Liquidia Technologies Reports Third Quarter 2019 Financial Results and Provides Corporate Update

November 13, 2019

Completed Registrational Studies of LIQ861 to Include in New Drug Application (NDA)
Targeting Submission of NDA for LIQ861 in 1Q 2020
Management to Host Webcast and Conference Call Today at 8:00 a.m. ET

RESEARCH TRIANGLE PARK, N.C., Nov. 13, 2019 (GLOBE NEWSWIRE) -- Liquidia Technologies, Inc. (Nasdaq: LQDA) ("Liquidia" or the "Company"), a late-stage clinical biopharmaceutical company, today reported financial results for the quarter ended September 30, 2019, and provided a corporate update.

"We continue to deliver on our key objectives by completing the clinical program for LIQ861 and driving towards our first NDA submission," stated Neal Fowler, Liquidia's Chief Executive Officer. "We are engaged in pre-NDA meetings with the U.S. Food and Drug Administration (FDA) in preparation for the NDA submission. In parallel, we are executing concurrent clinical studies to supplement the medical information available upon the potential approval of LIQ861.

"We also strengthened our Board of Directors with the appointments of Dr. Joanna Horobin and Katie Rielly-Gauvin, both accomplished pharmaceutical industry executives, to provide advice and guidance as we mature into a commercial-stage biopharmaceutical company. We are fortunate to have the benefit of their experience and broad therapeutic area expertise as we plan for the future.

"Given our need for additional capital prior to a potential commercial launch of LIQ861, and interest to maximize value for our stockholders, we are exploring all funding options, including potential partnerships with companies offering strategic and commercial synergies. We are pleased to be working with our long-time financial advisor Jefferies LLC in this effort," Mr. Fowler concluded.

Recent 2019 Corporate Updates

- **Completed LIQ861 clinical program to support NDA submission**
  The registrational studies for LIQ861 have been completed and the Company is proceeding with plans to submit the NDA for the treatment of adults with pulmonary arterial hypertension (PAH). Final enrollment in the pivotal INSPIRE trial included 121 PAH patients to assess safety and tolerability through Month 2, the primary endpoint of the trial. Consistent with preliminary data presented in the second quarter of 2019, LIQ861 was observed to be well-tolerated and treatment-emergent adverse events ("TEAEs") were mostly mild to moderate in nature. In addition to INSPIRE, a second supplemental pharmacokinetics study was completed, the results of which the Company believes further confirm the comparative bioavailability of 75 mcg capsule strength LIQ861 to 54mcg (9 breaths) of Tyvaso®*, the reference listed drug.

  Highlights from the LIQ861 clinical program are provided below with detailed data to be presented at medical conferences and in publications during the course of 2020. Specifically, the following observations were made:

  - Initial analysis from the completed INSPIRE study indicates that LIQ861 is well-tolerated and may provide functional and quality-of-life benefits to PAH patients in NYHA functional classes II and III
  - Total patients enrolled in INSPIRE included 55 patients transitioned from a stable dose of Tyvaso ("Transition patients") and 66 prostacyclin-naïve patients stable on ≤2 approved oral PAH therapies ("Add-On patients")
  - Most Transition patients (96%) and Add-On patients (91%) remained on treatment with LIQ861 to Month 2
  - LIQ861 was observed to be well-tolerated and TEAEs were mostly mild to moderate in nature up to doses of 150 mcg capsule strength LIQ861, the highest dose studied at Month 2
  - Most Add-On patients (>80%) were titrated to 75mcg capsule strength or higher within the first two months of treatment
  - Most patients (>90%) completing two months of treatment maintained or improved their New York Heart Association Functional Class
  - Both patient groups saw improvement in six-minute-walk-distance and quality of life, as measured by the Minnesota Living with Heart Failure Questionnaire, both exploratory endpoints
  - Most patients (>80%) continued treatment to Month 4 with no significant changes in safety or tolerability observed compared to Month 2

- **Initiated clinical studies to evaluate long-term safety, tolerability and hemodynamic effects of LIQ861**
  The Company has transitioned patients from INSPIRE who wish to continue LIQ861 treatment into an open-label extension study, which the Company plans to continue until potential FDA approval. The Company is also enrolling patients in a clinical study to characterize the hemodynamic dose-response relationship to LIQ861 at certain investigational sites in Europe.

