
**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): **January 7, 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))

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

Liquidia Technologies, Inc. (the “Company”) has updated its company overview (the “Company Overview”) and a copy of the slides comprising the Company Overview is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company Overview may also be accessed under the “Investors” tab on the Company’s website at www.liquidia.com.

In accordance with General Instruction B.2 on Form 8-K, the information set forth in this Item 7.01 and the Company Overview slides, attached to this report as Exhibit 99.1, are “furnished” and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Please refer to Exhibit 99.1 for a discussion of certain forward-looking statements included therein and the risk and uncertainties related thereto.

Item 8.01 Other Events.

On January 7, 2019, the Company issued a press release reporting positive interim safety data from its open-label, multicenter Phase 3 clinical trial (INSPIRE) evaluating LIQ861, an inhaled dry powder formulation of treprostinil, for the treatment of pulmonary arterial hypertension. The safety data at the two-week timepoint addresses the U.S. Food and Drug Administration’s (the “FDA”) data request for inclusion in a New Drug Application (“NDA”) submission. The Company anticipates submitting the full NDA for LIQ861 to the FDA in late 2019.

The full text of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | Liquidia Technologies, Inc. January 2019 Company Overview. |
| 99.2 | Liquidia Technologies, Inc. Press Release, dated January 7, 2019. |

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.

January 7, 2019

Liquidia Technologies, Inc.

By: /s/ Kevin Gordon

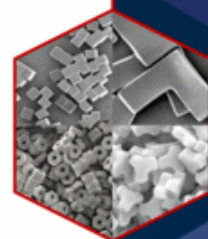
Name: Kevin Gordon

Title: President and Chief Financial Officer



Company Overview

January 2019



Forward-Looking Statements

This presentation includes, and our response to various questions may include, forward-looking statements. All statements contained in this presentation 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. 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, 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, are subject to a number of risks, 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 and trends discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, achievements or events and circumstances reflected in the forward-looking statements will occur. We are under no duty to update any of these forward-looking statements after the date of this presentation to conform these statements to actual results or revised expectations, except as required by law. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. This presentation includes long-term goals that are forward-looking, are subject to significant business, economic, regulatory and competitive uncertainties and contingencies, many of which are beyond the control of us and our management, and are based upon assumptions with respect to future decisions, which are subject to change. Actual results will vary and those variations may be material. Nothing in this presentation should be regarded as a representation by any person that these goals will be achieved and we undertake no duty to update our goals.

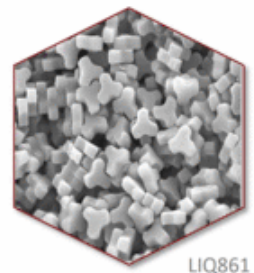
Disclaimers

Unless otherwise indicated, information contained in this presentation concerning our industry and the markets in which we operate is based on reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources as well as our own internal estimates and research. Decision Resources Group, the primary source for the market data included in this presentation, was commissioned by us to compile this information. Although we believe the data from these third-party sources is reliable, we have not independently verified any third-party information. In addition, projections, assumptions and estimates of the future performance of the industry in which we operate and our future performance are necessarily subject to uncertainty and risk due to a variety of factors. Such factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Novel products via precise control of drug particles

Late-stage clinical biopharmaceutical company focused on transforming the lives of patients

- LIQ861, Ph3 product candidate, with a clear regulatory path targeting a segment of the ~\$3.7B U.S. market for pulmonary arterial hypertension (PAH)
- Positive LIQ861 Ph3 interim safety data at 2-week timepoint, expected to support NDA submission targeted for late 2019
- Broader LIQ861 market opportunity beyond U.S. and WHO Group I – pipeline in a PRINT® particle
- LIQ865, Ph1 product candidate, targeting unmet need for local post-operative pain
- PRINT® technology not limited by therapeutic area, molecule or route of administration
- Seasoned team with relevant commercial and disease area expertise



LIQ861

Source: Decision Resources Group, Landscape & Forecast, PAH, Nov 2018.

Seasoned team with relevant commercial and disease area expertise



**Neal
Fowler**

Chief Executive
Officer



**Kevin
Gordon**

President &
Chief Financial
Officer



**Robert
Lippe**

Chief Operations
Officer



**Robert
Roscigno,
PhD**

Senior VP,
Product Dev.



**Ben Maynor,
PhD**

Senior VP, R&D







**Jeri
Thomas**

Senior VP,
Commercial

Management Employment History Highlights



Pipeline

| Product | Indication | Formulation & Route | Phase 1 | Phase 2 | Phase 3 | Next Key Milestone | Worldwide Commercial Rights |
|---------------------|----------------------------|------------------------------|---|--|---|---------------------------------------|-----------------------------|
| LIQ861 ¹ | PAH | Dry powder inhalation |  |  |  | PK sub-study data 2Q:19 | Liquidia |
| LIQ865 | Local, post-operative pain | Sustained-release injectable |  | | | Ph2-enabling studies commencing 1Q:19 | Liquidia |

