

**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): **October 2, 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**  
Common stock

**Trading Symbol(s)**  
LQDA

**Name of each exchange on which registered**  
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 7.01 Regulation FD Disclosure.**

On October 2, 2019, Liquidia Technologies, Inc. (the “Company”) provided an update on the Phase 3 development program for LIQ861, an investigational treatment for pulmonary arterial hypertension (“PAH”), and updated its company overview (the “Company Overview”). 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](http://www.liquidia.com).

The clinical program for LIQ861 has been completed and the Company is proceeding with plans for submission of the new drug application (the “NDA”) for the treatment of adults with PAH.

The Company has recently conducted a pre-NDA meeting with the U.S. Food and Drug Administration (the “FDA”) with respect to the chemistry, manufacturing and controls (“CMC”) aspects of the LIQ861 NDA and received no new CMC requirements from the FDA for NDA submission. Moreover, the supplemental healthy volunteer pharmacokinetics study showed minimized subject variability and the Company believes it has established comparative bioavailability to the reference listed drug.

The Company has also requested a pre-NDA meeting with the FDA focused on clinical and nonclinical contents of the NDA. The date of this meeting has not yet been confirmed but the Company anticipates that the meeting will likely occur in November, 2019. While the Company continues to focus its efforts on submitting the NDA as expeditiously as possible, without clear timing of its clinical and nonclinical pre-NDA meeting and potential follow-on FDA requirements, if any, the Company is now anticipating an early first quarter 2020 NDA submission for LIQ861.

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 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Exhibit</b>
99.1	<a href="#">Liquidia Technologies, Inc. October 2019 Company Overview.</a>

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.

October 2, 2019

Liquidia Technologies, Inc.

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

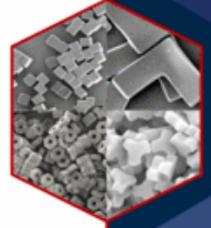
Name: Richard D. Katz, M.D.

Title: Chief Financial Officer



**2019 Cantor Fitzgerald  
Global Healthcare Conference**

October 2, 2019  
New York City



## 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.

# Novel products via precise control of drug particles

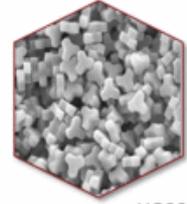
Late-stage clinical biopharmaceutical company focused on transforming the lives of patients

## Preparing NDA

- LIQ861: inhaled dry powder targeting segment of PAH market (\$3.7B U.S.)
- Completed clinical program and preparing NDA submission

## Pipeline Growth

- LIQ865: to manage local, post-operative pain for 3-5 days (Phase 1)
- Poised to expand PRINT Technology advantages into future products



LIQ861

## Proprietary Technology

- Broadly applicable across therapeutic areas, modalities and routes of delivery
- Fully scaled PRINT® platform offers multiple product advantages

# LIQ861 for PAH

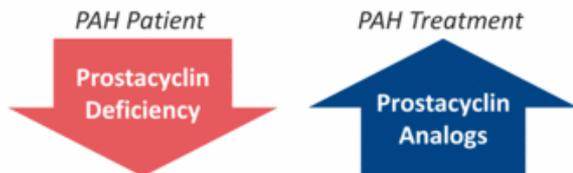
PRINT<sup>®</sup> treprostinil, dry powder inhalation

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

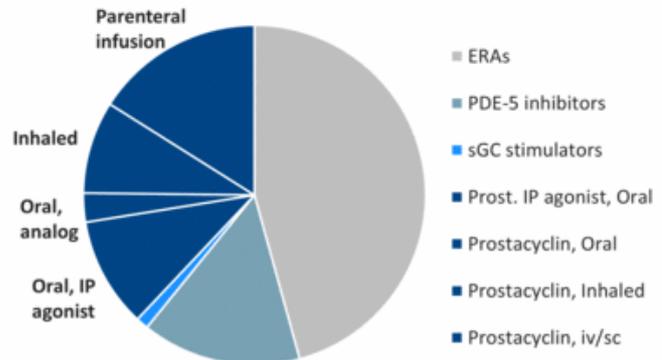
Abnormal changes in arteries of the lungs increase pressure in pulmonary arteries

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



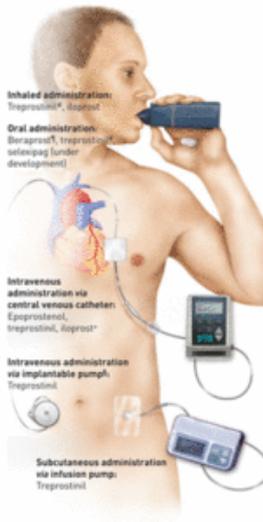
\$1.4B of \$3.7B market in prostacyclin pathway in 2017



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; Decision Resources Group, Landscape & Forecast, PAH, Nov 2018.

