

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** For the fiscal quarter ended March 31, 2023

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** For the transition period from to

Commission File Number: 001-39724

**LIQUIDIA CORPORATION**  
(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

**85-1710962**

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification No.)

**419 Davis Drive, Suite 100  
Morrisville, North Carolina**

**27560**

(Address of Principal Executive Offices)

(Zip Code)

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

**N/A**

(Former name, former address and former fiscal year, if changed since last report)

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, \$0.001 par value per share	LQDA	The Nasdaq Stock Market LLC

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

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

Large Accelerated Filer

Accelerated Filer

Non-accelerated Filer

Smaller Reporting Company

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

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

As of May 1, 2023, there were 64,717,549 shares of the registrant's common stock outstanding.

LIQUIDIA CORPORATION

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This Quarterly Report on Form 10-Q, or this Quarterly Report, includes our trademarks, trade names and service marks, such as Liquidia, the Liquidia logo, YUTREPIA and PRINT, or Particle Replication In Non-wetting Templates, which are protected under applicable intellectual property laws and are the property of Liquidia Technologies, Inc. This Quarterly Report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this Quarterly Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

### Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report may be forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” but are also contained elsewhere in this Quarterly Report. In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “would,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- those identified and disclosed in our public filings with the U.S. Securities and Exchange Commission (“SEC”) including, but not limited to (i) the timing of and our ability to obtain and maintain regulatory approvals for our product candidates, including YUTREPIA, the potential for, and timing regarding, eventual final approval by the United States Food and Drug Administration (the “FDA”) of and our ability to commercially launch YUTREPIA, including the potential impact of regulatory review, approval, and exclusivity developments which may occur for competitors; (ii) the timeline or outcome related to appeals or other motions arising in or from our patent litigation with United Therapeutics that was filed in the U.S. District Court for the District of Delaware or the inter partes reviews with the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office; and (iii) the timing and our ability to obtain and maintain regulatory approval for the infusion pump that we are developing with Sandoz Inc. (“Sandoz”) and Mainbridge Health Partners, LLC (“Mainbridge”);
- our ability to predict, foresee, and effectively address or mitigate future developments resulting from the COVID-19 pandemic or other global shutdowns, which could include a negative impact on the availability of key personnel, the temporary closure of our facility or the facilities of our business partners, suppliers, third-party service providers or other vendors, or delays in payments or purchasing decisions, or the interruption of domestic and global supply chains, the economy and capital or financial markets;
- our expectations regarding the size of the patient populations for, market acceptance and opportunity for those drug products that we commercialize in collaboration with third parties, including Sandoz’s first-to-file fully substitutable generic tadalafil injection;
- the availability and market acceptance of medical devices and components of medical devices used to administer our drug products and drug products that we commercialize with third parties, including Smith Medical’s CADD-MS 3 infusion pump, the RG 3ml Medication Cartridge that we developed in collaboration with Chengdu Shifeng Medical Technologies LTD. used for the subcutaneous administration of Sandoz’s generic tadalafil injection, Smith Medical’s CADD Legacy and CADD-Solis infusions pump used for the intravenous administration of Sandoz’s generic tadalafil injection, the infusion pump that we are developing with Sandoz and Mainbridge for the subcutaneous administration of Sandoz’s generic tadalafil injection and Plastiapne’s RS00 Model 8 dry powder inhaler, which we plan to use for the administration of YUTREPIA;
- our ability to draw down on our financing facility with Healthcare Royalty Partners IV, L.P. (“HCR”) and our ability to satisfy the covenants contained in the Revenue Interest Financing Agreement with HCR (the “RIFA”);
- our ability to retain, attract and hire key personnel;
- prevailing economic, market and business conditions;
- the cost and availability of capital and any restrictions imposed by lenders or creditors;
- changes in the industry in which we operate;
- the failure to renew, or the revocation of, any license or other required permits;
- unexpected charges or unexpected liabilities arising from a change in accounting policies, including any such changes by third parties with whom we collaborate and from whom we receive a portion of their net profits, or the effects of acquisition accounting varying from our expectations;
- the risk that the credit ratings of our company or our subsidiaries may be different from what the companies expect, which may increase borrowing costs and/or make it more difficult for us to pay or refinance our debts and require us to borrow or divert cash flow from operations in order to service debt payments;
- fluctuations in interest rates;

- adverse outcomes of pending or threatened litigation or governmental investigations, including our patent litigation with United Therapeutics and the litigation arising from United Therapeutics' claim that we and a former employee misappropriated trade secrets from United Therapeutics;
- the effects on the companies of future regulatory or legislative actions, including changes in healthcare, environmental and other laws and regulations to which we are subject;
- conduct of and changing circumstances related to third-party relationships on which we rely, including the level of credit worthiness of counterparties;
- the volatility and unpredictability of the stock market and credit market conditions;
- conditions beyond our control, such as natural disasters, global pandemics (including COVID-19), or acts of war or terrorism;
- variations between the stated assumptions on which forward-looking statements are based and our actual experience;
- other legislative, regulatory, economic, business, and/or competitive factors;
- our plans to develop and commercialize our product candidates;
- our planned clinical trials for our product candidates;
- the timing of the availability of data from our clinical trials;
- the timing of our planned regulatory filings;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the clinical utility of our product candidates and their potential advantages compared to other treatments;
- our commercialization, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for the manufacture of our product candidates and the sufficiency of our current manufacturing facilities to produce development and commercial quantities of our product candidates;
- our ability to establish and maintain collaborations;
- our estimates regarding the market opportunities for our product candidates;
- our intellectual property position and the duration of our patent rights;
- our estimates regarding future expenses, capital requirements and needs for additional financing; and
- our expected use of proceeds from prior public offerings and the period over which such proceeds, together with our available cash, will be sufficient to meet our operating needs.

You should refer to the "Risk Factors" section of this Quarterly Report on Form 10-Q for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements, including, but not limited to, the impact of the COVID-19 pandemic on our company and our financial condition and results of operations. The forward-looking statements in this Quarterly Report are only predictions, and we may not actually achieve the plans, intentions or expectations included in our 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 business, financial condition and results of operations. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

These forward-looking statements speak only as of the date of this Quarterly Report. While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

*Unless the context otherwise requires, references in this Quarterly Report on Form 10-Q to "we," "us," "our", "Liquidia" and the "Company" refer to Liquidia Corporation, a Delaware corporation, and unless specified otherwise, include our wholly owned subsidiaries, Liquidia Technologies, Inc., a Delaware corporation, or Liquidia Technologies, and Liquidia PAH, LLC (formerly known as RareGen, LLC, or RareGen), a Delaware limited liability company, or Liquidia PAH.*

**PART I. FINANCIAL INFORMATION**

**Item 1. Condensed Financial Statements**

**Liquidia Corporation**  
**Condensed Consolidated Balance Sheets (unaudited)**  
**(in thousands, except share and per share data)**

	March 31, 2023	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 94,412	\$ 93,283
Accounts receivable, net	4,131	5,017
Prepaid expenses and other current assets	1,147	1,511
Total current assets	99,690	99,811
Property, plant and equipment, net	4,346	4,151
Operating lease right-of-use assets, net	2,010	2,101
Indemnification asset, related party	6,612	6,595
Contract acquisition costs, net	8,411	8,604
Intangible asset, net	3,643	3,726
Goodwill	3,903	3,903
Other assets	307	307
Total assets	<u>\$ 128,922</u>	<u>\$ 129,198</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 841	\$ 2,197
Accrued expenses and other current liabilities	2,945	5,522
Revenue interest financing payable, current	2,000	—
Operating lease liabilities, current	932	900
Finance lease liabilities, current	102	181
Total current liabilities	6,820	8,800
Litigation finance payable	6,611	6,594
Revenue interest financing payable, noncurrent	30,617	—
Operating lease liabilities, noncurrent	3,086	3,332
Finance lease liabilities, noncurrent	145	171
Long-term debt	—	19,879
Total liabilities	47,279	38,776
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock — 10,000,000 shares authorized, none outstanding	—	—
Common stock — \$0.001 par value, 80,000,000 shares authorized, 64,710,444 and 64,517,912 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	65	64
Additional paid-in capital	443,919	440,954
Accumulated deficit	(362,341)	(350,596)
Total stockholders' equity	81,643	90,422
Total liabilities and stockholders' equity	<u>\$ 128,922</u>	<u>\$ 129,198</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Liquidia Corporation**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)**  
**(in thousands, except share and per share data)**

	<u>Three Months Ended March 31,</u>	
	<u>2023</u>	<u>2022</u>
Revenue	\$ 4,493	\$ 3,492
Costs and expenses:		
Cost of revenue	654	694
Research and development	5,278	4,728
General and administrative	7,793	12,542
Total costs and expenses	13,725	17,964
Loss from operations	(9,232)	(14,472)
Other income (expense):		
Interest income	922	4
Interest expense	(1,124)	(478)
Loss on extinguishment of debt	(2,311)	(997)
Total other expense, net	(2,513)	(1,471)
Net loss and comprehensive loss	\$ (11,745)	\$ (15,943)
Net loss per common share, basic and diluted	\$ (0.18)	\$ (0.30)
Weighted average common shares outstanding, basic and diluted	64,656,424	52,465,283

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Liquidia Corporation**  
**Condensed Consolidated Statements of Stockholders' Equity (unaudited)**  
(in thousands, except shares amounts)

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
<b>Balance as of December 31, 2022</b>	64,517,912	\$ 64	\$ 440,954	\$ (350,596)	\$ 90,422
Issuance of common stock upon exercise of stock options	21,447	—	79	—	79
Issuance of common stock upon vesting of restricted stock units	89,804	1	(1)	—	—
Issuance of common stock under employee stock purchase plan	81,281	—	335	—	335
Stock-based compensation	—	—	2,552	—	2,552
Net loss	—	—	—	(11,745)	(11,745)
<b>Balance as of March 31, 2023</b>	64,710,444	\$ 65	\$ 443,919	\$ (362,341)	\$ 81,643

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
<b>Balance as of December 31, 2021</b>	52,287,737	\$ 52	\$ 374,794	\$ (309,581)	\$ 65,265
Issuance of common stock upon exercise of stock options	143,048	—	593	—	593
Issuance of common stock upon vesting of restricted stock units	1,690	—	—	—	—
Issuance of common stock under employee stock purchase plan	5,017	—	28	—	28
Issuance of warrant	—	—	1,317	—	1,317
Equity consideration for acquisition	616,666	1	(1)	—	—
Stock-based compensation	—	—	4,129	—	4,129
Net loss	—	—	—	(15,943)	(15,943)
<b>Balance as of March 31, 2022</b>	53,054,158	\$ 53	\$ 380,860	\$ (325,524)	\$ 55,389

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Liquidia Corporation**  
**Condensed Consolidated Statements of Cash Flows (unaudited)**  
(in thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Operating activities</b>		
Net loss	\$ (11,745)	\$ (15,943)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,552	4,185
Depreciation and amortization	569	947
Non-cash lease expense	91	70
(Gain) on disposal of property and equipment	(2)	—
Loss on extinguishment of debt	2,311	997
Non-cash interest expense (income)	953	(6)
Changes in operating assets and liabilities:		
Accounts receivable, net	886	(297)
Prepaid expenses and other current assets	214	(82)
Other noncurrent assets	—	4
Accounts payable	(1,495)	458
Accrued expenses and other current liabilities	(2,577)	70
Operating lease liabilities	(214)	(185)
Net cash used in operating activities	<u>(8,457)</u>	<u>(9,782)</u>
<b>Investing activities</b>		
Purchases of property, plant and equipment	(366)	—
Proceeds from the sale of property, plant and equipment	2	—
Net cash used in investing activities	<u>(364)</u>	<u>—</u>
<b>Financing activities</b>		
Proceeds from revenue interest financing, net	31,814	—
Principal payments on long-term debt	(20,000)	(10,500)
Payments for debt prepayment and extinguishment costs	(2,190)	—
Proceeds from issuance of long-term debt with warrants, net	—	19,767
Principal payments on finance leases	(105)	(82)
Receipts from litigation financing	17	276
Proceeds from issuance of common stock under stock incentive plans	414	621
Net cash provided by financing activities	<u>9,950</u>	<u>10,082</u>
Net increase in cash and cash equivalents	1,129	300
Cash and cash equivalents, beginning of period	93,283	57,494
Cash and cash equivalents, end of period	<u>\$ 94,412</u>	<u>\$ 57,794</u>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	<u>\$ 360</u>	<u>\$ 261</u>
Cash paid for operating lease liabilities	<u>\$ 319</u>	<u>\$ 309</u>
Non-cash increase in property, plant and equipment through accounts payable	<u>\$ 122</u>	<u>\$ —</u>
Non-cash increase in indemnification asset through accounts payable	<u>\$ 17</u>	<u>\$ 138</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**Liquidia Corporation**  
**Notes to Condensed Consolidated Financial Statements (unaudited)**  
**(tabular dollars in thousands)**

**1. Business**

**Description of the Business**

We are a biopharmaceutical company focused on the development, manufacture, and commercialization of products that address unmet patient needs, with current focus directed towards the treatment of pulmonary hypertension (“PH”). We operate through our wholly owned operating subsidiaries, Liquidia Technologies, Inc. (“Liquidia Technologies”) and Liquidia PAH, LLC (“Liquidia PAH”), formerly known as RareGen, LLC (“RareGen”).