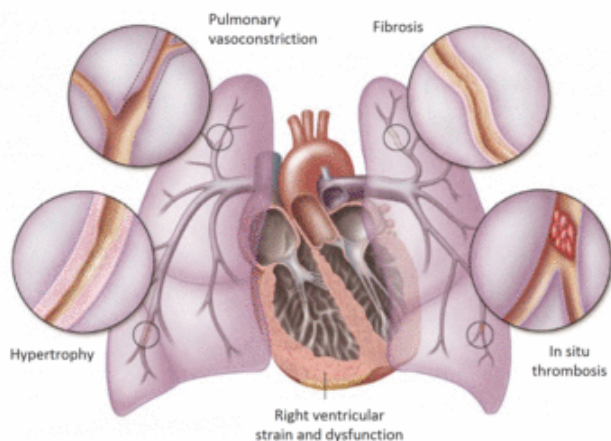
1. After consultation with the FDA, we advanced from a Phase 1 trial directly to a pivotal Phase 3 trial and will seek approval under the 505(b)(2) pathway.

LIQ861 for PAH

PRINT[®] treprostinil, dry powder inhalation

PAH is a rare, progressive disease that results in right heart failure

Multiple pathways are involved in pathogenesis



Abnormal changes in arteries of the lungs increase pressure in pulmonary arteries that leads to remodeling of the right ventricle

- **Prostacyclin is essential to normal lung function**

- Continually released by lungs to bind local receptors
- Vasodilates the pulmonary arteries
- Relaxes smooth muscle
- Inhibits platelet aggregation

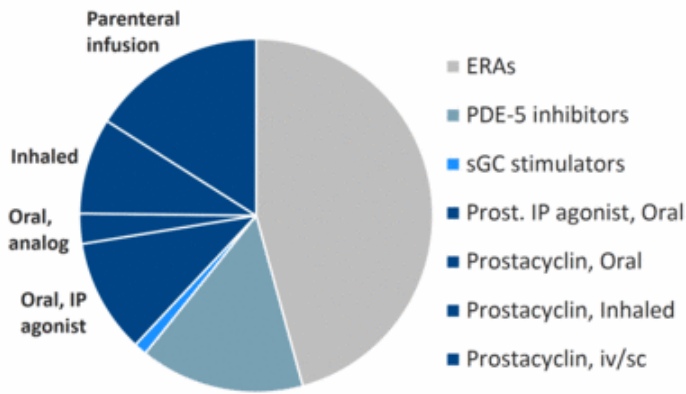


Goal of **prostacyclin therapy** is to **maximize a patient's exposure** to the highest tolerable level of drug

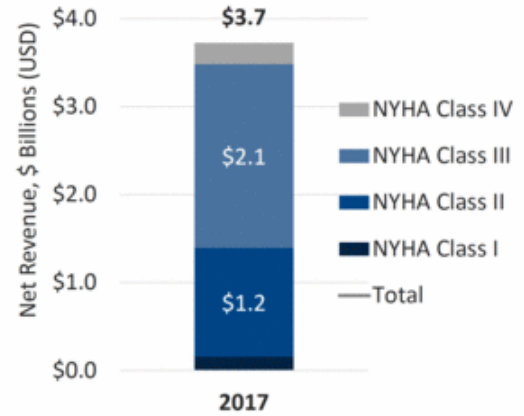
Sources: Farber *Eur Respir Rev* 2016; Lang *Eur Respir Rev* 2014; Channik *Advances in Pulmonary Hypertension Spring*, 2002, DRG, PH Disease Landscape, Nov 2016; Yen-Chun Lai et al. *Circ Res.* 2014;115:115-130.

U.S. market is reliant on prostacyclin products with ~\$1.4B in 2017

Prostacyclin products are significant share of PAH market



Many patients have limited physical ability

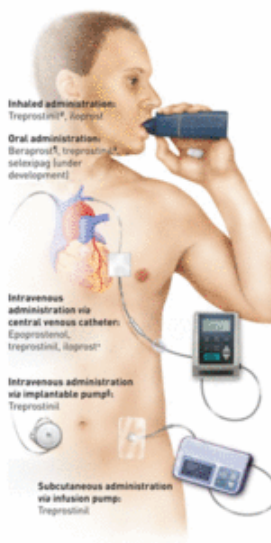


▶ **Despite the success of prostacyclin products, the therapy has not been fully optimized**

Source: Decision Resources Group, Landscape & Forecast, PAH, Nov 2018.

Maximizing prostacyclin to directly deliver to the lungs is key

Local delivery generates fewer off-tissue effects



Current prostacyclin products have clear tradeoffs

Infusion = Effective, but with systemic toxicities & site pain, as well as limits on lifestyle

- Delivers continuously via i.v. or s.c. line, 24 hours a day
- Poses potential for infection risk

Nebulized = Targeted, but provides limited dose range

- Limits max dose due to throat irritation, adverse events
- Requires water, power, supplies, cleaning and time to dose

Oral = Convenient, but with systemic toxicities and minimal symptom relief

- Increases side effects in GI, Nervous and Vascular systems
- Requires up-titration that can be challenging given side effects

Source: Decision Resources, Pulmonary Hypertension Disease landscape & Forecast, November 2018.

