

**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): **June 24, 2019**

LIQUIDIA TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-38601

(Commission
File Number)

20-1926605

(IRS Employer
Identification No.)

419 Davis Drive, Suite 100, Morrisville, North Carolina

(Address of principal executive offices)

27560

(Zip Code)

Registrant's telephone number, including area code: **(919) 328-4400**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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	LQDA	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 x

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. x

Item 1.01 Entry into a Material Definitive Agreement.

On June 26, 2019, Liquidia Technologies, Inc., a Delaware corporation (the “Company”), announced that it has entered into Amendment No. 3 (the “Third Amendment”) to the Inhaled Collaboration and Option Agreement, dated as of June 15, 2012, as amended (the “Agreement”), with Glaxo Group Limited (“GSK”). Pursuant to the Third Amendment, the Company may propose to GSK the research, development and commercialization by the Company of “Additional Liquidia Respiratory Products” (“ALRPs”, as defined therein). The Third Amendment also provides for three such ALRPs which have been approved by GSK. Any further potential ALRP that the Company proposes to research, develop and commercialize shall be requested no more frequently than quarterly and is subject to GSK approval, with such consent not to be unreasonably withheld. If GSK does not object to such a proposal within 90 days from the date of receipt, such proposal shall be deemed to be approved.

If the Company desires to grant a license or any rights to its interest in any ALRP to a third party, then it shall first notify GSK of such desire in writing, describing or providing, as the case may be, (a) in reasonable detail the scope of the license it is interested in granting to a third party from whom the Company has received a documented unsolicited offer, or (b) a full dataset from a Phase 1 clinical trial of the ALRP (the “ROFN Notice”) and GSK thereafter shall have the exclusive right of first negotiation to obtain an exclusive, worldwide sublicensable license to the Company’s interest in the ALRP, as applicable, and any other intellectual property rights then controlled by the Company that are necessary or reasonably useful for the making, having made, use, sale, offering for sale or importation of products in the Inhaled Field (as defined in the Agreement). The parties shall negotiate in good faith for 90 days (the “Negotiation Period”) from the receipt of the ROFN Notice. If the parties fail to reach a binding written agreement for the exclusive license by the end of the Negotiation Period, then the Company shall be free to enter into a license with any third party, subject to the milestones and royalties described below.

In the event the Company is unable to execute an agreement with a third party within six months after the expiration of the Negotiation Period, then the ROFN in favor of GSK shall be reinstated if such ROFN was triggered by an unsolicited third party licensing offer prior to the completion of a full data set from a Phase 1 clinical trial. If such ROFN was triggered by a full data set from a Phase 1 clinical trial, then the ROFN will not be reinstated.

With respect to the first three ALRPs that the Company develops and commercializes itself, milestone payments will be due to GSK upon (i) the first dosing of the first patient in the first Phase 3 clinical trial, (ii) approval of the New Drug Application or Biologics License Application, as applicable, by the U.S. Food and Drug Administration, (iii) approval of the Marketing Authorization Application by the European Medicines Agency, and (iv) achievement of certain specified sales levels. With respect to the next three ALRPs that the Company develops and commercializes itself, these milestones payments shall be reduced by 50%, and no milestone payments shall be due for any such ALRPs subsequently developed and commercialized by the Company. In addition, the Company shall pay to GSK tiered single-digit royalties on any sales of such ALRPs. Furthermore, should the Company enter into a third-party collaboration agreement with respect to any ALRP, in addition to the milestones and royalties described above, the Company shall pay to GSK a specified single-digit percentage of any revenues the Company receives from such third party.

Pursuant to the Third Amendment, the Company is also responsible for, among other things, (i) providing GSK with written reports on an annual basis which summarize the Company’s material activities with respect to the development of ALRPs, and (ii) providing GSK with quarterly reports setting forth the net sales of each ALRP on a country-by-country basis and the royalties due on each such ALRP, commencing with the calendar quarter in which the first commercial sale of any “Product” (as defined in the Agreement) and/or any ALRP is made anywhere in the world.

