosures regarding this Settlement Agreement (including good faith discussions as to the content of such disclosures) to comply with Applicable Law, including any disclosures to a Governmental Entity or other regulatory agencies, or the rules of any stock exchange or listing

entity, or in discovery, including cooperation with respect to requests for confidential treatment of proprietary information of any Party included in any such disclosure. If, in the opinion of a Party's counsel, this Settlement Agreement or any terms or conditions thereof must be disclosed to comply with Applicable Law, including any disclosures to a Governmental Entity or other regulatory agencies, or the rules of any stock exchange or listing entity, such Party shall notify the other Parties of the intended disclosure at least ten (10) business days (or at least three (3) business days if the disclosure is made in compliance with the rules and regulations for reporting information in accordance with Current Report on Form 8-K) prior to disclosing any terms of this Settlement Agreement to allow the Parties time to discuss the content of the disclosure. If a Party receives a request to disclose any of the terms or conditions of this Settlement Agreement pursuant to a discovery demand; subpoena; order of a court, administrative body or arbitrator; or administrative guidance that in the opinion of such Party's counsel requires disclosure, such Party shall notify the other Parties within five (5) business days' after receiving such request and provide the other Parties with the intended disclosure at least ten (10) business days' prior to disclosing any terms of this Settlement Agreement to allow the Parties to discuss the content of the disclosure and/or allow the other Parties to oppose disclosure or seek an appropriate protective order. After the Party provides such notice and after the Parties have discussed the content of the disclosure, such Party may then disclose the necessary terms and conditions of this Settlement Agreement, provided that it shall have used reasonable efforts to ensure that such disclosure is subject to, in the case of a disclosure to comply with Applicable Laws or to any Governmental Entity, adequate confidentiality protections, and, in the case of a disclosure in discovery, a protective order limiting access to the disclosure to outside counsel, expert witnesses and one employee or other representative of the entity receiving the Confidential Information.

Nothing herein shall preclude any Party from complying with an order requiring disclosure, or a guidance that in the opinion of such Party's counsel requires disclosure, of the terms of this Settlement Agreement that has been issued by a court, arbitrator or administrative agency of competent jurisdiction. Nothing herein shall prohibit the Parties from disclosing this Settlement Agreement and its terms in confidential submissions to the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ) pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Each Party reserves the right to communicate with the FTC and DOJ regarding such filings as it believes appropriate.

11. Additional Covenants.

(a) Each Party shall, to the extent permitted by law:

(i)promptly inform the other Parties of any communication made or received by such Party to or from any Governmental Entity or other governmental authority regarding this Settlement Agreement and/or any related agreements; and

(ii)use reasonable efforts to comply with and terminate any investigation or inquiry regarding the Settlement Agreement and/or any related agreements by any Governmental Entity or other government authority, including by providing requested information to such entity or authority and permitting reasonable access to its documents, officials and data related to the Settlement Agreement and/or any related agreements, subject to the terms and obligations in this Settlement Agreement.

(b) [* * * *]

(c) Alexion shall notify Amgen within [****] of the issuance of any court, patent office, or other tribunal decision finding invalid, unenforceable, or unpatentable any issued patent claims in any Licensed Patents in the U.S., that Alexion, in good faith, believes could be infringed by the making, using, selling, offering to sell, distributing, or importing the Amgen Eculizumab Products in/into the United States.

12. No Interference But No Consent For FDA Approval. Except in relation to public policy or safety, Alexion and its Affiliates shall not initiate or undertake, or cause or release any others to initiate or undertake, any activity directed against the Amgen Eculizumab Products or any BLA or aBLA relating to the Amgen Eculizumab Products, to interfere or seek to interfere with Amgen's, its Affiliates', or an Amgen Partner's efforts to: (a) carve out any information or indication from the label for the Amgen Eculizumab Products; (b) obtain FDA approval of any BLA or aBLA relating to the Amgen Eculizumab Products; (c) launch and sell the Amgen Eculizumab Products pursuant to the terms of this Settlement Agreement; or (d) maintain FDA approval of any BLA or aBLA relating to the Amgen Eculizumab Products. Nothing in this Settlement Agreement shall be interpreted as Alexion or any of its Affiliates consenting to the accuracy or sufficiency of any scientific, medical, regulatory, or other information contained in any BLA or aBLA relating to the Amgen Eculizumab Products.

