

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q/A
Amendment No. 1**

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 001-37553

REGENXBIO Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

47-1851754
(I.R.S. Employer
Identification No.)

9600 Blackwell Road, Suite 210
Rockville, MD
(Address of principal executive offices)

20850
(Zip Code)

(240) 552-8181
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 5, 2016, there were 26,465,379 outstanding shares of the registrant's common stock, \$0.0001 par value per share.

Explanatory Note

REGENXBIO Inc. (the “Company”) is filing this Amendment No. 1 to its Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 (the “Original Filing”), filed with the Securities and Exchange Commission (the “SEC”) on August 9, 2016, solely to revise Exhibit 10.36 (Third Amendment to License Agreement effective April 29, 2016 between the Registrant and The Trustees of the University of Pennsylvania) to the Original Filing to include certain portions of such exhibit in response to comments the Company received from the SEC in connection with the Company’s request for confidential treatment.

Pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended, this Amendment No. 1 also contains new certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, which are attached hereto. Because no financial statements have been included in this Amendment No. 1, and because this Amendment No. 1 does not contain or amend any disclosure with respect to Items 307 and 308 at Regulation S-K, paragraphs 3, 4 and 5 of the certifications have been omitted.

This Amendment No. 1 should be read in conjunction with the Original Filing, which continues to speak as of the date of the Original Filing. Except as specifically noted above, this Amendment No. 1 does not modify or update disclosures in the Original Filing. Accordingly, this Amendment No. 1 does not reflect events occurring after the filing of the Original Filing or modify or update any related or other disclosures.

PART II – OTHER INFORMATION

Item 6. Exhibits.

<u>Exhibit</u>	<u>Description</u>
3.1*	Restated Certificate of Incorporation (filed as Exhibit 3.1 to the Company’s Current Report on Form 8-K as filed on September 22, 2015, and incorporated herein by reference)
3.2*	Amended and Restated Bylaws (filed as Exhibit 3.2 to the Company’s Current Report on Form 8-K as filed on September 22, 2015, and incorporated herein by reference)
10.36†	Third Amendment to License Agreement effective April 29, 2016 between the Registrant and The Trustees of the University of Pennsylvania
31.1	Certification of the Principal Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Principal Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002

* Previously filed.

† Confidential treatment has been requested with respect to certain portions of this exhibit. These portions have been omitted and submitted separately to the SEC.

SIGNATURES

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

REGENXBIO Inc.

Dated: December 23, 2016

/s/ Kenneth T. Mills

Kenneth T. Mills
President and Chief Executive Officer
(Principal Executive Officer)

Dated: December 23, 2016

/s/ Vittal Vasista

Vittal Vasista
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT INDEX

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* Previously filed.

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CONFIDENTIAL TREATMENT REQUESTED

Final Execution Copy

UNIVERSITY of PENNSYLVANIA

Third Amendment to License Agreement

This Third Amendment to License Agreement (this “*Third Amendment*”) effective as of April 29, 2016 (this “*Third Amendment Effective Date*”), is made by and between The Trustees of the University of Pennsylvania (“*Penn*”) and REGENXBIO Inc. (“*Company*”) (collectively, the “*Parties*”) and amends the License Agreement between the Parties, which was effective as of February 24, 2009, as subsequently amended by a First Amendment dated March 6, 2009 and a Second Amendment dated September 9, 2014 (the “*License Agreement*”). All capitalized terms used but not defined herein shall have the meaning set forth in the License Agreement.

BACKGROUND

WHEREAS, the Parties are simultaneously entering into a Clinical Trial Research Agreement relating to evaluation of the safety of AAV8.TBG.hLDLR, a replication deficient recombinant adeno-associated virus vector 8 (AAV8) expressing human Low Density Lipoprotein receptor (LDLR) from liver-specific thyroxine-binding globulin (TBG) promoter, (the “*Study Drug*”) in certain patients with Homozygous Familial Hypercholesterolemia (HoFH) in a Phase 1/2 clinical trial as set forth in the Clinical Trial Research Agreement (the “*Study*”);

WHEREAS, Company wishes to license, and Penn agrees to provide to Company with, a license to data, results and other information generated in connection with the Study in the furtherance of Company’s commercialization objectives, including Company’s intention to seek marketing authorization from the FDA and other regulatory authorities for the Study Drug and the treatment of patients with HoFH; and