The foregoing description of the Third Amendment is qualified in its entirety by reference to the complete text of the Third Amendment, a copy of which is attached as Exhibit 10.1 to this Current Report and incorporated herein by reference. A copy of the Company’s press release relating to the Third Amendment is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
10.1*	Amendment No. 3 to the Inhaled Collaboration and Option Agreement, effective as of June 24, 2019, by and between Liquidia Technologies, Inc. and Glaxo Group Limited.
99.1	Press Release of Liquidia Technologies, Inc., dated June 26, 2019.

* Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10). The omitted information is not material and would likely cause competitive harm to the registrant 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.

June 28, 2019

Liquidia Technologies, Inc.

By: /s/ Richard D. Katz, M.D.

Name: Richard D. Katz, M.D.

Title: Chief Financial Officer

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [*] INDICATES THAT INFORMATION HAS BEEN REDACTED.**

Execution Copy

Amendment No.3 to the Inhaled Collaboration and Option Agreement

This Third Amendment (“Amendment 3”) is made effective as of the 24 day of June 2019 (“Amendment 3 Effective Date”) by and between:

LIQUIDIA TECHNOLOGIES, INC., a Delaware corporation, having its principal place of business at 419 Davis Dr., Suite 100, Morrisville, NC 27560 (“Liquidia”) on the one part and;

GLAXO GROUP LIMITED, a company organized and existing under the laws of England and having an office and place of business at 980 Great West Road, Brentford, Middlesex TW8 9GS England (“GSK”) on the other part.

WHEREAS, the Parties entered into the Inhaled Collaboration And Option Agreement, dated June 15, 2012, and subsequently amended by Amendment 1 to the Inhaled Collaboration and Option Agreement, dated May 13, 2015, and Amendment 2 to the Inhaled Collaboration and Option Agreement dated November 19, 2015, (collectively “the Agreement”);

WHEREAS, the Vaccines Option expired on April 30, 2016, and GSK exercised the Inhaled Option under section 4.2 of the Agreement on September 4, 2015;

WHEREAS, the Parties wish to amend the Agreement in order to enable Liquidia to progress molecules within the Inhaled Field in an effort to commercialize Inhaled Products; and

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants and conditions contained in this Amendment 3 and the Agreement, the Parties wish to amend the Agreement from and after the Amendment 3 Effective Date as follows:

1. Defined Terms. All capitalized terms in this Amendment 3 shall have the meaning assigned in the Agreement. All other terms and conditions of the Agreement necessary to effectuate this Amendment 3 shall be incorporated hereby by reference.
2. Amendments to Existing Definitions
- 2.1 The following defined terms and associated section references are hereby deleted in their entirety:

“Co Delivery Vaccine Field”; “Disease Field”; “Exercised Disease Field”; “GSK Bio”; “GSK Bio Alliance Manager”; and “Joint Vaccines Research Committee” or “JVRC”; “Vaccines”; “Vaccines Collaboration”; “Vaccines Collaboration Term”; “Vaccine Option”; “Vaccine Option Period”; and “Vaccine Plan” are hereby deleted.

2.2 The following defined terms and associated section references are hereby deleted in their entirety: “Inhaled Option”; “Inhaled Option Notice”; “Inhaled Option Period”.

2.3 New Definitions. The following defined terms are hereby added to Article 1 as new Sections 1.162 and 1.163, respectively:

“*Additional Liquidia Respiratory Product(s)*” means molecules within the Inhaled Field including those listed in Exhibit B.”

“*Milestones Event*” means those events described in Exhibit A to this Amendment 3 as applicable to Additional Liquidia Respiratory Product(s).”

3. Amendment to Article 2

3.1 The Parties hereby insert a new “xi” under Article 2.1 (d) as follows:

“(xi) review and approve the Additional Liquidia Respiratory Products”

3.2 The Parties hereby delete in its entirety Article 2.2 (“*Joint Inhaled Research Committee*”).

3.3 Sections 2.3 to 2.7 are hereby renumbered as Sections 2.2 to 2.6.

4. Amendments to Article 4

4.1 Section 4.2 is hereby deleted and replaced as follows:

“4.2 **Additional Liquidia Respiratory Product**. GSK hereby allows Liquidia to research, develop and commercialize Additional Liquidia Respiratory Product, subject to GSK approval based on the following:

- (a) Liquidia shall first submit each molecular candidate to GSK (each a “**Liquidia Proposal**”) not more frequently than one per quarter.
- (b) GSK will evaluate each Liquidia Proposal and provide Liquidia its written consent, not to be unreasonably withheld, within ninety (90) days following the submission date of the Liquidia Proposal. A rejected Liquidia Proposal shall remain exclusive to GSK under the terms of the Agreement. If Liquidia is not in receipt of GSK’s response to a Liquidia Proposal before expiration of the ninety (90) day evaluation period, then the Liquidia Proposal shall be deemed approved and become an Additional Liquidia Respiratory Product, subject to Section 4.3.”