We currently generate revenue pursuant to a promotion agreement between Liquidia PAH and Sandoz Inc. (“Sandoz”), dated as of August 1, 2018, as amended (the “Promotion Agreement”), sharing profit derived from the sale of Sandoz’s substitutable generic tadalafil injection (“Tadalafil Injection”) in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Tadalafil Injection. We employ a targeted sales force calling on physicians and hospital pharmacies involved in the treatment of pulmonary arterial hypertension (“PAH”) in the United States, as well as key stakeholders involved in the distribution and reimbursement of Tadalafil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient base to expand from for the launch of YUTREPIA upon final approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH patients.

We conduct research, development and manufacturing of novel products by applying our subject matter expertise in cardiopulmonary diseases and our proprietary PRINT® technology, a particle engineering platform, to enable precise production of uniform drug particles designed to improve the safety, efficacy and performance of a wide range of therapies. Through development of our own products and research with third parties, we have experience applying PRINT across multiple routes of administration and drug payloads including inhaled therapies, vaccines, biologics, nucleic acids and ophthalmic implants, among others.

Our lead product candidate is YUTREPIA for the treatment of PAH. YUTREPIA is an inhaled dry powder formulation of tadalafil designed with PRINT to improve the therapeutic profile of tadalafil by enhancing deep lung delivery while using a convenient, low resistance dry-powder inhaler (“DPI”) and by achieving higher dose levels than the labeled doses of current inhaled therapies. The United States Food and Drug Administration (“FDA”) tentatively approved our New Drug Application (“NDA”) for YUTREPIA for the treatment of PAH in November 2021. The FDA also confirmed that the clinical data in the NDA would support our pursuit of a supplemental NDA to treat patients with pulmonary hypertension and interstitial lung disease (PH-ILD) upon the expiration of regulatory exclusivity in March 2024.

**Risks and Uncertainties**

We are subject to risks and uncertainties common to companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on third parties and key personnel, protection of proprietary technology, compliance with government regulations, and the ability to secure additional capital to fund operations.

The current global macro-economic environment is volatile, which may result in supply chain constraints and elevated rates of inflation. In addition, we operate in a dynamic and highly competitive industry and believe that changes in any of the following areas could have a material adverse effect on our future financial position, results of operations, or cash flows: the ability to obtain future financing; advances and trends in new technologies and industry standards; results of clinical trials; regulatory approval and market acceptance of our products; development of sales channels; certain strategic relationships; litigation or claims against our related to intellectual property, product, regulatory, or other matters; and our ability to attract and retain employees necessary to support our growth.

Product candidates we develop require approval from the FDA and/or other international regulatory agencies prior to commercial sales. There can be no assurance that our product candidates will receive the necessary approvals. If we are denied approval, approval is delayed, or we are unable to maintain approval, it could have a material adverse impact on our business, financial position and results of operations.

We rely on single source manufacturers and suppliers for the supply of our product candidates, which adds to the manufacturing risks we face. In the event of any failure by a supplier, we could be left without backup facilities. Any disruption from these manufacturers or suppliers could have a negative impact on our business, financial position and results of operations.

### **Liquidity**

We expect to incur significant expenses and operating losses for the foreseeable future as we seek regulatory approval and prepare for commercialization of any approved product candidates. These efforts require significant amounts of capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if our development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales. We may require additional capital in advance of a potential commercial launch of YUTREPIA. If we are unable to access the contingent Investment Amounts from the RIFA (see Note 11) or generate meaningful YUTREPIA product revenue by the second quarter of 2024, we will require additional capital. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates. If we conclude we require but are unable to obtain funding, we could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect our business prospects.

In accordance with Accounting Standards Update (“ASU”) 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40)*, we have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. We have financed our growth and operations through a combination of funds generated from revenues, the issuance of convertible preferred stock and common stock, bank borrowings, bank borrowings with warrants, the issuance of convertible notes and warrants, and revenue interest financing. Since inception, we have incurred recurring losses, including a net loss of \$11.7 million for the three months ended March 31, 2023 and we had an accumulated deficit of \$362.3 million as of March 31, 2023. Although we expect to continue to generate operating losses for the foreseeable future, we believe that based on our current operating plan, excluding any potential contingent Investment Amounts from the RIFA and future YUTREPIA product revenue, that our cash and cash equivalents will be sufficient to fund operations and capital expenditure requirements and allow us to remain in compliance with the minimum cash covenants pursuant to the RIFA for at least twelve months from the issuance date of these consolidated condensed financial statements. If we are unable to access additional Investment Amounts from the RIFA, there could be substantial doubt about our ability to continue as a going concern as of the date of the issuance of our second quarter 2023 financial statements. We have based these estimates on assumptions that may differ from actual results, and it could use its available resources sooner than expected.

## **2. Basis of Presentation, Significant Accounting Policies and Fair Value Measurements**

### **Basis of Presentation**

The unaudited interim condensed consolidated financial statements as of March 31, 2023 and for the three months ended March 31, 2023 and 2022 have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for interim financial reporting. These condensed consolidated financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal recurring adjustments and accruals) necessary for a fair statement of the results for the periods presented in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The year-end condensed consolidated balance sheet data was derived from our audited consolidated financial statements but does not include all disclosures required by GAAP. Operating results for the three months ended March 31, 2023 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2023. Certain information and footnote disclosures normally included in the annual consolidated financial statements prepared in accordance with GAAP have been omitted in accordance

with the SEC's rules and regulations for interim reporting. Our financial position, results of operations and cash flows are presented in U.S. Dollars.

The accompanying unaudited condensed consolidated financial statements and related notes should be read in conjunction with our audited consolidated financial statements for the year ended December 31, 2022, which are included in our 2022 Annual Report on Form 10-K.

### ***Use of Estimates***

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities, at the date of the financial statements, as well as the reported amounts of revenues and expenses during the period. These estimates are based on historical experience and various other assumptions believed to be reasonable under the circumstances. We evaluate our estimates on an ongoing basis, including those related to the valuation of stock-based awards, certain accruals, the revenue interest financing payable, and intangible and contract acquisition cost amortization, and makes changes to the estimates and related disclosures as our experience develops or new information becomes known. Actual results will most likely differ from those estimates.

### ***Segment Information***

GAAP requires segmentation based on an entity's internal organization and reporting of revenue and operating income based upon internal accounting methods commonly referred to as the "management approach." Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker (CODM), or decision making group, in deciding how to allocate resources and in assessing performance. Our CODM is our Chief Executive Officer. We have determined that we have one operating and reporting segment.

### ***Summary of Significant Accounting Policies***

Our significant accounting policies are disclosed in Note 2 of the consolidated financial statements for the years ended December 31, 2022 and 2021, which are included in our 2022 Annual Report on Form 10-K. There have been no material changes to our significant accounting policies during the three months ended March 31, 2023.

### ***Recent Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board under its accounting standards codifications (ASC) or other standard setting bodies and are adopted by us as of the specified effective date. For the three months ended March 31, 2023, there were no newly adopted accounting pronouncements that had a material impact on our condensed consolidated financial statements. As of March 31, 2023, there are no recently issued but not yet adopted accounting pronouncements that are expected to materially impact our condensed consolidated financial statements.

### ***Cash, Cash Equivalents, and Concentration of Credit Risk***

We consider all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents.

Financial instruments that potentially subject us to concentrations of credit risk consist of cash and cash equivalents. We are exposed to credit risk, subject to federal deposit insurance, in the event of default by the financial institutions holding our cash and cash equivalents to the extent of amounts recorded on the condensed consolidated balance sheet. As of December 31, 2022, all of our cash and cash equivalents were held with Silicon Valley Bank ("SVB"). Following the March 10, 2023 Federal Deposit Insurance Corporation takeover of SVB, substantially all of our cash and cash equivalents were moved to a different accredited financial institution. We have not experienced any losses on such

accounts and do not believe that we are subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Such deposits have exceeded and will continue to exceed federally insured limits.

#### ***Accounts Receivable***

Accounts receivable are stated at net realizable value and net of an allowance for credit losses as of each balance sheet date, if applicable. One customer accounted for 99% of our accounts receivable, net at March 31, 2023 and December 31, 2022. As of March 31, 2023 and December 31, 2022, we have not recorded an allowance for credit losses.

#### ***Long-Lived Assets***

We review long-lived assets, including definite-life intangible assets, for realizability on an ongoing basis. Changes in depreciation and amortization, generally accelerated depreciation and variable amortization, are determined and recorded when estimates of the remaining useful lives or residual values of long-term assets change. We also review for impairment when conditions exist that indicate the carrying amount of the assets may not be fully recoverable. In those circumstances, we perform undiscounted operating cash flow analyses to determine if an impairment exists. When testing for asset impairment, we group assets and liabilities at the lowest level for which cash flows are separately identifiable. Any impairment loss is calculated as the excess of the asset's carrying value over its estimated fair value. Fair value is estimated based on the discounted cash flows for the asset group over the remaining useful life or based on the expected cash proceeds for the asset less costs of disposal. Any impairment losses would be recorded in the consolidated statements of operations. To date, no such impairments have occurred.

#### ***Goodwill***

We assess goodwill for impairment at least annually as of July 1 or whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. For example, significant and unanticipated changes or our inability to obtain or maintain regulatory approvals for our product candidates, including the NDA for YUTREPIA, could trigger testing of our goodwill for impairment at an interim date. We have one reporting unit. We have the option to first assess qualitative factors to determine whether events or circumstances indicate it is more likely than not that the fair value of a reporting unit is greater than its carrying amount, in which case a quantitative impairment test is not required.

Per ASC 350, *Intangibles Goodwill and Other*, the quantitative goodwill impairment test is performed by comparing the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is not impaired. An impairment loss is recognized for any excess of the carrying amount of the reporting unit's goodwill over the fair value up to the amount of goodwill allocated to the reporting unit. Income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit are considered when measuring the goodwill impairment loss, if applicable.

We completed our last annual impairment test as of July 1, 2022 and concluded that no impairments had occurred. As of March 31, 2023, we concluded there were no events or changes in circumstances which indicated that the carrying amount of goodwill was not recoverable.

#### ***Royalty Interest Financing Payable***

In January 2023, we recognized a liability related to the Revenue Interest Financing Agreement (the "RIFA") with HealthCare Royalty Partners IV, L.P. ("HCR") and HealthCare Royalty Management, LLC under ASC 470-10, *Debt* and ASC 835-30, *Interest - Imputation of Interest*. We recorded the initial funds received from HCR under the terms of the RIFA as a liability which will be accreted under the effective interest method upon the estimated amount of future royalty payments to be made pursuant to the RIFA. The issuance costs were recorded as a deduction to the carrying amount of the liability and will be amortized under the effective interest method over the estimated period in which the liability will be repaid. We have estimated the total amount of future revenue to be generated over the life of the RIFA, and a significant increase or decrease in these estimates could materially impact the liability balance and related interest expense. If the

timing or amounts of any estimated future revenue and related payments change, we will prospectively adjust the effective interest and the related amortization of the liability and related issuance costs.