WHEREAS, the Parties desire that the License Agreement be amended as set forth below in order to amend the license grants to include within the scope of the License Agreement certain rights to data, results and other information generated from the Study;

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, the Parties, intending to be bound, hereby mutually agree to the following:

1. The following definitions in Section 1.2 of the License Agreement shall be amended and restated in their entirety as follows:

“*Background Know-How*” means all (i) Know-How that (a) was developed by Dr. Wilson, or other Penn researchers working under his direct supervision, at Penn, and (b) is related to the adeno associated virus technology platform discovered by Dr. Wilson at Penn prior to September 9, 2014 or is related to the adeno associated virus technology platform discovered by Dr. Wilson at Penn during the performance of a Company sponsored research program

after September 9, 2014, and (c) is owned by Penn, (d) is necessary or useful for the practice of the Patent Rights in connection with the manufacture, use, sale, importation and/or other exploitation of the Licensed Products or the practice of the Licensed Processes in the Territory in the Field of Use, including, without, limitation, any Know-How necessary for the Company to manufacture or have manufactured the materials produced by the Penn Vector Core or Dr. Wilson's lab at Penn; and (ii) Penn Study Data.

"*Field of Use*" means any and all fields of use, except with respect to (i) the Patent Rights listed in Exhibit A, Part 2 and all related Know-How and data, for which the Field of Use is limited to viral vector mediated gene therapy, and (ii) the Penn Study Data, for which the Field of Use is limited to the treatment of familial hypercholesterolemia (FH).

"*Licensed Products*" means any products that are made, made for, used, imported, offered for sale or sold by or for Company or its Affiliates or sublicensees and that either (i) in the absence of this Agreement, would infringe or misappropriate the Licensed IP, or any claim thereof whether or not the claim is issued or pending, or (ii) use, or are manufactured using, a Licensed Process, or (iii) rely on the Penn Study Data in connection with the regulatory approval of such a product for treating FH, or (iv) are supported by Penn Study Data that corresponds to and/or supports the patentability of such product or its use in the field. Licensed Products include Licensed Pharmaceutical Products and Licensed Reagents.

2. The following definitions shall be added to Section 1.2 of the License Agreement:

"*Clinical Research*" means all those tests, studies and other activities described in the Protocol or required in order to obtain the information set out in the Protocol together with such other activities as may be agreed on to be undertaken by Penn and Company in accordance with Clinical Trial Research Agreement between Penn and the Company dated April 29, 2016 (the "*HoFH CTRA*").

"*Penn Study Data*" means all data and information that are generated in the performance of the Clinical Research during the term of this Agreement.

"*Protocol*" means a description of the research to be undertaken by Penn and/or Company as set forth in Exhibit A of the HoFH CTRA, as may be amended pursuant to Section 20 of the HoFH CTRA.

3. The following definitions in Section 3.5 of the License Agreement shall be amended and restated in their entirety as follows:

"*Royalty Term*" means, on a product-by-product, country-by-country basis with respect to Licensed Products in a Field of Use other than for treating FH, the period commencing on the date of the first Sale of such Licensed Product and ending on the date the Licensed Product ceases to be covered by a valid claim (issued or pending) of the Patent Rights. With respect to Licensed Products for treating FH, "*Royalty Term*" means, on a product-by-product,

country-by-country basis, the period commencing on date of the first Sale of such Licensed Product for treating FH and ending on the later of: (i) the date the Licensed Product for treating FH ceases to be infringed or covered by a valid claim (issued or pending) of the Patent Rights, and (ii) seven (7) years following the first Sale of such Licensed Product for treating FH.

4. Exhibit A of the License Agreement is hereby amended and restated in its entirety by Exhibit A-1 to this Third Amendment to add the additional Patent Rights and Know-How.

5. This Third Amendment amends the terms of the License Agreement and is deemed incorporated into, and governed by all other terms of, the License Agreement. To the extent that the License Agreement is explicitly amended by this Third Amendment, the terms of this Third Amendment will control where the terms of the License Agreement are contrary to or conflict with the terms of this Third Amendment. All other terms and conditions of the License Agreement not explicitly amended by this Third Amendment shall remain in full force and effect. The License Agreement, as previously amended, shall, together with this Third Amendment, be read and construed as a single instrument.