13. Expiration. This Settlement Agreement shall continue from the Execution Date until the earlier of: (a) the expiration of the Licensed Patents, including any extensions and pediatric exclusivity; or (b) the date of a final judgment, from which no appeal has been or can be taken, that all of the claims of the Licensed Patents are invalid or unenforceable. The releases set forth in Section 4(c) shall survive expiration of this Settlement Agreement. The covenants provided in Section 4(c) shall survive until expiration of the latest expiring patent covered by this Settlement Agreement. The confidentiality obligations set forth in Section 10 shall survive for a period of [* * * *] from the Execution Date, notwithstanding any earlier expiration or termination of this Settlement Agreement.

14. Representations and Warranties.

(a) Each Party hereby represents, warrants, and covenants to the other Parties as follows:

(i)It is a limited partnership, limited liability company, company or corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated or organized, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Settlement Agreement, including, without limitation, the ability to grant the rights granted to the other Parties hereunder.

(ii)As of the Execution Date: (i) it has the corporate power and authority and the legal right to enter into this Settlement Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Settlement Agreement and the performance of its obligations hereunder; and (iii) this Settlement Agreement has been duly executed and delivered on behalf of such Party and constitutes legal, valid and binding obligations of such Party that are enforceable against it in accordance with their terms.

(iii)It has not entered, and shall not enter, into any agreement with any Third Party that is in conflict with the rights granted to the other Parties in this Settlement Agreement and has not taken and shall not take any action that would in any way prevent it from granting the rights granted to the other Parties under this Settlement Agreement or that would otherwise materially conflict with or adversely affect the rights granted to the other Parties under this Settlement Agreement. Its performance and execution of this Settlement Agreement does not and will not result in a breach of any other contract to which it is a party.

(iv)The execution and delivery of this Agreement and the performance by the Party or its Affiliates of any of its obligations hereunder do not and will not conflict with any judgment of any court or governmental body applicable to the Party or its Affiliates or its respective properties, or to the Party’s knowledge, any statute, decree, order, rule or regulation of any court or governmental agency or body applicable to the Party or its properties.

(b) Additional Alexion Representations and Warranties.

(i)Alexion represents and warrants that, as of the Execution Date, (a) it has the necessary rights, title, interest, and authority to grant Amgen the license to the Licensed Patents contained herein; (b) Alexion owns or controls the Eculizumab Patents and all additional now-existing Licensed Patents; and (c) the Eculizumab Patents and all additional now-existing Licensed Patents are not subject to any liens or encumbrances.

(ii)[* * * *].

(c) Except as expressly provided in this Settlement Agreement, neither Party makes any representations or warranties, express or implied, either in fact or by operation of applicable law.

15. Notice. Any notice or other communication required to be delivered under or pursuant to this Settlement Agreement shall be in writing in the English language, delivered personally or sent by air mail or express courier service providing evidence of receipt, postage pre-paid where applicable, to the following addresses of the Parties (or such other address for a Party as it specifies by like notice):

For Alexion:
Alexion Pharmaceuticals, Inc.
121 Seaport Boulevard
Boston, MA 02210
Attn: Chief Legal Officer
Attn: Head of Intellectual Property
Facsimile: (203) 271-8189

For Amgen:
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320
Attn: Jonathan Graham, Executive VP, General Counsel and Secretary

Any notice shall be effective upon receipt by the Party to which it is addressed.

16. Governing Law; Venue. This Settlement Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware governing agreements fully executed therein and to be performed therein, without regard for any conflict of law principles that would dictate the application of the laws of another jurisdiction. The Parties agree that the United States District Court for the District of Delaware shall have exclusive and sole jurisdiction to enforce any violation of this Settlement Agreement, except that, if for any reason that Court does not accept jurisdiction, then the state courts located in the state of Delaware, shall have exclusive and sole jurisdiction to enforce any violation of this Settlement Agreement. The Parties hereby consent to the personal jurisdiction of those courts for any dispute arising from or relating to this Settlement Agreement.