Choice of inhaled options is driven by convenience

Tyvaso® share was over 80% of the U.S. inhaled patient population in 2017

TYVASO
(treprostinil) INHALATION SOLUTION



INHALED Ventavis®
(iloprost) INHALATION SOLUTION

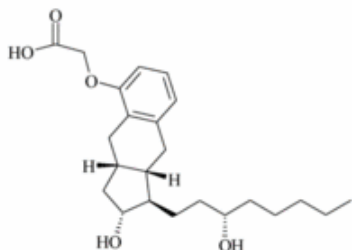
- **4x daily**, titrated to target of **54 mcg/dose (9 breaths)**, the maximum recommended dose in label
- Most common AEs - **cough**, headache, nausea, dizziness, flushing, **throat irritation, pharyngolaryngeal pain**, diarrhea
- **Wash daily** in warm soapy water (mouthpiece assembly and filter shells)
- **Proprietary nebulizer + 13 additional accessories** listed in patient starter kit
- **4-10 mins, 6-9x daily**, titrated to target of **5 mcg/dose**
- Most common AEs - flushing, **cough**, headache, trismus, insomnia, nausea, hypotension, vomiting, alkaline phosphatase increased, flu syndrome, back pain, tongue pain, palpitations, syncope, GGT increased, muscle cramps, hemoptysis, pneumonia
- **Wash after each use** in warm soapy water & **boil weekly**
- **Proprietary nebulizer + 10 additional spare parts** listed in patient user guide

Sources: Decision Resources Group, Landscape & Forecast, PAH, Nov 2018; Tyvaso® (treprostinil) package insert 2014; Ventavis (iloprost) package insert 2013. Tyvaso is a registered trademark of United Therapeutics Corporation. Ventavis is a licensed trademark of Bayer Schering Pharma AG.

LIQ861 combines Effective + Targeted + Convenient into one product

Treprostinil = Proven efficacy

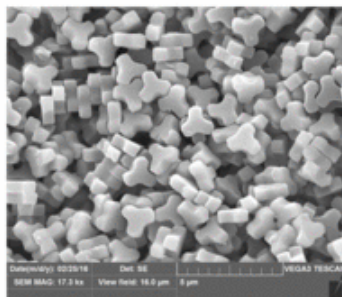
Trusted prostacyclin-analog



Proven compound with FDA approvals for i.v., s.c., inhaled and oral routes

PRINT® = Deep-lung delivery

Precise Uniform Trefoil-like



Delivers higher dose levels than approved inhaled formulations

Device = Simple, Disposable

Disposable & long track record



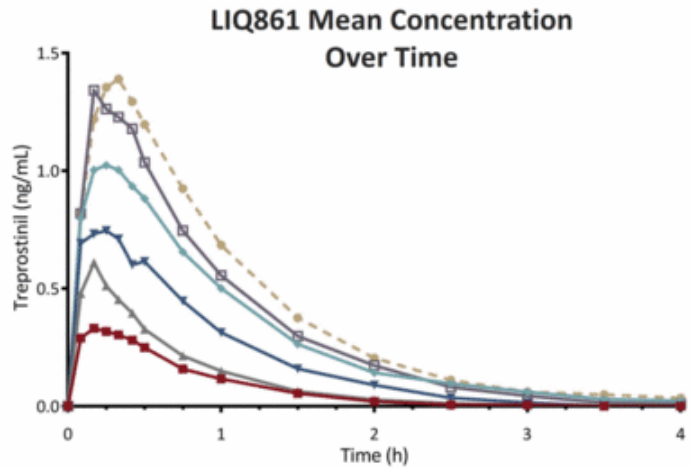
RS00 Model 8 (DMF # 18418)

Compact, easy inhaler with established commercial track record

Phase 1 results supported continued development of LIQ861

LIQ861 was observed to be well-tolerated with no reported study drug-related SAEs

- n=57 healthy volunteers
- Single, ascending dose
- Dose proportional response
- No dose-limiting toxicities
- TEAEs related to treatment were mild
- No study drug-related SAEs



| | | | | | | |
|--------------------------------|-------|-------|-------|--------|--------|--------|
| Approx. Capsule (TRE fill wt.) | 25 µg | 50 µg | 75 µg | 100 µg | 125 µg | 150 µg |
| Approx. Emitted Dose (mcg) | 20 | 40 | 60 | 80 | 100 | 120 |
| Breaths | 1-2 | 1-2 | 1-2 | 1-2 | 2-4 | 2-4 |

Sources: Ph 1 study design: 57 subjects enrolled; 43 on LIQ861, 14 on placebo; each cohort = 8 subjects in 3:1 ratio (LIQ861:placebo) – randomized, placebo-controlled; Royal M, Roscigno R, et al. Preclinical and Phase 1 Clinical Characterization of LIQ861, a New Dry Powder Formulation of Treprostinil [\[poster\]](#). In: PVRI Annual World Congress; 2018 January 21-24; Singapore, Asia.

After consultation with the FDA, we advanced to a pivotal trial (INSPIRE) pursuant to the 505(b)(2) pathway in the U.S.

Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil

| | |
|---------------------------------|--|
| Design | <ul style="list-style-type: none">• Open-label, U.S. multicenter |
| Population | <ul style="list-style-type: none">• At least 100 WHO Group I (PAH) patients; NYHA Class II, III and IV |
| Criteria | <ul style="list-style-type: none">• On stable dose of Tyvaso® for ≥3 months (or) taking ≤2 approved non-PGI oral PAH therapies |
| Primary endpoint | <ul style="list-style-type: none">• Incidence of TEAEs and SAEs |
| Secondary endpoints | <ul style="list-style-type: none">• 6 minute walk distance• Sustained treatment transition (Tyvaso® transitions)• NYHA functional class improvement• Quality of life questionnaire / Patient satisfaction with LIQ861 DPI |
| PK Sub-Study¹ | <ul style="list-style-type: none">• Transitions from Tyvaso® in a one-directional crossover to compare bioavailability and PK |
| Data collection | <ul style="list-style-type: none">• Baseline, Week 2, Month 1, Month 2 Visits, with bimonthly follow up for up to 30 months |

“...LIQ861 is designed to provide the benefits of delivering PGI analogs **locally to the lungs** via inhalation, potentially offering a **targeted & effective approach** with an **acceptable systemic side effect profile**” -Dr. Nick Hill

 **First patient was dosed in March 2018 and we expect to continue to treat patients and collect data up to our U.S. launch**

Sources: <https://clinicaltrials.gov/ct2/show/NCT03399604>; PGI – prostacyclin; TEAEs – treatment-emergent adverse events; SAEs – serious adverse events; Quote from Nicholas Hill, MD, Chief Pulmonary, Critical Care & Sleep Division and Professor of Medicine at Tufts University School of Medicine and INSPIRE Principal Investigator.

1. Adjusting dose levels to comparable Tyvaso® emitted dose

In Phase 3 trial, LIQ861 was observed to be well-tolerated with no reported SAEs at two-week timepoint

Safety endpoint requested by U.S. FDA; data to be included in NDA submission

- No dose-limiting toxicities
- No study drug-related SAEs
- TEAEs related to treatment were mostly mild in nature
- Have not yet reached an MTD
 - At 2-wk timepoint, evaluated up to ~125mcg
 - To-date, evaluated up to ~150mcg

| Adverse Events in ≥ 4% of PAH Patients Receiving LIQ861 | LIQ861 (treprostinil) | | |
|---|-----------------------|---------------------|----------------|
| | Treated (n=109) | Tyvaso® Transitions | LIQ861 Add-ons |
| Cough | 27 (25%) | 4 | 23 |
| Headache | 14 (13%) | 6 | 8 |
| Throat irritation | 13 (12%) | 4 | 9 |
| Diarrhea | 8 (7%) | 2 | 6 |
| Dizziness | 7 (6%) | 4 | 3 |
| Oropharyngeal pain | 5 (5%) | 1 | 4 |
| Chest discomfort | 5 (5%) | 0 | 5 |

Source: INSPIRE Phase 3 two-week safety data as reported in Liquidia press release on 07Jan2019 in PAH patients (n=109).

Enrollment suggests LIQ861 is attractive across disease severity

Faster than expected enrollment driven primarily by interest from Functional Class II add-on patients

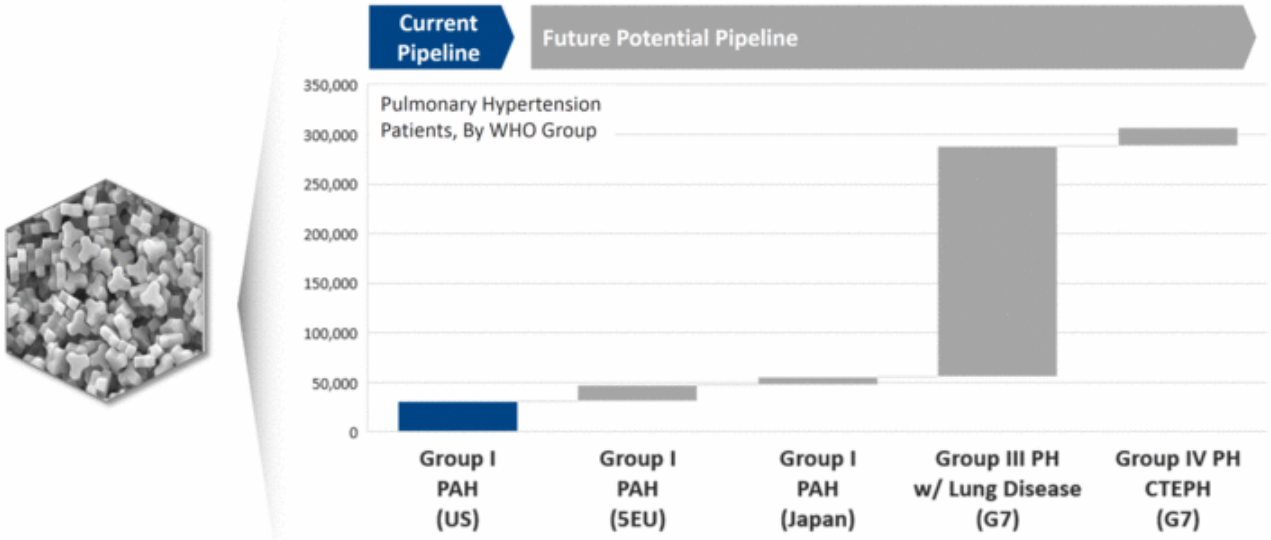
| | | No. Subjects (% of Study) at 2-week timepoint | | |
|---------------------------------------|-----------|---|--------------------------|--------------------|
| | | Tyvaso® Transitions (N=44) | LIQ861 Add-Ons (N=65) | Overall (N=109) |
| NYHA Functional Class at Screening | Class II | 36 (81.8%) | 36 (55.4%) | 72 (66.1%) |
| | Class III | 8 (18.2%) | 29 (44.6%) | 37 (33.9%) |