6. Signatures on this Third Amendment may be communicated by facsimile or e-mail transmission and shall be binding upon the Parties upon receipt by transmitting the same by facsimile or e-mail transmission, which signatures shall be deemed originals. If executed in counterparts, the Third Amendment shall be effective as if simultaneously executed.

[Intentionally left blank]

IN WITNESS WHEREOF, the Parties, intending to be legally bound, have caused this Third Amendment to be executed by their duly authorized representatives.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

By: /s/ John S. Swartley, PhD
Name: John S. Swartley, PhD
Title: Associate Vice Provost for Research and Executive Director, PCI
Date: June 2, 2016

REGENXBIO INC.

By: /s/ Kenneth T. Mills
Name: Kenneth T. Mills
Title: President and CEO
Date: June 6, 2016

Exhibit A-1

Patents and Patent Applications in the Patent Rights

Part 1; No Field of Use Limitation

<u>Serial No</u>	<u>Patent No</u>	<u>App Type</u>	<u>File Date</u>	<u>Status</u>	<u>Country</u>	<u>Issue Date</u>
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Docket V5085

Combinational method to generate novel and/or hybrid coding sequences within the defined domains

<u>Serial No</u>	<u>Patent No</u>	<u>App Type</u>	<u>File Date</u>	<u>Status</u>	<u>Country</u>	<u>Issue Date</u>
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Docket V5131

A domain of the adeno-associated virus stereotypic 6 capsid that confers transduction of conducting airway epithelium

<u>Serial No</u>	<u>Patent No</u>	<u>App Type</u>	<u>File Date</u>	<u>Status</u>	<u>Country</u>	<u>Issue Date</u>
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<u>Docket X5836</u>		<u>The receptor for AAV9 and its modification in vivo to improve lung gene therapy</u>					
<u>Serial No</u>	<u>Patent No</u>	<u>App Type</u>	<u>File Date</u>	<u>Status</u>	<u>Country</u>	<u>Issue Date</u>	
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<u>Docket Z6622</u>		<u>Compositions and Methods for Treatment of MPS11</u>					
<u>Serial No</u>	<u>Patent No</u>	<u>App Type</u>	<u>File Date</u>	<u>Status</u>	<u>Country</u>	<u>Issue Date</u>	
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**Exhibit A, Part 2-
Field of Use limited to viral vector mediated delivery of gene therapy product.**

<u>Docket 14-7025</u>		<u>Improved AAV-LDLR for treating human disease</u>					
<u>Serial No</u>	<u>Patent No</u>	<u>App Type</u>	<u>File Date</u>	<u>Status</u>	<u>Country</u>	<u>Issue Date</u>	
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<u>Docket 14-7037</u>		<u>AAV OTC for treating human disease</u>					
<u>Serial No</u>	<u>Patent No</u>	<u>App Type</u>	<u>File Date</u>	<u>Status</u>	<u>Country</u>	<u>Issue Date</u>	
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Docket 16-7717

Serial No

Patent No

App Type

Methods and compositions for treating lowering cholesterol

File Date

Status

Country

Issue Date

Docket 15-7487

Serial No

Patent No

App Type

Compositions and Methods for Treating MPSI

File Date

Status

Country

Issue Date

Penn / Wilson Lab Know-How for the Familial Hypercholesterolemia and Onithine Transcarbamylase Deficiency (OTC) Programs

FH Know-How (associated with ****)

OTC Know-How (associated with ****)

****CERTAIN INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

CERTIFICATION

I, Kenneth T. Mills, certify that:

1. I have reviewed this Amendment No. 1 to Quarterly Report on Form 10-Q of REGENXBIO Inc.; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: December 23, 2016

/s/ Kenneth T. Mills

Kenneth T. Mills
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Vittal Vasista, certify that:

1. I have reviewed this Amendment No. 1 to Quarterly Report on Form 10-Q of REGENXBIO Inc.; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: December 23, 2016

/s/ Vittal Vasista

Vittal Vasista
Chief Financial Officer
(Principal Financial and Accounting Officer)