# Goal of prostacyclin therapy is to maximize exposure to highest tolerable level

Local delivery generates fewer off-tissue effects



## Current prostacyclin products have clear tradeoffs

**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

**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

**Infusion = Effective, but systemic toxicities & site pain, limits on lifestyle**

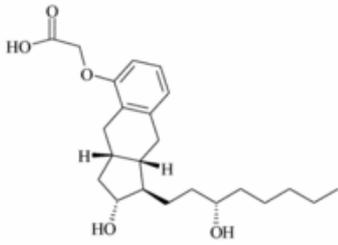
- Delivers continuously via i.v. or s.c. line, 24 hours a day
- Poses potential for infection risk

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

# LIQ861 combines Effective + Targeted + Convenient into one product

Treprostinil = Proven efficacy

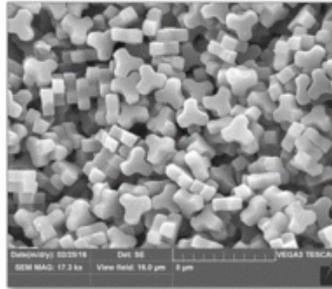
*Trusted prostacyclin-analog*



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

PRINT® = Deep-lung delivery

*Precise, Uniform, Trefoil*



**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

## After consulting FDA, initiated Phase 3 INSPIRE pursuant to 505(b)(2)

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

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

### ▶ We will continue to treat patients and collect data in a roll-over safety study

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

## LIQ861 met primary endpoint at Month 2 in pivotal INSPIRE study

TEAEs observed are consistent with inhaled prostacyclins

- **93% of patients completed 2 months\***
- **No SAEs related to LIQ861 at Month 2**
- **TEAEs  $\geq$  4% patients all mild to moderate**
  - Most observed during first 2-weeks
- **Have not yet reached an MTD**
  - At Month 2, dosed up to 150mcg capsule strength<sup>^</sup>

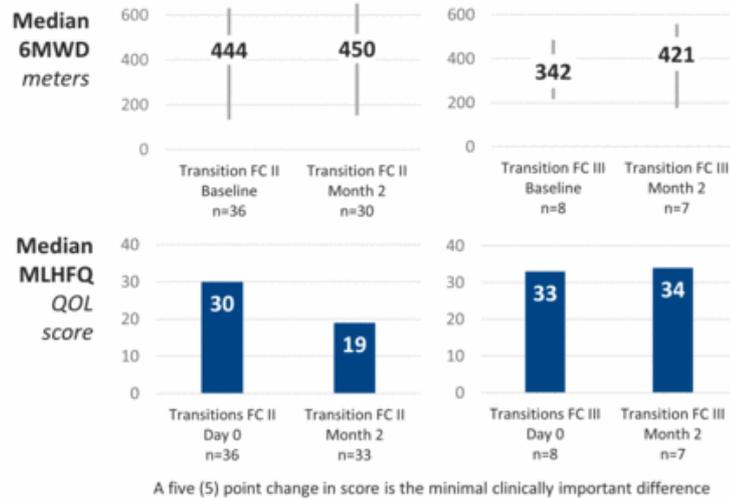
TEAEs at Month 2* in $\geq$ 4% of Patients Receiving LIQ861	LIQ861 (tresprostinil)		
	Transitions (n=44)	Add-ons (n=65)	All Treated (n=109)
Cough	13.6%	46.2%	33.0%
Headache	20.5%	16.9%	18.3%
Throat irritation	9.1%	16.9%	13.8%
Dizziness	9.1%	10.8%	10.1%
Diarrhea	4.5%	10.8%	8.3%
Oropharyngeal pain	2.3%	7.7%	5.5%
Nausea	4.5%	6.2%	5.5%
Dyspnea	6.8%	4.6%	5.5%
Flushing	2.3%	7.7%	5.5%
Chest discomfort	2.3%	6.2%	4.6%

1. Preliminary data from INSPIRE at Month 2; Serious Adverse Events (SAEs); Treatment Emergent Adverse Events (TEAEs) deemed related to LIQ861; Maximum Tolerated Dose (MTD)  
<sup>^</sup>LIQ861 capsule strength doses 125 mcg and 150 mcg are two capsules but if approved, they could be developed as single capsules.