► Suggests that LIQ861 may have utility as a first-line prostacyclin

Source: INSPIRE Phase 3 two-week safety data as reported in Liquidia press release on 07Jan2019 in PAH patients (n=109).

LIQ861 = Pipeline in a PRINT® particle

Potential addressable PH patient populations over time



Source: Decision Resources, Pulmonary Hypertension Disease landscape & Forecast, November 2018.

LIQ865 for Local Post-Operative Pain

PRINT[®] bupivacaine, sustained-release injectable

Significant unmet medical need for extended, non-opioid pain relief

- Approximately 50%+ of patients report inadequate local post-operative pain relief
- Reducing opioids is a priority for hospitals, payors and FDA
- Improved pain relief and reducing opioid use can drive key metrics, such as faster recovery and time to discharge
- Representing a \$761.1M market, local anesthetics have a known efficacy profile but are limited to 8 hours
- EXPAREL® demonstrates demand for longer acting relief, but too short
 - Physicians are seeking 3 to 5 days of pain relief, according to our market research
 - EXPAREL reportedly offers 24-36 hours in practice

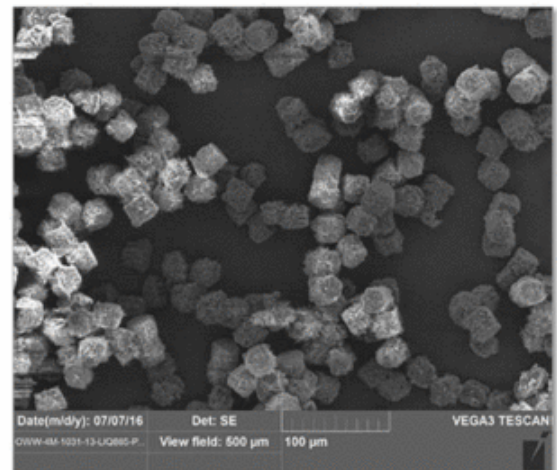


Sources: Wheeler, 2011; Collins, 2013; Shah 2017; EXPAREL package insert; EXPAREL® is a registered trademark of Pacira Pharmaceuticals; IMS data 2017; accessed 04 Dec 2018.

LIQ865 offers the potential for an optimal product profile

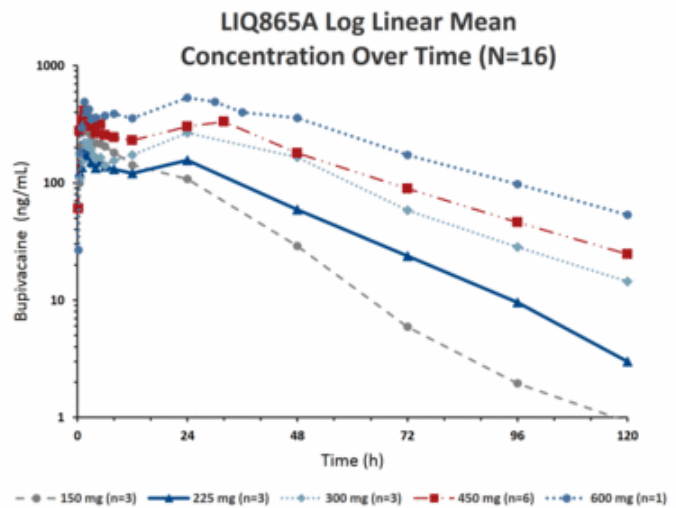
- **Target 3 to 5 days duration of action**
 - Supported by PK & PD data from Ph 1 studies
- **Simple, uniform particles of a single active**
 - Easy reconstitution from a powder
- **Flexible application at the surgical site**
 - Adjustable concentration range to deliver the dose
 - Enables instillation or injection around incision
- **Limited potential for dose dumping**
 - Compatible with co-administration of instant-release local anesthetics

LIQ865: Bupivacaine + PLGA blend



LIQ865 was well-tolerated at all doses with dose proportional PK in Ph1

- Ph1a, healthy volunteers in Denmark
- Single, ascending dose
- No dose-limiting toxicities
- All adverse events were mild to moderate
- C_{max} well below reported thresholds for neurotoxicity and cardiotoxicity
- QST demonstrated pharmacodynamic effect for up to 5 days