17. Validity. If any provision of this Settlement Agreement shall be held by a court of competent jurisdiction to be illegal, invalid, or unenforceable, in whole or in part, the remaining provisions shall remain in full force and effect and the Parties shall negotiate in good faith to replace the invalid or unenforceable provision with a valid and enforceable provision that has the effect nearest to that of the provision to be replaced.

18. Construction. This Settlement Agreement has been negotiated by the Parties and their respective counsel and shall be interpreted fairly in accordance with its terms and without any strict construction in favor of or against any Party. Headings of paragraphs or sections of this Settlement Agreement are for reference only and shall not be deemed to be a part of this Settlement Agreement.

19. Waiver. Waiver by a Party of any breach of any provision of this Settlement Agreement by another Party shall not operate or be construed as a waiver of any subsequent or other breach. For the avoidance of doubt, no terms or conditions of this Agreement will be discharged, terminated, varied, or modified by any prior or subsequent written or oral statement, or by the conduct or act of any Party. No provision of this Settlement Agreement may be waived except by a written instrument signed by the Party waiving compliance.

20. Counterparts. This Settlement Agreement may be executed in one or more counterparts (including via electronic copy), each of which when so executed and delivered shall be deemed to be an original, but all of which taken together form but one and the same instrument.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

IN WITNESS HEREOF, the Parties have caused their duly authorized representatives to execute this Settlement Agreement to be effective as of the Execution Date.

ALEXION PHARMACEUTICALS, INC.

By: /s/Aradhana Sarin
Name: Aradhana Sarin
Title: EVP & CFO

Date: May 28, 2020

ALEXION PHARMA INTERNATIONAL OPERATIONS UNLIMITED COMPANY.

By: /s/Todd Spalding
Name: Todd Spalding
Title: Director

Date: May 28, 2020

AMGEN INC.

By: /s/ Peter H. Griffith
Name: Peter H. Griffith
Title: EVP & CFO

Date: May 28, 2020

Certain information indicated with [****] in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

CONFIDENTIAL
EXECUTION COPY

SCHEDULE A

Alexion Reference Number	US Patent/Application Number
[****]	[****]

ANNEX A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMGEN INC.,

Petitioner,

v.

ALEXION PHARMACEUTICALS, INC.,

Patent Owner.

Case IPR2019-00739[1]
Patent 9,725,504

JOINT MOTION TO TERMINATE PROCEEDING
PURSUANT TO 35 U.S.C. § 317 and 37 C.F.R. § 42.74

Mail Stop PATENT BOARD
Patent Trial and Appeal Board
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313–1450

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[1]Substantially the same paper will be filed in IPR2019-00740 and IPR2019-00741, if authorized by the PTAB

I. Statement of Precise Relief Requested

Pursuant to 35 U.S.C. § 317(a) and as authorized by the Board on [DATE], Petitioner Amgen Inc. ("Amgen") and Patent Owner Alexion Pharmaceuticals, Inc. ("Alexion") jointly request termination of the *Inter Partes* Review of U.S. Patent No. 9,725,504 ("the '504 patent"), Case No. IPR2019-00739.

II. Argument

The parties have executed a settlement agreement that resolves all of their disputes concerning the '504 patent, expressly including the present *Inter Partes* Review (IPR). Termination of IPR by the Board is appropriate for a least the following reasons:

a) The parties are jointly requesting termination. 77 Fed. Reg. 48756, 48768 (Aug. 14, 2012) ("There are *strong public policy reasons to favor settlement* between the parties to a proceeding") (emphasis added);

b) The Board has not yet "decided the merits of the proceeding *before the request for termination is filed*." 35 U.S.C. § 317(a) (emphasis added); 77 Fed. Reg. 48768 ("The Board expects that a proceeding will terminate after the filing of a settlement agreement, unless the Board has already decided the merits of the proceeding."). This supports the propriety of terminating this proceeding.. *See, e.g., Toyota Motor Corp. v. Blitzsafe Tex. LLC*, IPR2016-00421, Paper 28 (Feb. 21, 2017)