# Transitioning to LIQ861 may build on known benefits of inhaled treprostinil

Exploratory endpoints presented at ISHLT 2019 and ATS 2019

Tyvaso Transitions	NYHA Class II	NYHA Class III
Physical Activity 6MWD	Maintained	Increased
Quality of Life MLHFQ	Improved	Maintained

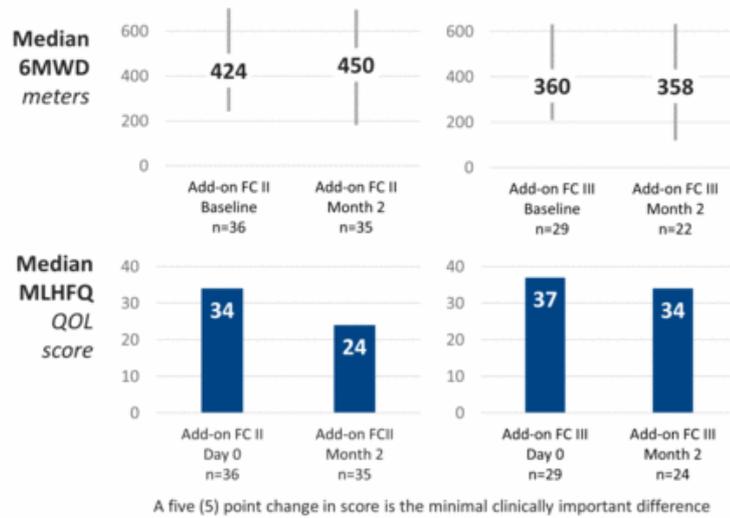


\*Preliminary data from INSPIRE at Month 2; Minnesota Living with Heart Failure Questionnaire (MLHFQ); 6 Minute Walk Distance (6MWD); Quality of Life (QoL)  
 ISHLT 2019 Presentation: Hill N. S., et al. INSPIRE: A Phase 3 Open-Label, Multicenter Study to Evaluate the Safety and Tolerability of LIQ861 in Pulmonary Arterial Hypertension (PAH)  
 ATS 2019 Poster: Hill N. S., et al. INSPIRE: A Phase 3, Open-Label, Multicenter Study to Evaluate the Safety and Tolerability of LIQ861 in Pulmonary Arterial Hypertension (PAH)

# Adding LIQ861 as first prostacyclin earlier in disease may be a viable option

Exploratory endpoints presented at ISHLT 2019 and ATS 2019

Add-on patients	NYHA Class II	NYHA Class III
Physical Activity 6MWD	Increased	Maintained
Quality of Life MLHFQ	Improved	Maintained



\*Preliminary data from INSPIRE at Month 2; Minnesota Living with Heart Failure Questionnaire (MLHFQ); 6 Minute Walk Distance (6MWD); Quality of Life (QoL)  
 ISHLT 2019 Presentation: Hill N. S., et al. INSPIRE: A Phase 3 Open-Label, Multicenter Study to Evaluate the Safety and Tolerability of LIQ861 in Pulmonary Arterial Hypertension (PAH)  
 ATS 2019 Poster: Hill N. S., et al. INSPIRE: A Phase 3, Open-Label, Multicenter Study to Evaluate the Safety and Tolerability of LIQ861 in Pulmonary Arterial Hypertension (PAH)

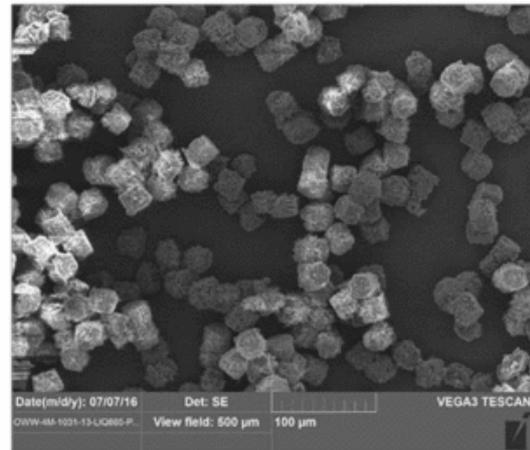
# **LIQ865 for Local Post-Operative Pain**