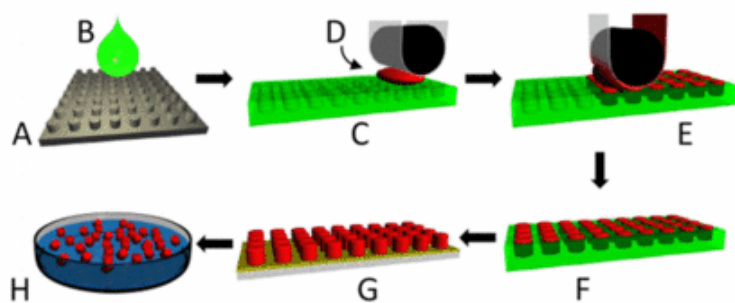
▶ We are initiating Ph2-enabling tox studies in 1Q:19 with initial Ph2 proof of concept clinical trials in 2020.

Sources: Randomized, double-blind, controlled, single ascending dose, safety, PK, PD trial of two different formulations of LIQ865 in 28 healthy male volunteers; QST - Quantitative Sensory Testing.

PRINT[®] Technology

Discrete particles through a molding process

Overview of PRINT® Technology



- **Step A:** Etch master template with 3D geometric structures of the desired particle size and shape
- **Step B:** Apply our proprietary polymeric mold material over master template
- **Step C:** Cure polymeric material to form PRINT molds with discrete molding cavities that replicate structures of master template
- **Step D:** Design chemical composition of drug particle
- **Step E:** Apply the drug particle composition to the cavities in the mold to fill the cavities
- **Step F:** Form the drug particles in cavities of the mold
- **Step G:** Remove drug particles from mold cavities on a harvesting film
- **Step H:** Remove particles from harvesting film

Visit <http://liquidia.com/print-technology/> to view corporate video on PRINT technology

PRINT® production technology is highly capable and widely applicable

Preclinical and R&D
Highly versatile, flexible



Lab Line 2 (2008)

- Highly agile platform enabling process experimentation
- Ideal for early stage process development

cGMP Process Development
Optimization, scale-up



Lab Line 3 (non-cGMP 2015; cGMP 2017)

- Capable of larger batches with increased process control
- We believe Lab Line 3 is fully cGMP compliant to support product launch

cGMP Production
Repeatable and deployable



Commercial Line 1 (expected 2019)

- Optimized drug substance production process
- Designed for continued market supply and scale

Conclusion

Financial Overview

Financials

- Approx. \$300M market cap
- \$47.5 million cash as of Sept 30, 2018
- Approx. 15.5M shares outstanding
- Closed \$53.2M IPO in gross proceeds at \$11 per share in 3Q:2018
- Trades on Nasdaq: LQDA

Covering Analysts

Jefferies

COWEN

Needham

WEDBUSH

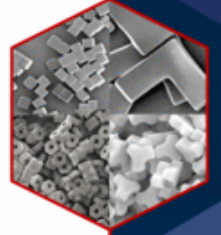
Source: LQDA 3Q 2018 filing reported as of Oct 30, 2018.

Anticipated Upcoming Milestones

| Milestone | Anticipated Timing | |
|--|--------------------|---|
| Report LIQ861 Ph 3 two-week safety data from INSPIRE trial | 1Q:2019 | ✓ |
| Initiate LIQ865 Ph 2-enabling tox studies | 1Q:2019 | |
| Report LIQ861 Ph 3 PK results from PK sub-study | 2Q:2019 | |
| NDA submission to the FDA for LIQ861 | Late 2019 | |



Thank You



Most common AEs as listed in Tyvaso® package insert

Adverse Events in ≥4% of PAH Patients Receiving Tyvaso® and More Frequent* than Placebo

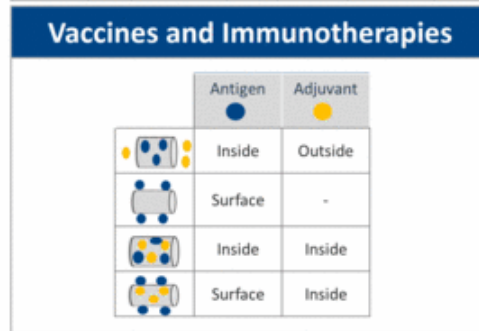
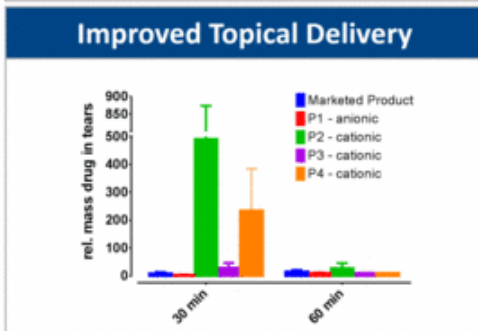
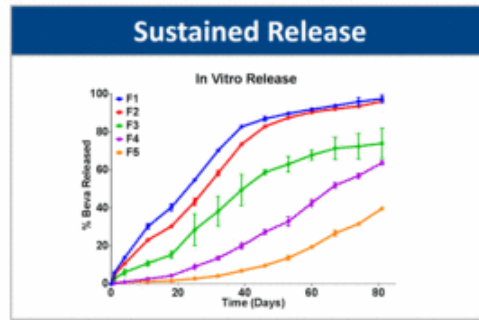
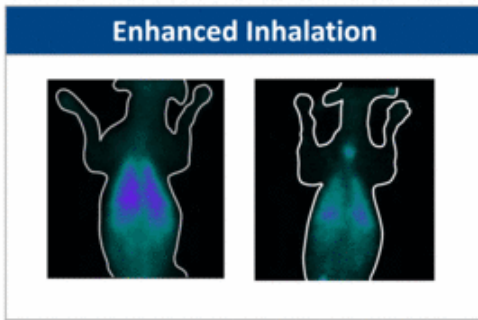
| | Tyvaso (treprostinil) | |
|--|-----------------------|--------------------|
| | Treated (n=115) | Placebo (n=120) |
| Cough | 62 (54%) | 35 (29%) |
| Headache | 47 (41%) | 27 (23%) |
| Throat irritation, Pharyngolaryngeal pain | 29 (25%) | 17 (14%) |
| Nausea | 22 (19%) | 13 (11%) |
| Flushing | 17 (15%) | 1 (<1%) |
| Syncope | 7 (6%) | 1 (<1%) |