### ***Revenue Recognition***

We recognize revenue in accordance with ASC 606, *Revenue from Contracts with Customers* (“ASC 606”). The core principle of ASC 606 is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

In order to identify the performance obligations in a contract with a customer, we assess the promised goods or services in the contract and identify each promised good or service that is distinct.

If a good or service is not distinct, the good or service is combined with other promised goods or services until a bundle of goods or services is identified that is distinct.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both.

Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. We evaluate any non-cash consideration, consideration payable to the customer, potential returns and refunds, and whether consideration contains a significant financing element in determining the transaction price.

Revenue is measured based on consideration specified in a contract with a customer. We recognize revenue when it satisfies a performance obligation by transferring control over a service to a customer. The amount of revenue recognized reflects estimates for refunds and returns, which are presented as a reduction of Accounts receivable where the right of setoff exists.

### ***Stock-Based Compensation***

We estimate the grant date fair value of stock-based awards and amortize this fair value to compensation expense over the requisite service period or the vesting period of the respective award. In arriving at stock-based compensation expense, we estimate the number of stock-based awards that will be forfeited due to employee turnover. The forfeiture assumption is based primarily on turn-over historical experience. If the actual forfeiture rate is higher than the estimated forfeiture rate, then an adjustment will be made to increase the estimated forfeiture rate, which will result in a decrease to the expense recognized in our financial statements. If the actual forfeiture rate is lower than the estimated forfeiture rate, then an adjustment will be made to lower the estimated forfeiture rate, which will result in an increase to expense recognized in our financial statements. The expense we recognize in future periods will be affected by changes in the estimated forfeiture rate and may differ from amounts recognized in the current period. See Note 8.

**Net Loss Per Share**

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration of common stock equivalents.

Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. Due to their anti-dilutive effect, the calculation of diluted net loss per shares excludes the following common stock equivalent shares:

	Three Months Ended March 31,	
	2023	2022
Stock Options	9,402,106	7,054,395
Restricted Stock Units	1,590,469	365,382
Warrants	450,000	430,556
Total	<u>11,442,575</u>	<u>7,850,333</u>

Certain common stock warrants are included in the calculation of basic and diluted net loss per share since their exercise price is de minimis.

**Fair Value Measurements**

ASC 825 *Financial Instruments* defines fair value the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants (an exit price). As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. ASC 825 establishes a three-tiered approach for valuation of financial instruments, which requires that fair value measurements be classified and disclosed in one of three tiers, whether or not recognized on our condensed consolidated balance sheets at fair value. The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities;

Level 2 — Inputs other than quoted prices included in active markets that are observable for the asset or liability, either directly or indirectly; and

Level 3 — Unobservable inputs for the asset and liability used to measure fair value, to the extent that observable inputs are not available.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. As of March 31, 2023, we did not have any financial assets and liabilities that are measured at fair value. The following table presents the placement in the fair value hierarchy of financial assets and liabilities measured at fair value as of December 31, 2022:

December 31, 2022	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Carrying Value
Money market funds (cash equivalents)	<u>\$ 92,283</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 92,283</u>

Money market funds are included in cash and cash equivalents on our December 31, 2022 condensed consolidated balance sheet and are classified within Level 1 of the fair value hierarchy since they are valued using quoted market prices.

The carrying amounts reflected in our condensed consolidated balance sheets for cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses and other liabilities approximate their fair values due to their short-term nature. The carrying value of long-term debt and the revenue interest financing payable approximate fair value as the respective interest rates are reflective of current market rates on debt with similar terms and conditions. In addition, the revenue interest financing payable is updated with the expected amount to be paid back each reporting period based on the contractual terms and current projections.

### 3. Property, Plant, and Equipment

Property, plant and equipment consisted of the following:

	March 31, 2023	December 31, 2022
Lab and build-to-suit equipment	\$ 6,344	\$ 6,257
Office equipment	19	19
Furniture and fixtures	134	134
Computer equipment	400	291
Leasehold improvements	11,409	11,409
Construction-in-progress	447	155
Total property, plant and equipment	18,753	18,265
Accumulated depreciation and amortization	(14,407)	(14,114)
Property, plant and equipment, net	<u>\$ 4,346</u>	<u>\$ 4,151</u>

We recorded depreciation and amortization expense related to property, plant and equipment of \$0.3 million and \$0.4 million for the three months ended March 31, 2023 and 2022, respectively.

### 4. Contract Acquisition Costs and Intangible Asset

Contract acquisition costs and intangible asset are summarized as follows:

	March 31, 2023			December 31, 2022		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Contract acquisition costs	\$ 12,980	\$ (4,569)	\$ 8,411	\$ 12,980	\$ (4,376)	\$ 8,604
Intangible asset	\$ 5,620	\$ (1,977)	\$ 3,643	\$ 5,620	\$ (1,894)	\$ 3,726

We are amortizing the value of the contract acquisition costs and intangible asset on a pro-rata basis based on the estimated total revenue or net profits to be recognized over the period from November 18, 2020 through December 2032, the termination date of the Promotion Agreement (see Note 2-Revenue Recognition for our accounting policies). Amortization of contract acquisition costs is recorded as a reduction of revenue and amortization of the intangible asset is recorded as cost of revenue.

We recorded amortization related to the contract acquisition costs of \$0.2 million and \$0.4 million for the three months ended March 31, 2023 and 2022, respectively. We recorded amortization related to the intangible asset of \$0.1 million and \$0.2 million for the three months ended March 31, 2023 and 2022, respectively. Annual amortization over the next five years is expected to be lower than prior years primarily due to an amendment to the Promotion Agreement entered into during the fourth quarter of 2022, which extended the term of the Promotion Agreement by five years.

## 5. Indemnification Asset with Related Party and Litigation Finance Payable

On June 3, 2020, Liquidia PAH entered into a litigation financing arrangement (the “Financing Agreement”) with Henderson SPV, LLC (“Henderson”). Liquidia PAH, along with Sandoz (collectively the “Plaintiffs”), are pursuing litigation against United Therapeutics Corporation (“United Therapeutics”) and, prior to entering into a binding settlement term sheet with Smiths Medical ASC (“Smiths Medical”) in November 2020, were pursuing litigation against Smiths Medical (collectively, the “RareGen Litigation”). Under the Financing Agreement, Henderson will fund Liquidia PAH’s legal and litigation expenses (referred to as “Deployments”) in exchange for a share of certain litigation or settlement proceeds. Deployments received from Henderson are recorded as a Litigation finance payable.

Litigation proceeds will be split equally between Liquidia PAH and Sandoz. Unless there is an event of default by Henderson, litigation proceeds received by Liquidia PAH must be applied first to repayment of total Deployments received. Litigation proceeds in excess of Deployments received are split between Liquidia PAH and Henderson according to a formula. Unless there is an event of default by PBM, proceeds received by Liquidia PAH are due to PBM as described further below.

On November 17, 2020, Liquidia PAH entered into a Litigation Funding and Indemnification Agreement (“Indemnification Agreement”) with PBM. PBM is considered to be a related party as it is controlled by a major stockholder (which beneficially owns approximately 9.3% of Liquidia Corporation Common Stock as of May 1, 2023) who is also a member of our Board of Directors.

Under the terms of the Indemnification Agreement, PBM now controls the litigation, with Liquidia PAH’s primary responsibility being to cooperate to support the litigation proceedings as needed. The Indemnification Agreement provides that Liquidia PAH and its affiliates will not be entitled to any proceeds resulting from, or bear any financial or other liability for, the RareGen Litigation unless there is an event of default by PBM. Any Liquidia PAH litigation expenses not reimbursed by Henderson under the Financing Agreement will be reimbursed by PBM. Any proceeds received which Henderson is not entitled to under the Financing Agreement will be due to PBM.

The Indemnification Asset is increased as we record third party legal and litigation expenses related to the United Therapeutics and Smiths Medical litigation.

As of March 31, 2023 and December 31, 2022, the Indemnification Asset and Litigation Finance Payable were classified as long-term assets and liabilities, respectively as it is considered unlikely that the RareGen Litigation would conclude prior to March 31, 2024.

## 6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	<b>March 31, 2023</b>	<b>December 31, 2022</b>
Accrued compensation	\$ 1,048	\$ 2,862
Accrued research and development expenses	749	1,757
Accrued other expenses	1,148	903
Total accrued expenses and other current liabilities	<u>\$ 2,945</u>	<u>\$ 5,522</u>

## 7. Stockholders' Equity

### Common Stock

#### *Issuance of Common Stock on April 18, 2022 from an Underwritten Public Offering*

On April 12, 2022, we sold 11,274,510 shares of our common stock in an underwritten registered public offering at an offering price of \$5.10 per share (the "Offering").

The Offering closed on April 18, 2022, and we received net proceeds of approximately \$54.5 million from the sale of the shares, after deducting the underwriting discounts and commissions and other offering expenses.

Caligan Partners LP ("Caligan"), our largest stockholder, and Paul B. Manning, a member of our Board of Directors, participated in the Offering and purchased shares of common stock in an aggregate amount of \$11.0 million at the public offering price per share and on the same terms as the other purchasers in the Offering. Caligan purchased 1,764,705 shares of common stock in the Offering for an aggregate purchase price of \$9.0 million and Paul B. Manning purchased 392,156 shares of common stock in the Offering for an aggregate purchase price of \$2.0 million.

#### *Issuance of Common Stock on March 31, 2022 from Merger Transaction*

On November 18, 2020 (the "Closing Date"), we completed the acquisition of RareGen as contemplated by that certain Agreement and Plan of Merger, dated as of June 29, 2020, as amended by a Limited Waiver and Modification to the Merger Agreement, dated as of August 3, 2020 (the "Merger Agreement"). On the Closing Date, an aggregate of 5,550,000 shares of our common stock, were issued to RareGen members in exchange for all of the issued and outstanding RareGen equity. On March 31, 2022, an aggregate of 616,666 shares of our common stock, which were held back on the Closing Date for indemnification purposes, were issued to RareGen members.

### Warrants

During the three months ended March 31, 2023 and 2022, no warrants to purchase shares of common stock were exercised.

Outstanding warrants consisted of the following March 31, 2023

	<u>Number of warrants</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
A&R SVB Warrant (see Note 12)	250,000	\$ 5.14	January 6, 2032
SVB Warrant - Initial Tranche (see Note 12)	100,000	\$ 3.05	February 26, 2031
SVB Warrant - Term B and Term C Tranches (see Note 12)	100,000	\$ n/a	February 26, 2031
Other warrants	65,572	\$ 0.02	December 31, 2026

## 8. Stock-Based Compensation

### 2020 Long-Term Incentive Plan

Our 2020 Long-Term Incentive Plan (the "2020 Plan") provides for the granting of stock appreciation rights, stock awards, stock units, and other stock-based awards and for accelerated vesting under certain change of control transactions. The number of shares of our common stock available for issuance under the 2020 plan will automatically increase on January 1 of each year through 2030, by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the Board of Directors (the "Evergreen Provision"). On January 1, 2023, the number of shares of common stock available for issuance under the 2020 Plan automatically increased by 2,580,716 shares pursuant to the Evergreen Provision. As of March 31, 2023, 242,036 shares of common stock were available for issuance under the 2020 Plan.

The 2020 Plan replaced all prior equity award plans and such plans have been discontinued, however, the outstanding awards will continue to remain in effect in accordance with their terms. Shares that are returned under these prior plans upon cancellation, termination or expiration of awards outstanding will not be available for grant under the 2020 Plan. As of March 31, 2023, a total of 672,193 shares of common stock were reserved for issuance related to the remaining outstanding equity awards granted under the prior plans.