- **Engaged the FDA in pre-NDA meetings in preparation for the NDA submission targeted for 1Q 2020**
  During the third quarter of 2019, the Company hosted the FDA at its headquarters as part of the FDA's Emerging Technologies program in preparation for interactions related to the CMC aspects of the Company's NDA submission. The Company more recently conducted a pre-NDA CMC meeting with the FDA and received no new CMC requirements for NDA submission. Later this quarter, a pre-NDA meeting will be held to discuss clinical and nonclinical matters of the NDA. The Company continues to target an NDA submission in the first quarter of 2020.

- **Conducting toxicology studies with LIQ865**
  Phase 2-enabling toxicology studies were initiated earlier in 2019 to assess LIQ865 in multiple non-clinical tissue models. Results from a study to assess incision tensile strength after healing were acceptable and not statistically different from controls. In a study to assess bone fracture healing, the Company observed dose-dependent delayed healing at the two LIQ865 doses studied; however, there were no adverse effects noted on surrounding soft tissues. Additional studies are planned with lower doses of LIQ865 to determine a no adverse effect level (NOAEL) on bone healing. Results from an additional soft tissue toxicology study are expected later in the fourth quarter of 2019. Results from these toxicology studies will be reviewed in 2020, and provided the data are supportive, the Company intends to initiate a Phase 2 program.

Anticipated Upcoming Milestones

- Submit NDA for LIQ861 in the first quarter of 2020
- Present and publish clinical data from the LIQ861 program in 2020
- Complete LIQ865 toxicology studies with the goal of initiating a Phase 2 program in 2020

Third Quarter 2019 Financial Highlights

- **Revenues:** No revenue was recorded for the third quarter of 2019, compared with $0.2 million for the third quarter of 2018. The decrease of $0.2 million, or 100.0%, was due to the full recognition in the second quarter of 2019 of $8.1 million of deferred revenue from the Inhaled Collaboration and Option Agreement with GlaxoSmithKline plc (GSK) resulting from the third amendment to such agreement that was entered into in June 2019.
- **Cost of Sales:** Cost of sales was $0.0 million for the third quarter of 2019 and for the third quarter of 2018.
- **Research and Development (R&D):** R&D expenses were $10.9 million for third quarter of 2019, compared to $7.2 million for third quarter of 2018. The increase of $3.7 million was primarily due to the ongoing clinical development of LIQ861 which commenced in late December 2017.
- **General and Administrative (G&A):** G&A expenses were $2.4 million for third quarter of 2019, compared to $2.3 million for third quarter of 2018. The increase of $0.1 million was primarily due to an increase in employee-related expenses and professional fees.
- **Interest Expense:** Interest expense was $0.3 million for third quarter of 2019, compared to $0.6 million for third quarter of 2018. The decrease in interest expense was primarily due to lower levels of outstanding debt.
- **Net Loss:** We recorded a net loss of $13.4 million for third quarter of 2019, compared to $9.7 million for third quarter of 2018. The increase of $3.7 million was primarily due to an increase in R&D expenses.
- **Cash Position:** Cash totaled $39.3 million as of September 30, 2019.
- **Shares Outstanding**: There were 18.7 million shares of common stock outstanding as of September 30, 2019.

Webcast and Conference Call

Liquidia's management team will host a webcast and conference call at 8:00 a.m. ET today to discuss the financial results and provide a corporate update. The live call may be accessed by dialing 1-877-707-8711 (domestic) and 1-857-270-6219 (international) and entering the conference code: 8390077. A live and archived webcast of the call will be available on the Events & Presentations page of Liquidia's website.