*More than 3% greater than placebo

- In addition, adverse reactions occurring in ≥10% of patients were dizziness and diarrhea.

Sources: <https://www.tyvaso.com/hcp/>; data accessed 18Dec2018; Tyvaso® package insert.

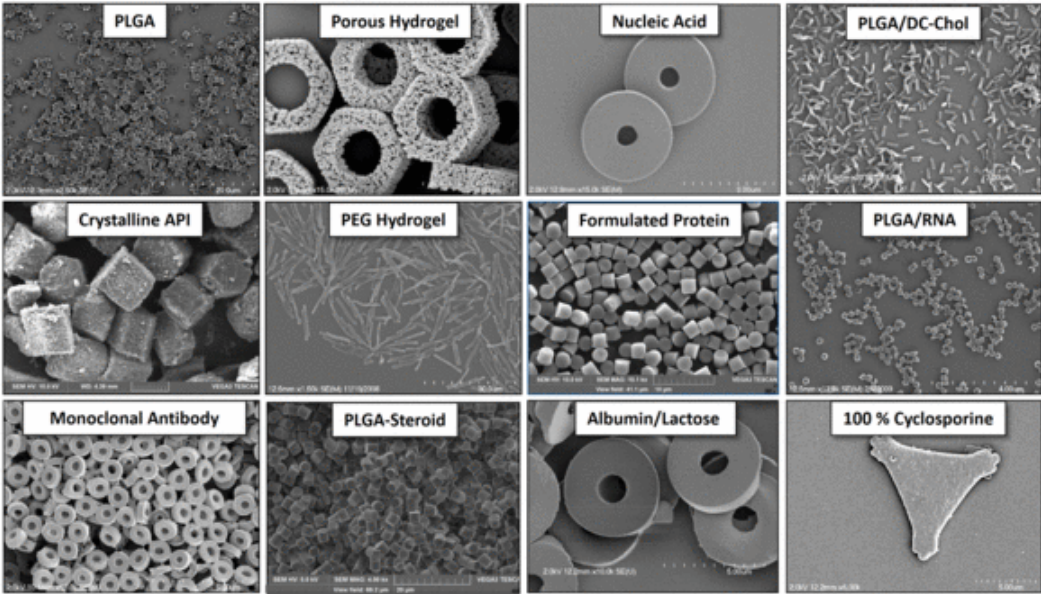
Desirable pharmacological benefits by precisely engineering particles



Sources: Garcia A, et al. "Microfabricated Engineered Particle Systems for Respiratory Drug Delivery and Other Pharmaceutical Applications" *Journal of Drug Delivery*; 2012; Herlihy K, et al. "Extended Release of Microfabricated Protein Particles from Degradable Hydrogel Implants for the Treatment of Age Related Macular Degeneration" [poster], in ARVO, 2014; Williams S, et al. "Fabrication of Shape and Size Specific Nanoparticles for Ocular Drug Delivery" [poster], in ARVO, 2015.

Compatible with nearly any material, payload and route of delivery

Examples, not exhaustive





Liquidia Technologies Reports Positive Interim LIQ861 Safety Data on 109 Patients from Pivotal INSPIRE Trial

*LIQ861 was well-tolerated in PAH patients at two-weeks of treatment, the safety endpoint requested by U.S. FDA
NDA submission targeted for late 2019*

RESEARCH TRIANGLE PARK, NC — January 7, 2019 — Liquidia Technologies, Inc. ([Nasdaq:LQDA](#)) (“Liquidia”), a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using its proprietary PRINT® technology to transform the lives of patients, today reported positive interim safety data from its open-label, multicenter Phase 3 clinical trial (INSPIRE) evaluating LIQ861, an inhaled dry powder formulation of treprostinil, for the treatment of pulmonary arterial hypertension (“PAH”). The safety data at the two-week timepoint addresses the U.S. Food and Drug Administration’s (“FDA”) data request for inclusion in a New Drug Application (“NDA”) submission. Liquidia anticipates submitting the full NDA for LIQ861 to the FDA in late 2019.