### **2022 Inducement Plan**

On January 25, 2022, the Board of Directors approved the adoption of our 2022 Inducement Plan (the “2022 Inducement Plan”). The 2022 Inducement Plan was recommended for approval by the Compensation Committee of the Board (the “Compensation Committee”), and subsequently approved and adopted by the Board of Directors without stockholder approval pursuant to Rule 5635(c)(4) of the rules and regulations of The Nasdaq Stock Market, LLC (the “Nasdaq Listing Rules”).

310,000 shares of our common stock were reserved for issuance pursuant to equity awards that may be granted under the 2022 Inducement Plan, and the 2022 Inducement Plan will be administered by the Compensation Committee. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, equity awards under the 2022 Inducement Plan may only be made to an employee who has not previously been an employee or member of the Board of Directors, or following a bona fide period of non-employment by us, if he or she is granted such equity awards in connection with his or her commencement of employment with us and such grant is an inducement material to his or her entering into employment with us. As of March 31, 2023, a total of 2,800 shares were available for issuance under the 2022 Inducement Plan.

### **Employee Stock Purchase Plan**

In November 2020, stockholders approved the Liquidia Corporation 2020 Employee Stock Purchase Plan (the “ESPP”). The number of shares of our common stock available for issuance under the ESPP will automatically increase by the lesser of (a) 1.0% of the number of shares of common stock issued and outstanding on the immediately, (b) 150,000 shares, or (c) an amount determined by the Board of Directors. On January 1, 2023, the number of shares of common stock available for issuance under the ESPP increased by 150,000 shares. As of March 31, 2023, a total of 616,778 shares of common stock are reserved for issuance under the ESPP. The ESPP allows eligible employees to purchase shares of our common stock at a discount through payroll deductions, subject to plan limitations. Unless otherwise determined by the administrator, the common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is 85% of the lesser of the fair market value of our common stock on the first and last trading day of the offering period. During the three months ended March 31, 2023 and 2022, 81,281 and 5,017 shares were issued under the ESPP, respectively.

### **CEO Options**

During December 2020, we issued a stock option grant to our then new Chief Executive Officer, Damian deGoa, to purchase up to 2,000,000 shares of our common stock (the “CEO Option”) at an exercise price of \$3.00 per share. The CEO Option was issued outside of the 2020 Plan and 1,375,000 options vested in the fourth quarter of 2021 upon the achievement of certain milestones and the passage of time, and ceased vesting upon the termination of Mr. deGoa’s employment on January 31, 2022. However, the CEO Option will remain exercisable so long as Mr. deGoa remains a member of our Board of Directors in accordance with his Separation Agreement. This change to vesting terms was treated as a modification of the original award resulting in a stock-based compensation charge of \$2.9 million during the three months ended March 31, 2022.

### **Stock-Based Compensation Valuation and Expense**

We account for employee stock-based compensation plans using the fair value method. The fair value method requires us to estimate the grant-date fair value of stock-based awards and amortize this fair value to compensation expense over the requisite service period or vesting term. The fair value of each option grant is estimated using a Black-Scholes option-pricing model.

For restricted stock units (“RSUs”), the grant-date fair value is based upon the market price of our common stock on the date of the grant. This fair value is then amortized to compensation expense over the requisite service period or vesting term.

Total stock-based compensation expense recognized for employees and non-employees was as follows:

By Expense Category:	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 581	\$ 383
General and administrative	1,971	3,802
Total stock-based compensation expense	<u>\$ 2,552</u>	<u>\$ 4,185</u>

The following table summarizes the unamortized compensation expense and the remaining years over which such expense would be expected to be recognized, on a weighted average basis, by type of award:

	As of March 31, 2023	
	Unamortized Expense	Weighted Average Remaining Recognition Period (Years)
Stock options	\$ 19,293	2.9
Restricted stock units	\$ 10,692	3.6

#### Fair Value of Stock Options Granted and Purchase Rights Issued under the ESPP

We use the Black-Scholes option-pricing model to determine the fair value of stock options granted and purchase rights issued under the ESPP.

The following table summarizes the assumptions used for estimating the fair value of stock options granted under the Black-Scholes option-pricing model:

	Three Months Ended March 31,	
	2023	2022
Expected dividend yield	—	—
Risk-free interest rate	3.46% - 3.64%	1.46% - 2.34%
Expected volatility	94% - 95%	90% - 92%
Expected life (years)	5.9 - 6.1	6.0 - .6.1

The weighted average fair value for options granted during the three months ended March 31, 2023 and 2022 was \$4.80 and \$4.37 per share, respectively.

The following table summarizes the assumptions used for estimating the fair value of purchase rights granted to employees under the ESPP under the Black-Scholes option-pricing model:

	Three Months Ended March 31,	
	2023	2022
Expected dividend yield	—	—
Risk-free interest rate	5.20%	0.69%
Expected volatility	64%	80%
Expected life (years)	0.50	0.50

The following table summarizes stock option activity during the three months ended March 31, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value
<b>Outstanding as of December 31, 2022</b>	8,398,262	\$ 4.49		
Granted	1,144,146	6.17		
Exercised	(21,447)	3.68		
Cancelled	(6,120)	2.97		
<b>Outstanding as of March 31, 2023</b>	<u>9,514,841</u>	<u>\$ 4.69</u>	<u>8.5</u>	<u>\$ 22,693</u>
Exercisable as of March 31, 2023	<u>4,366,134</u>	<u>\$ 4.27</u>	<u>7.8</u>	<u>\$ 13,072</u>
Vested and expected to vest as of March 31, 2023	<u>9,112,607</u>	<u>\$ 4.69</u>	<u>8.5</u>	<u>\$ 21,845</u>

The aggregate intrinsic value of stock options in the table above represents the difference between the \$6.91 closing price of our common stock as of March 31, 2023 and the exercise price of outstanding, exercisable, and vested and expected to vest in-the-money stock options.

### Restricted Stock Units

Restricted Stock Units (“RSUs”) represent the right to receive shares of our common stock at the end of a specified time period or upon the achievement of a specific milestone. RSUs can only be settled in shares of our common stock. RSUs generally vest over a four-year period similar to stock options granted to employees.

A summary of unvested RSU awards outstanding as of March 31, 2023 and changes during the three months ended March 31, 2023 is as follows:

	Number of RSUs	Weighted Average Grant-Date Fair Value (per RSU)
Unvested as of December 31, 2022	407,726	\$ 5.57
Granted	1,483,166	6.48
Vested	(89,804)	6.00
Forfeited	(1,617)	6.75
Unvested as of March 31, 2023	<u>1,799,471</u>	<u>\$ 6.30</u>

### 9. Revenue From Contracts With Customers

In August 2018, we entered into a Promotion Agreement with Sandoz under which we have the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection for the treatment of patients with PAH in the United States. We paid Sandoz \$20 million at the inception of the Promotion Agreement in consideration for these rights. In exchange for conducting these commercial activities, we are entitled to receive a share of Net Profits (as defined within the Promotion Agreement) based on specified profit levels. The share of Net Profits received is subject to adjustments from Sandoz for certain items such as distributor chargebacks, rebates, inventory returns, inventory write-offs and other adjustments. We expect to refund certain amounts to Sandoz through a reduction of the cash received from future Net Profits generated under the Promotion Agreement. As of March 31, 2023, a \$0.9 million refund liability is offset against accounts receivable from Sandoz related to expected refund amounts. Approximately 99% of revenue during three months ended March 31, 2023 was generated from the Promotion Agreement.

## 10. Leases

### Operating Leases

We are party to a non-cancelable operating lease for our laboratory and office space in Morrisville, North Carolina. The lease expires on October 31, 2026 with an option to extend for an additional period of five years with appropriate notice. We have not included the optional extension period in the measurement of lease liabilities because it is not reasonably certain that we will exercise the option to extend. The payments under this lease is subject to escalation clauses. Operating lease cost is allocated between research and development and general and administrative expenses based on the usage of the leased facilities. The related right-of-use assets are amortized on a straight-line basis over the lesser of the lease term or the estimated useful life of the asset.

### Finance Leases

We lease specialized laboratory equipment under finance leases. We do not have access to certain inputs used by our lessors to calculate the rate implicit in its finance leases and, as such, use our estimated incremental borrowing rate at the time of lease inception for the discount rate applied to our finance leases. The incremental borrowing rate used on finance leases was 6.5%. Certain finance leases also include options to purchase the leased property. We recognize all such purchase options as part of our right-of-use assets and lease liabilities if we are reasonably certain that such purchase options will be exercised.

### Lease Balances, Costs, and Future Minimum Payments

Leases with an initial term of 12 months or less are not recorded on the balance sheet. As of March 31, 2023, we have not entered into any short-term leases. For lease agreements entered into or reassessed after the adoption of ASC 842 *Leases*, we combine lease and non-lease components, if any. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Our lease cost is reflected in the accompanying condensed statements of operations and comprehensive loss as follows:

	Classification	Three Months Ended March 31,	
		2023	2022
Operating lease cost:			
Fixed lease cost	Research and development	\$ 176	\$ 176
Fixed lease cost	General and administrative	19	19
Finance lease cost:			
Amortization of lease assets	Research and development	30	38
Interest on lease liabilities	Interest expense	5	10
Total Lease Cost		<u>\$ 230</u>	<u>\$ 243</u>

The weighted average remaining lease term and discount rates as of March 31, 2023 were as follows:

Weighted average remaining lease term (years):	
Operating leases	3.6
Finance leases	2.1
Weighted average discount rate:	
Operating leases	10.3 %
Finance leases	6.5 %

The discount rate for leases was estimated based upon market rates of collateralized loan obligations of comparable companies on comparable terms at the time of lease inception.

The future minimum lease payment as of March 31, 2023 were as follows:

Year ending December 31:	Operating Leases	Finance Leases	Total
2023 (nine months remaining)	\$ 964	\$ 86	\$ 1,050
2024	1,317	115	1,432
2025	1,356	64	1,420
2026	1,158	—	1,158
Total minimum lease payments	4,795	265	5,060
Less: interest	(777)	(18)	(795)
Present value of lease liabilities	\$ 4,018	\$ 247	\$ 4,265

## 11. Revenue Interest Financing Payable

On January 9, 2023, we entered into the RIFA with HCR and HealthCare Royalty Management, LLC, pursuant to which and subject to the terms and conditions contained therein, HCR agreed to pay us an aggregate investment amount of up to \$100.0 million (the “Investment Amount”). On January 27, 2023, \$32.5 million of the Investment Amount was funded, \$22.2 million of which was used to satisfy our existing obligations under the A&R SVB LSA (see Note 12).

An additional \$7.5 million of the Investment Amount will be funded fifteen business days after a request made by us to HCR to fund acquisition of rights, whether in the form of an acquisition, license, joint venture or similar transaction, to a clinical stage or commercial stage biopharmaceutical product to diagnose, prevent, or treat pulmonary hypertension, an additional \$35.0 million of the Investment Amount will be funded fifteen business days after the earlier of regulatory approval of YUTREPIA or a favorable determination relating to the asserted patents in the ongoing patent litigation with United Therapeutics, and the remaining \$25.0 million of the Investment Amount will be funded fifteen business days after the mutual agreement of HCR and us to fund such amount (the “Fourth Investment Amount”).

As consideration for the Investment Amount and pursuant to the RIFA, we have agreed to pay HCR a tiered royalty on our annual net revenue after the first commercial sale of YUTREPIA (the “Revenue Interests”). Except as may otherwise be mutually agreed to in connection with the funding of the Fourth Investment Amount, the applicable tiered percentage will range from 3.60% to 10.00% on the first \$250 million on annual net revenue, 1.44% to 4.00% on the next \$250 million in annual net revenue, and 0.36% to 1.00% on all annual net revenue in excess of \$500 million. The specific royalty rate within such ranges will depend upon the total amount advanced by HCR and our achievement of a certain annual net revenue threshold for the calendar year 2025. We will also make certain fixed quarterly payments to HCR, plus an additional amount on a ratable basis to reflect the funding of additional amounts by HCR under the RIFA. We will be required to make additional payments to HCR in the event that the first commercial sale of YUTREPIA does not occur by June 30, 2025 and certain minimum quarterly royalty payments beginning in 2026.