(granting motion to terminate even after all substantive papers were filed, "particularly in light of the fact that a final written decision is not due until more than four months from now"); *Plaid Techs., Inc. v. Yodlee, Inc.*, IPR2016-00273, Paper 29 (Feb. 8, 2017) (granting motion to terminate because "the parties' joint motions to terminate were filed prior to the oral hearings in these cases"); *Apex v. Resmed*, IPR2013-00512, Paper 39 (Sept. 12, 2014) (granting joint motion to terminate after the parties had fully briefed the matter); *Rackspace Hosting, Inc. v. Clouding IP, LLC*, CBM2014-00034, Paper 28 (Dec. 9, 2014) (granting motion to terminate after close of evidentiary record and less than ten days before trial); *Volution v. Versata Software*, CBM2013-00018, Paper 52 (June 17, 2014) (granting motion to terminate after oral hearing); *AM General LLC v. Uusi, LLC*, IPR2016-1050, Paper 44 (Nov. 7, 2017) (granting motion to terminate after oral hearing); and

c) No dispute remains between the Parties involving the '504 patent. The only related pending proceedings regarding the '504 patent before the Board are IPR2019-00740 (U.S. Patent No. 9,718,880) and IPR2019-00741 (U.S. Patent No. 9,732,149). Joint Motions to Terminate are being filed in these cases concurrently with this Joint Motion to Terminate.

Further, maintaining this proceeding would contradict the Congressional goal to establish a more efficient and streamlined patent system that limits unnecessary and counterproductive litigation costs. *See, e.g.*, *AM General LLC*, IPR2016-01050, Paper 44 ("Generally, the Board expects that a proceeding will terminate after the filing of a settlement agreement.").

III. Written Settlement Agreement

As set forth in 35 U.S.C. § 317 and 37 C.F.R. § 42.74, the agreement has been made in writing in the form of a settlement agreement executed by the parties, and a true and correct copy of that settlement agreement has been filed as Exhibit ____. The parties hereby represent that the document filed as Exhibit ____ represents all agreements made in connection with, or in contemplation of, the termination of this proceeding.

As stated in 35 U.S.C. § 317(a), because Amgen and Alexion request this termination, no estoppel under 35 U.S.C. § 315(e) shall attach to Amgen.

Submitted concurrently herewith is a joint request to file the settlement agreement as business confidential information pursuant to 35 U.S.C. § 317(b) and § 42.74(c).

IV. Conclusion

Based on the above, Petitioner and Patent Owner respectfully request termination of the *Inter Partes* Review of U.S. Patent No. 9,725,504, Case No. IPR2019-00739.

By:

Deborah A. Sterling, Ph.D.
Reg. No. 62,732
Sterne, Kessler, Goldstein & Fox P.L.L.C
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
Tel: (202) 371-2600

Lead Attorney for Petitioner Amgen Inc.

Dated: [DATE]

Respectfully submitted,

By:

Gerald J. Flattmann, Jr.
Reg. No. 37,324
King And Spalding LLP
1185 Avenue of the Americas
New York, NY 10002
Tel: (212) 556-2100

Lead Attorney for Patent Owner Alexion Pharmaceuticals, Inc.

ANNEX B

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMGEN INC.,

Petitioner,

v.

ALEXION PHARMACEUTICALS, INC.,

Patent Owner.

Case IPR2019-00739[1]
Patent 9,725,504

JOINT MOTION TO FILE SETTLEMENT AGREEMENT AS BUSINESS CONFIDENTIAL INFORMATION UNDER 35 U.S.C. § 317

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Patent Trial and Appeal Board
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313–1450

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[1]Substantially the same paper will be filed in IPR2019-00740 and IPR2019-00741, if authorized by the PTAB

Pursuant to 35 U.S.C. § 317(b) and § 42.74, Petitioner Amgen Inc. and Patent Owner Alexion Pharmaceuticals, Inc. jointly request to keep the Settlement Agreement (Exhibit ____, which comprises business confidential information, separate from the public files in accordance with this statute and regulation.

By:

Deborah A. Sterling, Ph.D.
Reg. No. 62,732
Sterne, Kessler, Goldstein & Fox P.L.L.C
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
Tel: (202) 371-2600

Lead Attorney for Petitioner Amgen Inc.

Dated: [DATE]

Respectfully submitted,

By:

Gerald J. Flattmann, Jr.
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Lead Attorney for Patent Owner Alexion Pharmaceuticals, Inc.