LIQ861 was observed to be well-tolerated at the two-week timepoint in PAH patients. During this time period, LIQ861 was evaluated at doses up to approximately 125 mcg with no study-drug related serious adverse events or dose-limiting toxicities. Reported treatment-emergent adverse events (“TEAEs”) were mostly mild in nature and consistent with inhaled prostacyclin therapy. The most common TEAEs reported with LIQ861 in $\geq 4\%$ of PAH patients (n=109) were cough (25%), headache (13%), throat irritation (12%), diarrhea (7%), dizziness (6%), oropharyngeal pain (5%) and chest discomfort (5%). Patients have continued to receive treatment beyond two-weeks with the first patient dosed in March 2018. To date, a maximum tolerated dose of LIQ861 has not yet been reached, with patients having been administered doses up to approximately 150 mcg.

“LIQ861 has the potential to maximize the therapeutic benefit of inhaled treprostinil in treating PAH by safely delivering higher doses into the lungs,” stated Nicholas Hill, MD, Chief Pulmonary, Critical Care & Sleep Division and Professor of Medicine at Tufts University School of Medicine and INSPIRE Principal Investigator. “Enabled by Liquidia’s proprietary PRINT technology, LIQ861 is designed to provide the benefits of delivering prostacyclin analogs locally to the lungs via inhalation, potentially offering a targeted and effective approach with an acceptable systemic side effect profile.”

The INSPIRE clinical trial is designed to evaluate patients who have either been under stable treatment with nebulizer-delivered treprostinil for at least three months and are transitioned to LIQ861 under the protocol or patients who have been on stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and have their treatment regimen supplemented with LIQ861 under the protocol. Patients adding LIQ861 to current non-prostacyclin oral therapies started at a dose of approximately 25 mcg and those transitioned from nebulizer-delivered treprostinil at a stable dose were initiated at a dose of LIQ861 lower than their current stable treprostinil dose. In both cases, LIQ861 was uptitrated in 25 mcg incremental doses to symptom relief or the limit of tolerance.

“Patient demographics and baseline characteristics in the trial suggest that LIQ861 may be attractive across disease severity and may have utility as a first-line prostacyclin,” added Robert Roscigno, PhD, Liquidia’s Senior Vice President of Product Development and LIQ861 Program Lead. “Interestingly,

enrollment of the safety portion of the trial was driven primarily by stronger than anticipated interest from New York Heart Association Functional Class II add-on patients, which may imply that dry-powder delivery could be an alternative to oral delivery in prostacyclin naïve patients. We are pleased with these findings and believe they support the therapeutic potential and versatility of LIQ861 among patients across different functional classes.”

Liquidia continues to enroll patients in the INSPIRE clinical trial in support of the one-directional crossover pharmacokinetic (“PK”) sub-study. The sub-study is designed to compare bioavailability and PK of treprostinil as patients are transitioned from nebulizer-delivered treprostinil to LIQ861. PK results are expected to be reported in the second quarter of 2019. To further support Liquidia’s future marketing and commercial activities with additional medical information, Liquidia expects to continue to treat patients and collect data until the launch of LIQ861 in the United States, if approved.

About LIQ861

LIQ861 is an inhaled dry powder formulation of treprostinil designed using Liquidia’s PRINT technology to enhance deep-lung delivery using a convenient, palm-sized, disposable dry powder inhaler for the treatment of PAH. Liquidia believes LIQ861 can overcome the limitations of current inhaled therapies and has the potential to maximize the therapeutic benefits of treprostinil in treating PAH by safely delivering higher doses into the lungs.

About INSPIRE Clinical Trial

Liquidia’s pivotal open-label Phase 3 clinical trial, known as INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, is designed to evaluate patients who have either been under stable treatment with nebulizer-delivered treprostinil for at least three months and are transitioned to LIQ861 under the protocol or patients who have been on stable treatment with no more than two non-prostacyclin oral PAH therapies for at least three months and have their treatment regimen supplemented with LIQ861 under the protocol. The primary objective of the INSPIRE study is to evaluate the long-term safety and tolerability of LIQ861. For more information, please visit <https://clinicaltrials.gov/ct2/show/NCT03399604>.

About Liquidia Technologies

Liquidia Technologies is a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using its proprietary PRINT® technology to transform the lives of patients. Currently, Liquidia is focused on the development of two product candidates using its PRINT® particle engineering platform: LIQ861 for the treatment of pulmonary arterial hypertension and LIQ865 for the treatment of local post-operative pain. Being evaluated in a Phase 3 clinical trial (INSPIRE), LIQ861 is designed to improve the therapeutic profile of treprostinil by enhancing deep-lung delivery and achieving higher dose levels than current inhaled therapies by using a convenient, palm-sized, disposable DPI. LIQ865, for which Liquidia has completed two Phase 1 clinical trials, is designed to deliver sustained-release particles of bupivacaine, a non-opioid anesthetic, to treat local post-operative pain for three to five days through a single administration. For more information visit our 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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