If HCR has not received cumulative payments equaling at least 60% of the amount funded to date by December 31, 2026 or at least 100% of the amount funded to date by December 31, 2028, we will be obligated to make a cash payment to HCR immediately following each applicable date in an amount sufficient to achieve such percentage funded amounts to HCR giving full consideration of the cumulative amounts paid to HCR by us through each date.

HCR’s rights to receive the Revenue Interests will terminate on the date on which HCR has received payments equal to 175% of funded portion of the Investment Amount less the aggregate amount of all payments made to HCR as of such date (the “Hard Cap”), plus an amount, if any, that HCR would need to receive to yield an internal rate of return on the funded Investment Amount equal to 18% (the “IRR True-Up Payment”), unless the RIFA is earlier terminated. If a change of control occurs or upon the occurrence of an event of default, HCR may accelerate payments due under the RIFA up to the Hard Cap, plus the IRR True-Up Payment, plus any other obligations payable under the RIFA.

The RIFA contains customary affirmative and negative covenants and customary events of default and other events that would cause acceleration, including, among other things, the occurrence of certain material adverse events or the material breach of certain representations and warranties and specified covenants, in which event HCR may elect to terminate the RIFA and require us to make payments to HCR equal to the lesser of (a) the Hard Cap, plus any other

obligations payable under the RIFA, or (b) the funded portion of the Investment Amount, minus payments received by HCR in respect of the Revenue Interests, plus the IRR True-Up Payment. If the FDA grants final approval to an inhaled treprostinil product therapeutically equivalent to YUTREPIA and HCR has not received 100% of the amount funded by HCR to date, then we will be required to make payments to HCR equal to 100% of the amount funded by HCR to date, minus payments received by HCR in respect of the Revenue Interests.

The RIFA contains certain restrictions on our ability, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, dispose of assets, pay dividends and distributions, subject to certain exceptions. In addition, the RIFA contains a financial covenant that requires us to maintain cash and cash equivalents in an amount at least equal to \$7.5 million during the calendar year beginning on January 1, 2024 and at least equal to \$15.0 million for the remainder of the payment term after the calendar year ended December 31, 2024.

As of the filing date of these condensed consolidated financial statements, we are not aware of any breach of covenants, occurrence of material adverse event, nor have we received any notice of event of default from HCR.

We recorded the initial funds received from HCR of \$32.5 million under the terms of the RIFA as a liability. The issuance costs, consisting primarily of legal fees, totaled \$0.8 million and were recorded as a deduction of the carrying amount of the liability and will be amortized under the effective interest method over the estimated period the liability will be repaid. We estimated the total amount of future revenue to be generated over the life of the RIFA to determine the non-cash interest expense to record to accrete the liability to the amount ultimately due. For the three months ended March 31, 2023, we estimated an effective annual interest rate of approximately 17%. Over the course of the RIFA, the actual interest rate will be affected by the amount and timing of net revenue recognized and changes in the amount and timing of forecasted net revenue. On a quarterly basis, we will reassess the expected amount and timing of the net revenue, recalculate the amortization and effective interest rate and adjust the accounting prospectively as needed.

The following table presents the changes in the liability related to RIFA during the three months ended March 31, 2023:

	<b>March 31, 2023</b>
Balance as of January 27, 2023 closing	\$ 32,500
Issuance costs	(836)
Non-cash interest expense	938
Amortization of issuance costs	15
Balance as of March 31, 2023	\$ 32,617
Less: current portion of revenue interest financing payable	(2,000)
Long-term portion of revenue interest financing payable	<u>\$ 30,617</u>

## 12. Long-Term Debt

Long-term debt consisted of the following:

	<b>Maturity Date</b>	<b>March 31, 2023</b>	<b>December 31, 2022</b>
A&R Silicon Valley Bank term loan	December 1, 2025	\$ —	\$ 19,879

Concurrent with the closing of the RIFA on January 27, 2023 (see Note 11), we repaid the amounts due under the SVB A&R LSA (as defined below), including termination fees and the Final Payment Fee, in full. This repayment resulted in a loss on extinguishment during the three months ended March 31, 2023 of \$2.3 million.

On January 7, 2022 (the “A&R SVB LSA Effective Date”), we entered into an Amended and Restated Loan and Security Agreement with SVB and SVB Innovation Credit Fund VIII, L.P. (“Innovation”) (the “A&R SVB LSA”), under which \$20.0 million was funded on the A&R SVB LSA Effective Date. \$10.5 million of the proceeds were used to satisfy its existing obligations with SVB and such obligations are considered fully repaid and terminated as of that date.

We accounted for such repayment in accordance with ASC 405-20, *Extinguishments of Liabilities*, which resulted in a loss on extinguishment during the three months ended March 31, 2022 of \$1.0 million.

The A&R SVB LSA was to mature on December 1, 2025, and consisted of interest-only payments equal to the greater of 7.25% and the prime rate of interest plus 4.0% of the outstanding principal amount. The SVB A&R LSA also provided for a “Final Payment Fee” of 5.0% of the aggregate original principal amount of all loans made and a payment solely to SVB of \$185,000 due on the earliest of the maturity date, the repayment of the debt in full, any optional prepayment or mandatory prepayment, or the termination of the A&R SVB LSA.

As an inducement to enter into the A&R SVB LSA, we issued SVB, Innovation, and Innovation Credit Fund VIII-A L.P. (“Innovation Credit”) warrants to purchase an aggregate of 250,000 shares of our common stock at an exercise price of \$5.14 per share. The A&R SVB Warrants provide an option for a cashless exercise.

We evaluated the features of the A&R SVB LSA and A&R SVB Warrants in accordance with ASC 480, *Distinguishing Liabilities from Equity* and ASC 815, *Derivatives and Hedging* and determined that they did not contain any features that would qualify as a derivative or embedded derivative. In addition, we determined that the A&R SVB Warrants should be classified as equity.

In accordance with ASC 470, *Debt*, the value of the A&R SVB Warrants and A&R SVB LSA was allocated using a relative fair value allocation. The fair value of the A&R SVB Warrants was determined to be \$1.3 million and included in additional paid-in-capital, of which \$0.7 million was recognized as a component of the loss on extinguishment and \$0.6 million as a debt discount. The remaining \$19.4 million was allocated to the A&R SVB LSA. In addition, we incurred fees of less than \$0.1 million, which were recorded as debt issuance costs. The debt discount and debt issuance costs were being amortized to interest expense and the Final Payment Fee was being accreted using the effective interest method over the term of the A&R SVB LSA.

The estimated fair value of the SVB Warrant was calculated using the Black-Scholes Option Pricing Model based on the following inputs:

Expected dividend yield	—
Risk-free interest rate	1.76%
Expected volatility	97.2%
Expected life (years)	10.0

### 13. Commitments and Contingencies

#### Mainbridge Health Care Device Development and Supply Agreement

On December 1, 2022, we entered into a Device Development and Supply Agreement (the “Pump Development Agreement”) with Mainbridge Health Partners, LLC (“Mainbridge”) and Sandoz Inc. (“Sandoz”). The Pump Development Agreement provides for the cooperation between us, Sandoz and Mainbridge to develop a new pump that is suitable for the subcutaneous administration of Trepstinil Injection. Mainbridge will perform all development, validation and testing activities required for the pump and related consumables in anticipation of submitting a 510(k) clearance application for the pump to the FDA in 2023. In connection with the Pump Development Agreement, we and Sandoz have agreed to pay Mainbridge certain future contingent milestone payments in accordance with the terms and conditions set forth therein.

#### UNC License Agreement

We perform research under a license agreement with The University of North Carolina at Chapel Hill (“UNC”) as amended to date (the “UNC License Agreement”). As part of the UNC License Agreement, we hold an exclusive license to certain research and development technologies and processes in various stages of patent pursuit, for use in its research and development and commercial activities, with a term until the expiration date of the last to expire patent subject to the

UNC License Agreement, subject to industry standard contractual compliance. Under the UNC License Agreement, we are obligated to pay UNC royalties equal to a low single digit percentage of all net sales of drug products whose manufacture, use or sale includes any use of the technology or patent rights covered by the UNC License Agreement, including YUTREPIA. We may grant sublicenses of UNC licensed intellectual property in return for specified payments based on a percentage of any fee, royalty or other consideration received.

### **Chasm Technologies**

In March 2012, we entered into an agreement, as amended, with Chasm Technologies, Inc. for manufacturing consulting services related to our manufacturing capabilities during the term of the agreement. We agreed to pay future contingent milestones and royalties on net sales totaling no more than \$1.5 million, none of which has been earned as of March 31, 2023.

### **Employment Agreements**

We have agreements with certain employees which require payments if certain events, such as a change in control or termination without cause, occur.

### **Purchase Obligations**

We enter into contracts in the normal course of business with contract service providers to assist in the performance of research and development and manufacturing activities. Subject to required notice periods and obligations under binding purchase orders, we can elect to discontinue the work under these agreements at any time. As of March 31, 2023, we have non-cancelable commitments for product manufacturing costs of approximately \$5.5 million for the year ending 2023.

In addition, we are party to a multi-year supply agreement with LGM Pharma, LLC (LGM) to produce active pharmaceutical ingredients for YUTREPIA. Under the supply agreement with LGM, we are required to provide rolling forecasts, a portion of which will be considered a binding, firm order, subject to an annual minimum purchase commitment of \$2.7 million for the term of the agreement. The agreement expires five years from the first marketing authorization approval of YUTREPIA.

### **Other Contingencies and Commitments**

From time-to-time we are subject to claims and litigation in the normal course of business, none of which do we believe represent a risk of material loss or exposure. See Note 14 for further discussion of pending legal proceedings.

In addition to the commitments described above, we are party to other commitments, including non-cancelable leases and long-term debt, which are described elsewhere in these notes to the consolidated condensed financial statements.

## **14. Legal Proceedings**

### **YUTREPIA-Related Litigation**

In June 2020, United Therapeutics filed a complaint for patent infringement against the Company in the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-RGA) (the “Hatch-Waxman Litigation”), asserting infringement by the Company of U.S. Patent Nos. 9,604,901, entitled “Process to Prepare Treprostinil, the Active Ingredient in Remodulin®” (the “‘901 Patent”), and 9,593,066, entitled “Process to Prepare Treprostinil, the Active Ingredient in Remodulin®” (the “‘066 Patent”), relating to United Therapeutics’ Tyvaso®, a nebulized treprostinil solution for the treatment of PAH. United Therapeutics’ complaint was in response to the Company’s NDA for YUTREPIA, filed with the FDA, requesting approval to market YUTREPIA, a dry powder inhalation of treprostinil for the treatment of PAH. The YUTREPIA NDA was filed under the 505(b)(2) regulatory pathway with Tyvaso® as the reference listed drug.

In July 2020, the U.S. Patent and Trademark Office (the “USPTO”) issued U.S. Patent No. 10,716,793 (the “’793 Patent”), entitled “Treprostinil Administration by Inhalation”, to United Therapeutics. In July 2020, United Therapeutics filed an amended complaint in the Hatch-Waxman Litigation asserting infringement of the ’793 Patent by the practice of YUTREPIA.

In June 2021, the Court held a claim construction hearing. Based on the Court’s construction of the claim terms, United Therapeutics filed a stipulation of partial judgment with respect to the ’901 Patent in December 2021 under which United Therapeutics agreed to the entry of judgment of the Company’s non-infringement of the ’901 Patent. United Therapeutics preserved its appellate rights with respect to the ’901 Patent in the event the Court’s construction of those terms is reversed.

Trial proceedings in the Hatch-Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Hatch-Waxman Litigation, issued an opinion that claims 1, 2, 3, 6 and 9 of the ’066 Patent were invalid, that the remaining asserted claims of the ’066 Patent were not infringed by the Company, and that all of the asserted claims of the ’793 Patent were both valid and infringed by the Company, based on the arguments presented by the Company in the Hatch-Waxman Litigation. In September 2022, Judge Andrews entered a final judgment in the Hatch-Waxman Litigation that incorporated the findings from his opinion and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the ’793 Patent, which will be in 2027. Both the Company and United Therapeutics have appealed Judge Andrews’ decision to the United States Court of Appeals for the Federal Circuit. The appeal remains pending and oral argument was held on May 3, 2023.