4.2 Section 4.3 is hereby deleted in its entirety and replaced as follows:

“4.3 **Right of First Negotiation (“ROFN”)**. If Liquidia desires to grant a license or any rights to its interest in any Additional Liquidia Respiratory Product to a Third Party, then it shall first notify GSK of such desire in writing, describing or providing, as

the case may be, (a) in reasonable detail the scope of the license it is interested in granting to a Third Party from whom Liquidia has received a documented unsolicited offer by means of a term sheet or letter of intent, or (b) a full dataset from a Phase 1 Clinical Trial of the Additional Liquidia Respiratory Product in scope (the “**ROFN Notice**”) and GSK thereafter shall have the exclusive right of first negotiation to obtain an exclusive, worldwide sublicensable license to Liquidia’s interest in the Additional Liquidia Respiratory Product, as applicable, and any other intellectual property rights (which may include Liquidia Technology) then controlled by Liquidia that are necessary or reasonably useful for the making, having made, use, sale, offering for sale or importation of products in the Inhaled Field. The Parties shall negotiate in good faith for ninety (90) days (the “**Negotiation Period**”) from the receipt of the ROFN Notice. In any event, prior to Liquidia submitting the ROFN Notice to GSK, Liquidia must have (i) generated full dataset in a Phase 1 Clinical Trial of the Additional Liquidia Respiratory Product, or (ii) received a documented unsolicited offer by means of a term sheet or letter of intent to acquire rights to the Additional Liquidia Respiratory Product prior to the completion of a Phase 1 Clinical Trial.

If the Parties fail to reach a binding written agreement for the exclusive license by the end of the Negotiation Period, then Liquidia shall be free to negotiate with any Third Party, and enter into, a license, such license shall be subject to the milestones and royalties contained in Exhibit A to this Amendment 3 and subject to the following conditions:

- I. The Phase III Clinical Trial milestone and NDA/MAA approval milestones for each Additional Liquidia Respiratory Product shall be paid at (i) one hundred percent (100%) for the first to third Additional Liquidia Respiratory Products reaching this Milestone Event; (ii) 50% for the fourth to sixth Additional Liquidia Respiratory Products reaching this Milestones Event. After the 6th Additional Liquidia Respiratory Product, there shall be no milestone payment due to GSK.
- II. For any sublicense Liquidia grants to a Third Party on any Additional Liquidia Respiratory Product, Liquidia shall pay GSK [***] percent ([***]%) of any revenue Liquidia receives under such sublicense. For the avoidance of doubt, this [***]% will be in addition to the milestones and royalties due under Exhibit A.

In the event, Liquidia is unable to execute an agreement with a Third Party within six (6) months after the expiration of the Negotiation Period pursuant to Article 4.3 (a), then the Parties hereby agree that the ROFN in favor of GSK shall be reinstated until the ROFN is triggered under Article 4.3 (b). For the avoidance of doubt, the ROFN could be triggered multiple times under Article 4.3 (a), but not under Article 4.3 (b).

Should the ROFN be triggered pursuant to Article 4.3 (b), then the ROFN in favor of GSK would cease after the Negotiation Period.”

4.3 GSK hereby approves the molecules in Exhibit B as Additional Liquidia Respiratory Products, each subject to the terms and conditions of this Amendment 3.