PRINT<sup>®</sup> bupivacaine, sustained-release injectable

## LIQ865 offers the potential for an optimal product profile

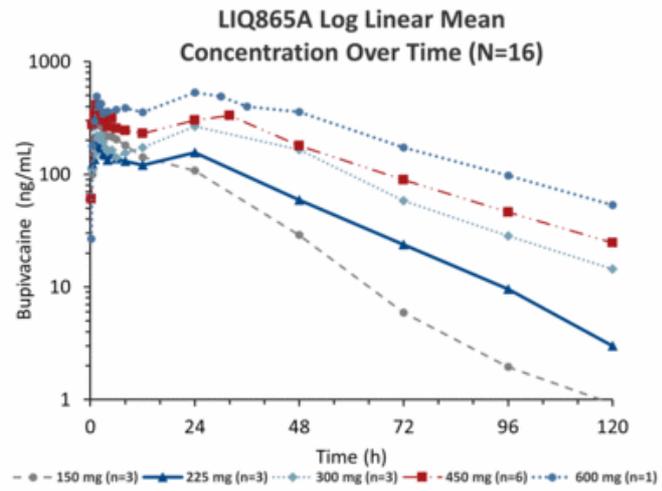
- **Target 3 to 5 days duration of action**
  - Supported by PK & PD data from Ph 1 studies
- **Simple, uniform particles of a single active**
  - Easy reconstitution from a powder
- **Flexible application at the surgical site**
  - Adjustable concentration range to deliver the dose
  - Enables instillation 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



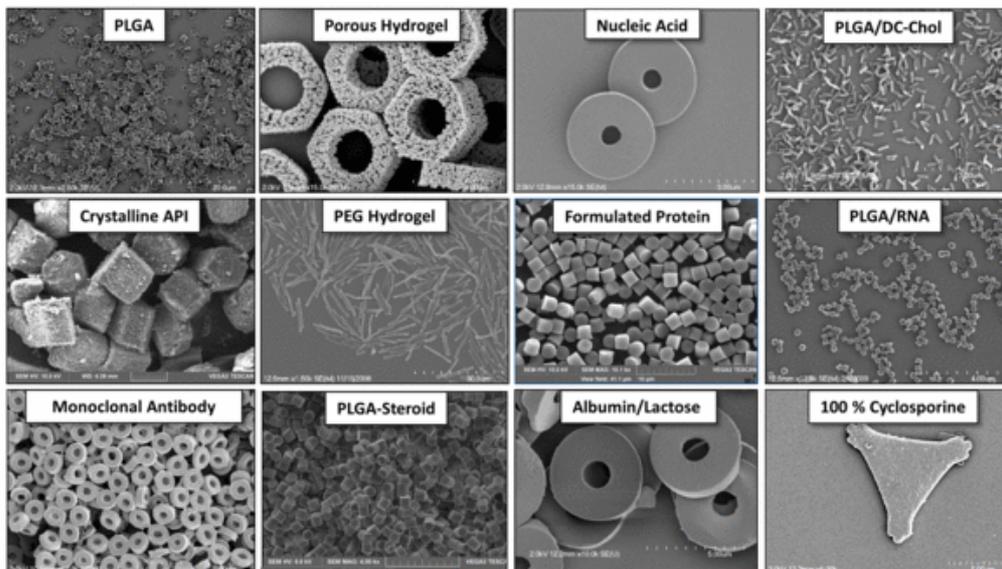
► Initiated Phase 2-enabling tox studies in March 2019 with Phase 2 trials planned for 2020

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

# PRINT® Technology

# Compatible with nearly any material, payload and route of delivery

Examples, not exhaustive



# PRINT® production has been scaled for clinical and commercial demands

**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*



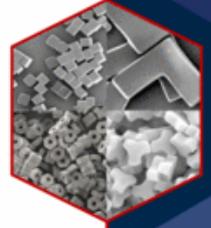
**Commercial Line 1** (expected 2019)

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

# Conclusion

## 2019 Milestones

Milestone	Anticipated Timing	
Report LIQ861 Ph 3 two-week safety data from INSPIRE trial	1Q:2019	✓
Report LIQ861 Ph 3 primary endpoint from INSPIRE trial	1Q:2019	✓
Initiate LIQ865 Ph 2-enabling tox studies	1Q:2019	✓
Conduct pre-NDA CMC meeting with FDA	3Q:2019	✓
Report LIQ861 final PK results from healthy volunteer study	4Q:2019	
Conduct pre-NDA Clinical/Non-Clinical meeting with FDA	4Q:2019	
Target NDA submission to the FDA for LIQ861	Early 1Q:2020	



**Thank You**