In September 2022, following entry of final judgment, the Company filed a motion requesting that Judge Andrews stay enforcement of the order delaying the effective date of any final approval by the FDA of YUTREPIA until the expiration of the ’793 Patent. Briefing on the motion for stay of enforcement is complete, and the motion remains pending with the Court.

In March 2020, the Company filed two petitions for *inter partes* review with the Patent Trial and Appeal Board (the “PTAB”) of the USPTO. One petition was for *inter partes* review of the ’901 Patent and sought a determination that the claims in the ’901 Patent are invalid, and a second petition was for *inter partes* review of the ’066 Patent and sought a determination that the claims in the ’066 Patent are invalid. In October 2020, the PTAB instituted an *inter partes* review of the ’901 Patent and concurrently denied institution on the ’066 Patent, stating that the ’066 petition has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable. In October 2021, the PTAB issued a final written decision concluding that seven of the claims in the ’901 patent were unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of treprostinil sodium. In November 2021, United Therapeutics submitted a rehearing request with respect to the PTAB’s decision in the *inter partes* review of the ’901 Patent. The rehearing request was denied in June 2022. In August 2022, United Therapeutics appealed the decision of the PTAB with respect to the ’901 Patent to the United States Court of Appeals for the Federal Circuit. The appeal remains pending.

In January 2021, the Company filed a petition for *inter partes* review with the PTAB relating to the ’793 Patent, seeking a determination that the claims in the ’793 Patent are invalid. In August 2021, the PTAB instituted an *inter partes* review of the ’793 Patent, finding that the Company had demonstrated a reasonable likelihood that it would prevail with respect to showing that at least one challenged claim of the ’793 patent is unpatentable as obvious over the combination of certain prior art cited by the Company in its petition to the PTAB. In July 2022, the PTAB ruled in the Company’s favor, concluding that based on the preponderance of the evidence, all the claims of the ’793 Patent have been shown to be unpatentable. In August 2022, United Therapeutics submitted a rehearing request with respect to the PTAB’s decision in the *inter partes* review of the ’793 Patent. The rehearing request was denied in February 2023. In April 2023, United Therapeutics appealed the decision of the PTAB with respect to the ’793 Patent to the United States Court of Appeals for the Federal Circuit. The appeal remains pending. The PTAB’s decision with respect to the ’793 Patent will not override Judge Andrews’ order in the Hatch-Waxman Litigation that YUTREPIA may not be approved due to infringement of the ’793 Patent unless and until the decision of the PTAB is affirmed on appeal.

### **Trade Secret Litigation**

In December 2021, United Therapeutics filed a complaint in the Superior Court in Durham County, North Carolina, alleging that the Company and a former United Therapeutics employee, who later joined the Company as an employee many years after terminating his employment with United Therapeutics, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. In January 2022, the Company's co-defendant in the lawsuit removed the lawsuit to the United States District Court for the Middle District of North Carolina. Subsequently, in January 2022, United Therapeutics filed an amended complaint eliminating their claim under the federal Defend Trade Secrets Act and a motion seeking to have the case remanded to North Carolina state court. In April 2022, the Court granted United Therapeutics' motion to have the case remanded to North Carolina state court. In May 2022, the Company filed a motion to dismiss all of the claims made by United Therapeutics in the lawsuit. The motion was denied by the Court in October 2022. Discovery in the case is ongoing.

### **RareGen Litigation**

In April 2019, Sandoz and Liquidia PAH (then known as RareGen) filed a complaint against United Therapeutics and Smiths Medical in the District Court of New Jersey (Case No. No. 3:19-cv-10170), (the "RareGen Litigation"), alleging that United Therapeutics and Smiths Medical violated the Sherman Antitrust Act of 1890, state law antitrust statutes and unfair competition statutes by engaging in anticompetitive acts regarding the drug tadalafil for the treatment of PAH. In March 2020, Sandoz and Liquidia PAH filed a first amended complaint adding a claim that United Therapeutics breached a settlement agreement that was entered into in 2015, in which United Therapeutics agreed to not interfere with Sandoz's efforts to launch its generic tadalafil, by taking calculated steps to restrict and interfere with the launch of Sandoz's competing generic product. United Therapeutics developed tadalafil under the brand name Remodulin® and Smiths Medical manufactured a pump and cartridges that are used to inject tadalafil into patients continuously throughout the day. Sandoz and Liquidia PAH allege that United Therapeutics and Smiths Medical entered into anticompetitive agreements (i) whereby Smiths Medical placed restrictions on the cartridges such that they can only be used with United Therapeutics' branded Remodulin® product and (ii) requiring Smiths Medical to enter into agreements with specialty pharmacies to sell the cartridges only for use with Remodulin®.

In November 2020, Sandoz and Liquidia PAH entered into a binding term sheet (the "Term Sheet") with Smiths Medical in order to resolve the outstanding RareGen Litigation solely with respect to disputes between Smiths Medical, Liquidia PAH and Sandoz. In April 2021, Liquidia PAH and Sandoz entered into a Long Form Settlement Agreement (the "Settlement Agreement") with Smiths Medical to further detail the terms of the settlement among such parties as reflected in the Term Sheet. Pursuant to the Term Sheet and the Settlement Agreement, the former RareGen members and Sandoz received a payment of \$4.25 million that was evenly split between the parties. In addition, pursuant to the Term Sheet and Settlement Agreement, Smiths Medical disclosed and made available to Sandoz and Liquidia PAH certain specifications and other information related to the cartridge that Smiths Medical developed and manufactures for use with the CADD-MS 3 infusion pump (the "CADD-MS 3 Cartridge"). Pursuant to the Settlement Agreement, Smiths Medical also granted Liquidia PAH and Sandoz a non-exclusive, royalty-free license in the United States to Smiths Medical's patents and copyrights associated with the CADD-MS 3 Cartridge and certain other information for use of the CADD-MS 3 pump and the CADD-MS 3 Cartridges. Smiths also agreed in the Settlement Agreement to provide information and assistance in support of Liquidia PAH's efforts to receive FDA clearance for the RG 3ml Medication Cartridge (the "RG Cartridge") and to continue to service certain CADD-MS 3 pumps that are available for use with the Tadalafil Injection through January 1, 2025. Liquidia PAH and Sandoz agreed, among other things, to indemnify Smiths from certain liabilities related to the RG Cartridge.

In September 2021, United Therapeutics filed a motion for summary judgment with respect to all of the claims brought by Sandoz and Liquidia PAH against United Therapeutics. At the same time, Sandoz filed a motion for summary judgment with respect to the breach of contract claim. In March 2022, the Court issued an order granting partial summary judgment to United Therapeutics with respect to the antitrust and unfair competition claims, denying summary judgment to United Therapeutics with respect to the breach of contract claim, and granting partial summary judgment to Sandoz with respect to the breach of contract claim. The RareGen Litigation will now proceed to a trial to determine the amount of damages due from United Therapeutics to Sandoz with respect to the breach of contract claim. The Court has expressed a goal of holding a three-day bench trial to be scheduled for the summer of 2023.

Under the Promotion Agreement, all proceeds from the litigation will be divided evenly between Sandoz and Liquidia PAH. Under the litigation finance agreements that Liquidia PAH has entered into with Henderson and PBM, any net proceeds received by Liquidia PAH with respect to the RareGen Litigation will be divided between Henderson and PBM.

## **Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

*You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes appearing in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the “Risk Factors” section of this Quarterly Report, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.*

### **Objective**

The following Management’s Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our condensed consolidated financial statements and highlight certain other information which, in the opinion of management, will enhance a reader’s understanding of our financial condition, changes in financial condition and results of operations. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the three months ended March 31, 2023 as compared to the three months ended March 31, 2022. Also refer to our Annual Report on Form 10-K for the year ended December 31, 2022, which includes detailed discussions of various items impacting our business, results of operations and financial condition.

### **Overview**

We are a biopharmaceutical company focused on the development, manufacture, and commercialization of products that address unmet patient needs, with current focus directed towards the treatment of pulmonary hypertension (“PH”). We operate through our wholly owned operating subsidiaries, Liquidia Technologies, Inc. (“Liquidia Technologies”) and Liquidia PAH, LLC (“Liquidia PAH”), formerly known as RareGen, LLC (“RareGen”).

We currently generate revenue pursuant to a promotion agreement between Liquidia PAH and Sandoz Inc. (“Sandoz”), dated as of August 1, 2018, as amended (the “Promotion Agreement”), sharing profit derived from the sale of Sandoz’s substitutable generic tadalafil injection (“Tadalafil Injection”) in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Tadalafil Injection. We employ a targeted sales force calling on physicians and hospital pharmacies involved in the treatment of pulmonary arterial hypertension (“PAH”) in the United States, as well as key stakeholders involved in the distribution and reimbursement of Tadalafil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient base to expand from for the launch of YUTREPIA upon final approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH patients.

We conduct research, development and manufacturing of novel products by applying our subject matter expertise in cardiopulmonary disease and our proprietary PRINT® technology, a particle engineering platform, to enable precise production of uniform drug particles designed to improve the safety, efficacy and performance of a wide range of therapies. Through development of our own products and research with third parties, we have experience applying PRINT across multiple routes of administration and drug payloads including inhaled therapies, vaccines, biologics, nucleic acids and ophthalmic implants, among others.

Our lead product candidate is YUTREPIA for the treatment of PAH. YUTREPIA is an inhaled dry powder formulation of tadalafil designed with PRINT to improve the therapeutic profile of tadalafil by enhancing deep lung delivery while using a convenient, low resistance dry-powder inhaler (“DPI”) and by achieving higher dose levels than the labeled doses of current inhaled therapies. The United States Food and Drug Administration (“FDA”) tentatively

approved our New Drug Application (“NDA”) for YUTREPIA for the treatment of PAH in November 2021. The FDA also confirmed that the clinical data in the NDA would support our pursuit of a supplemental NDA to treat patients with pulmonary hypertension and interstitial lung disease (PH-ILD) upon the expiration of regulatory exclusivity in March 2024.

Since our inception, we have incurred significant operating losses. Our net loss was \$11.7 million for the three months ended March 31, 2023 and \$41.0 million and \$34.6 million for the years ended December 31, 2022 and 2021, respectively. As of March 31, 2023, we had an accumulated deficit of \$362.3 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance product candidates through clinical trials, seek regulatory approval and prepare for commercialization of any approved product candidates. In addition, we may incur expenses in connection with the in-license or acquisition of additional product candidates.

## **Recent Events**

### ***Research License Agreement with Glaxo Group Limited***

On March 31, 2023, we entered into a Research License Agreement (the “Research License Agreement”) with Glaxo Group Limited (“GSK”), which superseded the Inhaled Collaboration and Option Agreement that we entered into with GSK on June 15, 2012. Under the terms of the Research License Agreement, GSK received a non-exclusive, non-sublicensable, royalty-free license to use Liquidia’s proprietary PRINT technology for the sole purpose of conducting pre-clinical research and pre-clinical development. Pursuant to the terms of the Research License Agreement, GSK will be required to seek an expanded license before it may use PRINT for clinical or commercial purposes and Liquidia will have the right to apply PRINT to all inhaled formulations other than certain identified GSK proprietary molecules.

## **Components of Consolidated Statements of Operations**

### ***Revenue***

We primarily generate revenue pursuant to the Promotion Agreement, under which we receive a 50% share in the profit derived from the sale of Treprostinil Injection in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection. On May 21, 2021, Liquidia PAH’s manufacturing partner, Chengdu Shifeng Medical Technologies LTD (“Chengdu”) began selling the RG Cartridge, which may be used to supply medications to PAH patients with the CADD-MS 3 pump manufactured by Smiths Medical ASD, Inc. During 2022, we became aware of shortages of critical components of the CADD-MS 3 pump that have caused the number of CADD-MS 3 infusion pumps available for the subcutaneous administration of Treprostinil Injection to be limited. Due to this limitation in the availability of pumps, specialty pharmacies are not currently placing new patients on to subcutaneous Treprostinil Injection therapy in order to preserve the available pumps for those patients already receiving subcutaneous administration of Treprostinil Injection. We are seeking to work with third parties to resolve the component shortage to increase the available supply of CADD-MS 3 pumps and to develop or procure other pumps that can be used to administer Treprostinil Injection in the future. Future revenue may be impacted until new components or alternative pumps are available.