5. Amendments to Article 6

5.1 The Parties hereby add a new section 6.4.

“6.4 Development Records and Reports. Liquidia shall maintain complete, current and accurate records of all development activities conducted on the Additional Liquidia Respiratory Products, and all data and other Know-How resulting from such activities in accordance with the principles set forth in Section 3.5(b) and 3.6. Liquidia shall provide GSK with written reports summarizing the material activities of Liquidia with respect to the development of such Additional Liquidia Respiratory Products, to enable GSK to determine Liquidia’s compliance with its diligence obligations hereunder. These reports shall be provided to GSK on an annual basis to GSK’s Alliance Manager and Liquidia shall make reasonably available to GSK appropriate technical or scientific personnel who are knowledgeable about the development activities conducted by Liquidia with respect to the Additional Liquidia Respiratory Products that are the subject of the report, to respond to such questions in a timely manner, via teleconference, in person or such other mode of communication as the Parties may mutually agree.”

6. Amendments to Article 10

6.1 The Parties hereby agree that Article 10 shall apply to the Additional Liquidia Respiratory Products. If a certain provision refers to “GSK”, it would be read as “Liquidia” for the purposes of the Additional Liquidia Respiratory Products.

6.2 For the purposes of Article 10.4 (d), Liquidia shall notify the Head of GSK R&D Business Development and the Head of GSK Alliance Manager with copy to the GSK’s Alliance Manager in writing promptly, but in no event later than ten (10) Business Days after each achievement of each milestone set forth herein in Exhibit A that triggers a payment. Liquidia shall pay all such milestone payments due in Dollars within sixty (60) days after Liquidia’s receipt of an invoice from GSK following the achievement of the corresponding milestone event. Such invoice shall be sent in PDF format to [***] (or such other e-mail address(es) as may be notified to GSK by Liquidia). Liquidia shall notify GSK of any deficiency in any invoice delivered to Liquidia hereunder promptly, and in no event more than seven (7) Business Days following Liquidia’s receipt thereof. The Parties hereby delete in its entirety Article 10.5 (a) (i). Article 10.5 (a) (ii) shall be renumbered to Article 10.5 (a) (i).

6.3 The Parties hereby amend Article 10.5 (d) as follows:

*“(d) **Royalty Reports and Payments.** Within sixty (60) days following the end of each calendar quarter, commencing with the calendar quarter in which the First Commercial Sale of any Product and/or any Additional Liquidia Respiratory Product is made anywhere in the world, Liquidia shall provide GSK with a report setting forth the Net Sales of each Additional Liquidia Respiratory Product on a country-by-country basis and the royalties*

due on such Additional Liquidia Respiratory Products. Concurrent with the delivery of the applicable quarterly report, Liquidia shall pay in Dollars all amounts.”

7. General

- 7.1 The terms of this Amendment 3 shall prevail over the Agreement in relation to the Additional Liquidia Respiratory Product approval process and milestones and royalties.
- 7.2 The Agreement shall remain in full force and effect and this Amendment 3 shall be read and construed as one document.
- 7.3 This Amendment 3 amends the Agreement, in accordance with the terms of Section 17.1 of the Agreement. Upon this Amendment 3 becoming effective each reference in the Agreement to “this Agreement,” “hereunder,” “hereof,” “herein” or words of similar meaning shall be a reference to the Agreement as amended by this Amendment 3. Other than as amended by this Amendment 3, the Agreement shall be otherwise unchanged and remain in full force and effect.
- 7.4 This Amendment 3 is governed by and shall be construed in accordance with the Laws of the State of New York and subject to the Article 16 of the Agreement.
- 7.5 This Amendment 3 may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

[Signature Page Follows]

In **WITNESS WHEREOF**, the Parties have executed this Amendment 3 by their duly authorized officers as of the Amendment 3 Effective Date.

GLAXO GROUP LIMITED

**LIQUIDIA
TECHNOLOGIES, INC.**

By: /s/ Paul Williamson
/s/ Joan Sadler

By: /s/ Neal Fowler

Name: Paul Williamson
Joan Sadler

Name: Neal Fowler

Title: Chief Executive
Officer

Title: Authorized Signatories

EXHIBIT A

Milestones and Royalties applicable to Additional Liquidia Respiratory Product

Milestone Event	Milestone / Royalty Payments for each Additional Liquidia Respiratory Product
First dosing of First Patient in First Phase III Clinical Trial	[\$***]
NDA/BLA approval by FDA	[\$***]
MAA approval by EMA	[\$***]
Sales Milestones per Worldwide Net Sales	Respective Payment
\$250M	[\$***]
\$500M	[\$***]
\$750M	[\$***]
\$1Bn	[\$***]
\$1.5Bn	[\$***]
Royalties per Worldwide Net Sales	Respective Royalty Rate
< \$750M	[***]%
\$750M - \$1.5Bn	[***]%
>\$1.5Bn	[***]%