About Liquidia

Liquidia is a late-stage clinical biopharmaceutical company focused on the development and commercialization of 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. Having been 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 dry powder inhaler. 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 Liquidia's website at www.liquidia.com.

**** Tyvaso® is a registered trademark of United Therapeutics Corporation.***

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 strategic and financial initiatives, including the potential licensing of LIQ861, 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 and our ability to execute on our strategic or financial initiatives, 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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-Financial Tables Follow-

Liquidia Technologies, Inc.

Balance Sheets (Unaudited)

	September 30, 2019	September 30, 2018
Assets		
Current assets:		
Cash	$ 39,304,564	$ 39,534,985
Accounts receivable – trade and other	945,662	272,557
Prepaid expenses and other current assets	486,471	219,057
Total current assets	40,736,697	40,026,599
Property, plant and equipment, net	8,090,272	8,130,708
Operating lease right-of-use assets, net	2,836,829	—
Prepaid expenses and other assets	574,857	1,260,951
Total assets	$ 52,238,655	$ 49,418,258
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 4,543,940	$ 3,235,949
Accrued expenses	1,531,133	1,459,182
Accrued compensation	2,263,083	2,515,519
Deferred rent	—	268,599
Current portion of operating lease liabilities	543,677	—
Current portion of finance lease liabilities	1,020,546	452,703
Current portion of long-term debt	4,293,611	316,906
Total current liabilities	14,195,990	8,248,858
Long-term operating lease liabilities	5,822,244	—
Long-term finance lease liabilities	1,106,083	376,082
Long-term deferred rent	—	2,406,084
Long-term deferred revenue	—	8,071,920
Long-term debt	11,565,636	11,627,643
Total liabilities	32,689,953	30,730,587
Stockholders' equity:		
Preferred stock — 10,000,000 shares authorized as of September 30, 2019 and December 31, 2018, 0 and 0 issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	—	—

Common stock — $0.001 par value, 40,000,000 shares authorized as of June 30, 2019 and December 31, 2018, 18,656,686 and 15,519,469 issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	18,656	15,520
Additional paid-in capital	220,277,054	185,726,048
Accumulated deficit	(200,747,008)	(167,053,897)
Total stockholders' equity	19,548,702	18,687,671
Total liabilities and stockholders' equity	$ 52,238,655	$ 49,418,258

Liquidia Technologies, Inc.

Statements of Operations and Comprehensive Loss (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenues	$ —	$ 169,730	$ 8,072,120	$ 2,138,579
Costs and expenses:				
Cost of sales	—	—	807,192	121,391
Research and development	10,942,561	7,156,618	32,330,454	20,701,022
General and administrative	2,377,687	2,283,936	7,807,920	6,424,892
Total costs and expenses	13,320,248	9,440,554	40,945,566	27,247,305
Loss from operations	(13,320,248)	(9,270,824)	(32,873,446)	(25,108,726)
Other income (expense):				
Interest income	162,207	128,120	519,861	139,965
Interest expense	(265,018)	(636,573)	(737,429)	(18,759,078)
Derivative and warrant fair value adjustments	—	106,265	—	277,715
Total other income (expense), net	(102,811)	(402,188)	(217,568)	(18,341,398)
Net loss	(13,423,059)	(9,673,012)	(33,091,014)	(43,450,124)
Other comprehensive loss	—	—	—	—
Comprehensive loss	$ (13,423,059)	$ (9,673,012)	$ (33,091,014)	$ (43,450,124)
Net loss per common share:				
Basic	$ (0.72)	$ (0.83)	$ (1.85)	$ (10.16)
Diluted	(0.72)	(0.84)	(1.87)	(10.27)
Weighted average common shares outstanding:				
Basic	18,757,166	11,606,489	17,856,826	4,277,554
Diluted	18,650,892	11,464,459	17,737,737	4,229,691

Source: Liquidia Technologies, Inc.