### ***Cost of Revenue***

Cost of revenue consists of (i) the cost of employing a targeted sales force calling on physicians and hospital pharmacies involved in the treatment of PAH, as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection and (ii) a portion of the amortization of the intangible asset associated with the Promotion Agreement. We amortize the intangible asset associated with the Promotion Agreement in a manner consistent with our recognition of the related revenue.

### ***Research and Development Expenses***

Research and development expenses consist of expenses incurred in connection with the development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- manufacturing process development and scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation for personnel in research and development functions;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- laboratory materials and supplies used to support our research activities; and
- allocated expenses for utilities and other facility-related costs.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. In the near term we expect that our research and development expenses to increase as we complete manufacturing activities and explore potential clinical trials. However, levels of research and development spending are highly dependent upon the selection and progression of product candidates. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, or our ability to

manufacture and supply product, we could be required to expend significant additional financial resources and time on the completion of clinical development. Drug commercialization will take several years and millions of dollars in development costs.

**General and Administrative Expenses**

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation. Other general and administrative expenses include facility-related costs, patent filing and prosecution costs and professional fees for marketing, legal, auditing and tax services and insurance costs.

**Other Income (Expense)**

Other income (expense) is comprised of interest income and expense and loss on extinguishment of debt. Interest income consists of interest earned on our cash deposits. Interest expense consists of interest charges on the revenue interest financing payable, finance leases and long-term debt. These charges include monthly recurring interest on such obligations in addition to non-cash charges. Non-cash charges include interest accretion, expensing of debt issuance costs and amortization of discounts on long-term debt to interest expense.

**Results of Operations**

**Three Months Ended March 31, 2023 compared with the Three Months Ended March 31, 2022**

The following table summarizes the results of our operations for the three months ended March 31, 2023 and 2022, together with the changes in those items in dollars and as a percentage (in thousands, except for percentages):

	Three Months Ended March 31,		\$ Change	% Change
	2023	2022		
Revenue	\$ 4,493	\$ 3,492	\$ 1,001	29 %
Costs and expenses:				
Cost of revenue	654	694	(40)	(6)%
Research and development	5,278	4,728	550	12 %
General and administrative	7,793	12,542	(4,749)	(38)%
Total costs and expenses	13,725	17,964	(4,239)	(24)%
Loss from operations	(9,232)	(14,472)	5,240	(36)%
Other income (expense):				
Interest income	922	4	918	22,950 %
Interest expense	(1,124)	(478)	(646)	135 %
Loss on extinguishment of debt	(2,311)	(997)	(1,314)	132 %
Total other expense, net	(2,513)	(1,471)	(1,042)	71 %
Net loss and comprehensive loss	\$ (11,745)	\$ (15,943)	\$ 4,198	(26)%

\* Not meaningful

**Revenue**

Revenue was \$4.5 million for the three months ended March 31, 2023, compared to \$3.5 million for the three months ended March 31, 2022. Revenue related primarily to the Promotion Agreement. The increase of \$1.0 million was primarily due to increased quantities and favorable gross-to-net rebate adjustments.

**Cost of Revenue**

Cost of revenue was \$0.7 million for both the three months ended March 31, 2023 and 2022. Cost of revenue related to the Promotion Agreement as noted above.

### **Research and Development Expenses**

Research and development expenses were \$5.3 million for the three months ended March 31, 2023, compared with \$4.7 million for the three months ended March 31, 2022. The increase of \$0.6 million or 12% was primarily due to a \$0.5 million increase in consulting and personnel expenses in preparation for the potential commercialization of YUTREPIA.

### **General and Administrative Expenses**

General and administrative expenses were \$7.8 million for the three months ended March 31, 2023, compared with \$12.5 million for the three months ended March 31, 2022. The decrease of \$4.7 million or 38% was primarily due to a \$4.0 million decrease in legal fees related to our ongoing YUTREPIA-related litigation and a \$1.8 million decrease in stock-based compensation expense driven by an option modification charge recorded in 2022. These decreases were offset by a \$1.1 million increase in commercial, marketing, and personnel expenses in preparation for the potential commercialization of YUTREPIA.

### **Other Income (Expense)**

Total other expense, net was \$2.5 million for the three months ended March 31, 2023, compared with \$1.5 million for the three months ended March 31, 2022. The three months ended March 31, 2023 included a \$2.3 million loss on extinguishment of debt related to repayment of the A&R SVB LSA in January 2023. The three months ended March 31, 2022 included a \$1.0 million loss on extinguishment of debt related to the refinance of our long-term debt with SVB during January 2022. We also incurred \$0.6 million higher interest expense in the three months ended March 31, 2023 as compared to that incurred in the three months ended March 31, 2022, which was attributable to the higher borrowings under the RIFA as compared to balances outstanding under the A&R SVB LSA.

### **Liquidity and Capital Resources**

We have financed our growth and operations through a combination of funds generated from revenues, the issuance of convertible preferred stock and common stock, bank borrowings, the issuance of convertible notes, and revenue interest financing. Our principal uses of cash have been for working capital requirements and capital expenditures. As of March 31, 2023 and December 31, 2022, we had cash and cash equivalents of \$94.4 million and \$93.3 million, respectively. As of March 31, 2023, we had stockholders' equity of \$81.6 million and an accumulated deficit of \$362.3 million.

In January 2023, we entered into a Revenue Interest Financing Agreement (the "RIFA") with HealthCare Royalty Partners IV, L.P. ("HCR") and HealthCare Royalty Management, LLC. Pursuant to the RIFA and subject to customary closing conditions, HCR has agreed to pay us an aggregate investment amount of up to \$100.0 million (the "Investment Amount"). \$32.5 million of the Investment Amount was funded on January 27, 2023 (the "Initial Investment Amount"), \$22.2 million of which was used to satisfy in full and retire the Company's indebtedness under the A&R SVB LSA with the excess proceeds funded to the Company. See Note 12 to the consolidated condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for information regarding repayment.

In April 2022, we sold 11,274,510 shares of our common stock in an underwritten registered public offering at an offering price of \$5.10 per share (the "Offering"). The Offering closed on April 18, 2022, and we received net proceeds of approximately \$54.5 million from the sale of the shares, after deducting the underwriting discounts and commissions and other offering expenses. We intend to use the net proceeds from this Offering for ongoing commercial development of YUTREPIA, for continued development of YUTREPIA in other clinical trials, for pre-clinical pipeline activities and for general corporate purposes.

### **Future Funding Requirements**

Prior to the potential FDA approval of YUTREPIA and until such time as we can generate significant revenues from its sale, if ever, we anticipate we will incur net losses and negative cash flows. We plan to focus in the near-term on preparations for the potential commercial launch of YUTREPIA, continuing promotion of Treprostinil Injection,

expanding our corporate infrastructure, and continuing to invest in research and development efforts to explore additional product candidates. We may not be able to complete the development and initiate commercialization of these programs if, among other things, our clinical trials are not successful or if the FDA does not approve our product candidates when we expect, or at all.

Our primary uses of capital are, and we expect will continue to be, compensation and related personnel expenses, clinical costs, manufacturing process development costs, external research and development services, laboratory and related supplies, regulatory expenses, legal costs, administrative and overhead costs and repayments under the RIFA. We also expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution as we prepare to potentially receive regulatory approval for YUTREPIA. Our future funding requirements will be heavily determined by the timing of the potential commercialization of YUTREPIA and the resources needed to support development of our product candidates. If the Company is unable to access the contingent Investment Amounts from the RIFA or generate meaningful YUTREPIA product revenue, the Company will require additional capital.

We believe based on our current operating plan, excluding any potential contingent Investment Amounts from the RIFA and future YUTREPIA product revenue, that cash and cash equivalents will be sufficient to fund operations and capital expenditure requirements and allow us to remain in compliance with our minimum cash covenants pursuant to the RIFA for at least twelve months from the issuance date of this Quarterly Report on Form 10-Q. If we are unable to access additional Investment Amounts from the RIFA, there could be substantial doubt about our ability to continue as a going concern as of the date of the issuance of our second quarter 2023 financial statements. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates. If we conclude that we require but are unable to obtain additional funding, we could be required to delay, reduce, or eliminate research and development programs, product portfolio expansion, or future commercialization efforts, which could adversely affect business prospects.

We may raise additional capital through licensing activities, other business arrangements or the sale of equity or convertible debt securities. In such an event, the ownership of our existing shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights associated with holdings of our common stock.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceuticals, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of manufacturing our product candidates and any product we successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

See “Risk Factors” for additional risks associated with our substantial capital requirements.

### **Cash Flows**

The following table summarizes our sources and uses of cash and cash equivalents:

	Three Months Ended	
	March 31,	
	2023	2022
Net cash provided by (used in):		
Operating activities	\$ (8,457)	\$ (9,782)
Investing activities	(364)	—
Financing activities	9,950	10,082
Net increase in cash and cash equivalents	<u>\$ 1,129</u>	<u>\$ 300</u>

### **Operating Activities**

Net cash used in operating activities decreased \$1.3 million to \$8.5 million for the three months ended March 31, 2023 from \$9.8 million for the three months ended March 31, 2022. The decrease was primarily due to \$4.5 million lower net loss adjusted for non-cash items offset by working capital changes of \$3.2 million. The decrease in working capital was primarily driven by the timing of vendor payments.

### **Investing Activities**

Net cash used in investing activities was \$0.4 million for the three months ended March 31, 2023 and primarily related to property, plant and equipment purchases.

### **Financing activities**

Net cash provided by financing activities was \$10.0 million during the three months ended March 31, 2023 compared with \$10.1 million during the three months ended March 31, 2022. During the three months ended March 31, 2023 we received \$31.8 million net proceeds from the revenue interest financing agreement of which \$22.2 million was used to repay the A&R SVB LSA. During the three months ended March 31, 2022, we received \$9.3 million excess proceeds from the refinancing of long-term debt, \$0.6 million from the issuance of common stock under stock incentive plans, and \$0.3 million in litigation financing deployments. Funds received from litigation deployments are paid directly to the attorneys involved in the RareGen Litigation (as described in Item 1, Legal Proceedings), ongoing costs of which are included as operating outflows.

### **Contractual Obligations and Commitments**

#### *Milestone and Royalty Obligations*

Under the UNC License Agreement, the Company is obligated to pay UNC royalties equal to a low single digit percentage of all net sales of drug products whose manufacture, use or sale includes any use of the technology or patent rights covered by the UNC License Agreement, including YUTREPIA.

In March 2012, we entered into an agreement, as amended, with Chasm Technologies, Inc. for manufacturing consulting services related to our manufacturing capabilities during the term of the agreement. We agreed to pay future contingent milestones and royalties, totaling no more than \$1.5 million, none of which has been earned as of March 31, 2023.

On December 1, 2022, we entered into a Device Development and Supply Agreement (the “Pump Development Agreement”) with Mainbridge Health Partners, LLC (“Mainbridge”) and Sandoz Inc. (“Sandoz”). The Pump Development Agreement provides for the cooperation between us, Sandoz and Mainbridge to develop a new pump that is suitable for the subcutaneous administration of Treprostinil Injection. Mainbridge will perform all development, validation and testing activities required for the pump and related consumables in anticipation of submitting a 510(k) clearance application for the pump to the FDA in 2023. In connection with the Pump Development Agreement,

we and Sandoz have agreed to pay Mainbridge certain future contingent milestone payments in accordance with the terms and conditions set forth therein.