EXHIBIT B

Approved Additional Liquidia Respiratory Product(s)

Molecule	Class / MoA	Hypothesis for Inhaled PRINT Delivery
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]



Liquidia and GSK Restructure Collaboration Agreement

RESEARCH TRIANGLE PARK, N.C., June 26, 2019 — Liquidia Technologies, Inc. (Nasdaq: LQDA) (“Liquidia” or the “Company”), a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using its proprietary PRINT® technology, today announced that it has amended its collaboration agreement with GlaxoSmithKline (GSK) for the development and commercialization of pharmaceuticals based upon the Company’s proprietary PRINT® technology delivered through the inhalation route of administration.

The amended collaboration agreement provides the Company with the right to develop and commercialize three additional PRINT®-based therapeutics delivered via inhalation. Additionally, under the amended collaboration agreement, the Company can acquire rights to pursue additional PRINT®-based programs for inhalation therapy, subject to GSK’s approval. The amended collaboration agreement provides GSK with a right of first negotiation prior to the Company entering into a license agreement with a third party for any GSK-approved program developed under this amended collaboration agreement. Any new PRINT®-based therapeutic delivered via inhalation developed by the Company under the amended collaboration agreement would carry milestone and royalty obligations due to GSK, beginning with the initiation of a Phase 3 clinical trial. Prior to entering into the amended collaboration agreement, GSK maintained exclusive rights to develop and commercialize any PRINT®-based therapeutic delivered via inhalation, with the exception of LIQ861, the Company’s Phase 3 product candidate for the treatment of pulmonary arterial hypertension (PAH).

Neal Fowler, CEO of Liquidia, stated: “We are very excited by the opportunity to build on the benefits of PRINT® technology in inhaled delivery, as evidenced by the success of our clinical studies with LIQ861, the first inhaled dry powder formulation of tadalafil to treat patients with pulmonary arterial hypertension. Although submitting the New Drug Application (NDA) for LIQ861 remains our top priority in 2019, we also see clear opportunities to further expand the Liquidia pipeline of respiratory products.”

About LIQ861

LIQ861, a dry powder formulation of tadalafil based upon Liquidia’s proprietary PRINT® technology, is currently being evaluated in a Phase 3 clinical trial (INSPIRE) for the treatment of pulmonary arterial hypertension (PAH). PRINT® technology results in a tadalafil drug candidate with particles of a precise, uniform size, shape and composition that are engineered for optimal deposition in the lung following oral inhalation using a convenient, palm-sized dry powder inhaler (DPI).

About Liquidia Technologies

Liquidia Technologies is a late-stage clinical biopharmaceutical company focused on the development and commercialization of therapeutics based upon the Company’s proprietary PRINT® particle engineering platform. The Company is currently conducting a Phase 3 clinical trial (INSPIRE) of LIQ861, a formulation of tadalafil for delivery via a dry powder inhaler, for the treatment of pulmonary arterial hypertension (PAH). Additionally, the Company has completed two Phase 1 clinical trials for LIQ865, a sustained release formulation of bupivacaine, a non-opioid anesthetic, for the treatment of local post-operative pain through a single injection. For more information please visit the Company’s website at www.liquidia.com.

Forward-Looking Statements

This press release may include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical facts, including statements regarding our future results of operations and financial position, our business strategy and plans and our objectives for future operations, are forward-looking statements. Such forward-looking statements, including statements regarding clinical trials, clinical studies and other clinical work (including the funding therefor, anticipated patient enrollment, safety data, study data, trial outcomes, timing or associated costs), regulatory applications and related timelines, including the filing of an NDA for LIQ861, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. The words “anticipate,” “believe,” “continue,” “estimate,” “expect,” “intend,” “may,” “will” and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks discussed in our filings with the Securities and Exchange Commission, as well as a number of uncertainties and assumptions. Moreover, we operate in a very competitive and rapidly changing environment and our industry has inherent risks. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Nothing in this press release should be regarded as a representation by any person that these goals will be achieved, and we undertake no duty to update our goals or to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise.

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