#### *Purchase Obligations*

We enter into contracts in the normal course of business with contract service providers to assist in the performance of our research and development and manufacturing activities. Subject to required notice periods and our obligations under binding purchase orders, we can elect to discontinue the work under these agreements at any time. As of March 31, 2023, the Company has non-cancelable commitments for product manufacturing costs of approximately \$5.5 million for the year ending December 31, 2023.

In addition, we have entered into a multi-year supply agreement with LGM Pharma, LLC (“LGM”) to produce active pharmaceutical ingredients for YUTREPIA. Under our supply agreement with LGM, we are required to provide rolling forecasts, a portion of which will be considered a binding, firm order, subject to an annual minimum purchase commitment of \$2.7 million for the term of the agreement. The agreement expires five years from the first marketing authorization approval of YUTREPIA.

#### *Lease Obligations*

We have operating lease obligations including rental amounts due on leases of certain laboratory, manufacturing and office space and equipment under the terms of non-cancelable operating leases. These leases expire at various times through October 2026. Minimum operating lease payments are \$1.0 million in the remaining nine months of 2023, \$1.3 million in 2024, \$1.4 million in 2025, and \$1.2 million in 2026.

#### *Other Obligations and Contingencies*

We from time-to-time are subject to claims and litigation in the normal course of business, none of which we believe represent a risk of material loss or exposure.

We also have employment agreements with certain employees which require the funding of a specific level of payments, if certain events, such as a change in control or termination without cause, occur.

#### **Critical Accounting Estimates**

We prepare our consolidated financial statements in conformity with U.S. GAAP. The preparation of these financial statements requires the use of estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the periods presented. Actual results could differ from those estimates and assumptions.

While we describe our significant accounting policies in Note 2 to the consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we have identified the following critical accounting estimates:

#### ***Research and Development Expenses***

As part of the process of preparing our consolidated financial statements, we are required to estimate our incurred expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses are related to expenses incurred with respect to CROs, CMOs and other vendors in connection with research and development and manufacturing activities. We do not currently capitalize costs associated with the production of YUTREPIA.

We base our expenses related to CROs and CMOs on our estimates of the services received and efforts expended pursuant to quotations and contracts with such vendors that conduct research and development and manufacturing activities on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the applicable research and development or manufacturing expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. There have been no material changes in estimates for the periods presented within this Quarterly Report on Form 10-Q.

#### ***Revenue Interest Financing Agreement***

In January 2023, we recognized a liability related to the RIFA with HCR under ASC 470-10, *Debt* and ASC 835-30 *Interest - Imputation of Interest*. The initial funds received by us from HCR pursuant to the terms of the RIFA were recorded as a liability and will be accreted under the effective interest method upon the estimated amount of future royalty payments to be made pursuant to the RIFA. The issuance costs were recorded as a direct deduction to the carrying amount of the liability and will be amortized under the effective interest method over the estimated period the liability will be repaid. We estimated the total amount of future product revenue to be generated over the life of the RIFA, and a significant increase or decrease in these estimates could materially impact the liability balance and the related interest expense. If the timing or amounts of any estimated future revenue and related payments change, we will prospectively adjust the effective interest and the related amortization of the liability and related issuance costs.

#### **JOBS Act**

As an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Subject to certain conditions, as an emerging growth company, we rely on certain of these exemptions, including without limitation:

- reduced disclosure about our executive compensation arrangements;
- no advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.07 billion or more; (ii) the last day of 2023; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

### **Smaller Reporting Company**

As a “smaller reporting company,” as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, in addition to providing reduced disclosure about our executive compensation arrangements and business developments, among other reduced disclosure requirements available to smaller reporting companies, we present only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

### **Item 4. Controls and Procedures.**

#### **Evaluation of Disclosure Controls and Procedures**

As of March 31, 2023, management, with the participation of the Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2023.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION.**

### **Item 1. Legal Proceedings.**

#### **YUTREPIA-Related Litigation**

In June 2020, United Therapeutics filed a complaint for patent infringement against the Company in the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-RGA) (the “Hatch-Waxman Litigation”), asserting infringement by the Company of U.S. Patent Nos. 9,604,901, entitled “Process to Prepare Treprostinil, the Active Ingredient in Remodulin®” (the “‘901 Patent”), and 9,593,066, entitled “Process to Prepare Treprostinil, the Active Ingredient in Remodulin®” (the “‘066 Patent”), relating to United Therapeutics’ Tyvaso®, a nebulized treprostinil solution for the treatment of PAH. United Therapeutics’ complaint was in response to the Company’s NDA for YUTREPIA, filed with the FDA, requesting approval to market YUTREPIA, a dry powder inhalation of treprostinil for the treatment of PAH. The YUTREPIA NDA was filed under the 505(b)(2) regulatory pathway with Tyvaso® as the reference listed drug.

In July 2020, the U.S. Patent and Trademark Office (the “USPTO”) issued U.S. Patent No. 10,716,793 (the “‘793 Patent”), entitled “Treprostinil Administration by Inhalation”, to United Therapeutics. In July 2020, United Therapeutics filed an amended complaint in the Hatch-Waxman Litigation asserting infringement of the ‘793 Patent by the practice of YUTREPIA.

In June 2021, the Court held a claim construction hearing. Based on the Court's construction of the claim terms, United Therapeutics filed a stipulation of partial judgment with respect to the '901 Patent in December 2021 under which United Therapeutics agreed to the entry of judgment of the Company's non-infringement of the '901 Patent. United Therapeutics preserved its appellate rights with respect to the '901 Patent in the event the Court's construction of those terms is reversed.

Trial proceedings in the Hatch-Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Hatch-Waxman Litigation, issued an opinion that claims 1, 2, 3, 6 and 9 of the '066 Patent were invalid, that the remaining asserted claims of the '066 Patent were not infringed by the Company, and that all of the asserted claims of the '793 Patent were both valid and infringed by the Company, based on the arguments presented by the Company in the Hatch-Waxman Litigation. In September 2022, Judge Andrews entered a final judgment in the Hatch-Waxman Litigation that incorporated the findings from his opinion and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent, which will be in 2027. Both the Company and United Therapeutics have appealed Judge Andrews' decision to the United States Court of Appeals for the Federal Circuit. The appeal remains pending and oral argument was held on May 3, 2023.

In September 2022, following entry of final judgment, the Company filed a motion requesting that Judge Andrews stay enforcement of the order delaying the effective date of any final approval by the FDA of YUTREPIA until the expiration of the '793 Patent. Briefing on the motion for stay of enforcement is complete, and the motion remains pending with the Court.

In March 2020, the Company filed two petitions for *inter partes* review with the Patent Trial and Appeal Board (the "PTAB") of the USPTO. One petition was for *inter partes* review of the '901 Patent, and sought a determination that the claims in the '901 Patent are invalid, and a second petition was for *inter partes* review of the '066 Patent, and sought a determination that the claims in the '066 Patent are invalid. In October 2020, the PTAB instituted an *inter partes* review of the '901 Patent and concurrently denied institution on the '066 Patent, stating that the '066 petition has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable. In October 2021, the PTAB issued a final written decision concluding that seven of the claims in the '901 patent were unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of treprostinil sodium. In November 2021, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '901 Patent. The rehearing request was denied in June 2022. In August 2022, United Therapeutics appealed the decision of the PTAB with respect to the '901 Patent to the United States Court of Appeals for the Federal Circuit. The appeal remains pending.

In January 2021, the Company filed a petition for *inter partes* review with the PTAB relating to the '793 Patent, seeking a determination that the claims in the '793 Patent are invalid. In August 2021, the PTAB instituted an *inter partes* review of the '793 Patent, finding that the Company had demonstrated a reasonable likelihood that it would prevail with respect to showing that at least one challenged claim of the '793 patent is unpatentable as obvious over the combination of certain prior art cited by the Company in its petition to the PTAB. In July 2022, the PTAB ruled in the Company's favor, concluding that based on the preponderance of the evidence, all the claims of the '793 Patent have been shown to be unpatentable. In August 2022, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '793 Patent. The rehearing request was denied in February 2023. In April 2023, United Therapeutics appealed the decision of the PTAB with respect to the '793 Patent to the United States Court of Appeals for the Federal Circuit. The appeal remains pending. The PTAB's decision with respect to the '793 Patent will not override Judge Andrews' order in the Hatch-Waxman Litigation that YUTREPIA may not be approved due to infringement of the '793 Patent unless and until the decision of the PTAB is affirmed on appeal.

### **Trade Secret Litigation**

In December 2021, United Therapeutics filed a complaint in the Superior Court in Durham County, North Carolina, alleging that the Company and a former United Therapeutics employee, who later joined the Company as an employee many years after terminating his employment with United Therapeutics, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. In January 2022, the Company's co-defendant

in the lawsuit removed the lawsuit to the United States District Court for the Middle District of North Carolina. Subsequently, in January 2022, United Therapeutics filed an amended complaint eliminating their claim under the federal Defend Trade Secrets Act and a motion seeking to have the case remanded to North Carolina state court. In April 2022, the Court granted United Therapeutics' motion to have the case remanded to North Carolina state court. In May 2022, the Company filed a motion to dismiss all of the claims made by United Therapeutics in the lawsuit. The motion was denied by the Court in October 2022. Discovery in the case is ongoing.

### **RareGen Litigation**

In April 2019, Sandoz and Liquidia PAH (then known as RareGen) filed a complaint against United Therapeutics and Smiths Medical in the District Court of New Jersey (Case No. No. 3:19-cv-10170), (the "RareGen Litigation"), alleging that United Therapeutics and Smiths Medical violated the Sherman Antitrust Act of 1890, state law antitrust statutes and unfair competition statutes by engaging in anticompetitive acts regarding the drug treprostinil for the treatment of PAH. In March 2020, Sandoz and Liquidia PAH filed a first amended complaint adding a claim that United Therapeutics breached a settlement agreement that was entered into in 2015, in which United Therapeutics agreed to not interfere with Sandoz's efforts to launch its generic treprostinil, by taking calculated steps to restrict and interfere with the launch of Sandoz's competing generic product. United Therapeutics developed treprostinil under the brand name Remodulin® and Smiths Medical manufactured a pump and cartridges that are used to inject treprostinil into patients continuously throughout the day. Sandoz and Liquidia PAH allege that United Therapeutics and Smiths Medical entered into anticompetitive agreements (i) whereby Smiths Medical placed restrictions on the cartridges such that they can only be used with United Therapeutics' branded Remodulin® product and (ii) requiring Smiths Medical to enter into agreements with specialty pharmacies to sell the cartridges only for use with Remodulin®.

In November 2020, Sandoz and Liquidia PAH entered into a binding term sheet (the "Term Sheet") with Smiths Medical in order to resolve the outstanding RareGen Litigation solely with respect to disputes between Smiths Medical, Liquidia PAH and Sandoz. In April 2021, Liquidia PAH and Sandoz entered into a Long Form Settlement Agreement (the "Settlement Agreement") with Smiths Medical to further detail the terms of the settlement among such parties as reflected in the Term Sheet. Pursuant to the Term Sheet and the Settlement Agreement, the former RareGen members and Sandoz received a payment of \$4.25 million that was evenly split between the parties. In addition, pursuant to the Term Sheet and Settlement Agreement, Smiths Medical disclosed and made available to Sandoz and Liquidia PAH certain specifications and other information related to the cartridge that Smiths Medical developed and manufactures for use with the CADD-MS 3 infusion pump (the "CADD-MS 3 Cartridge"). Pursuant to the Settlement Agreement, Smiths Medical also granted Liquidia PAH and Sandoz a non-exclusive, royalty-free license in the United States to Smiths Medical's patents and copyrights associated with the CADD-MS 3 Cartridge and certain other information for use of the CADD-MS 3 pump and the CADD-MS 3 Cartridges. Smiths also agreed in the Settlement Agreement to provide information and assistance in support of Liquidia PAH's efforts to receive FDA clearance for the RG Cartridge and to continue to service certain CADD-MS 3 pumps that are available for use with the Treprostinil Injection through January 1, 2025. Liquidia PAH and Sandoz agreed, among other things, to indemnify Smiths from certain liabilities related to the RG Cartridge.

In September 2021, United Therapeutics filed a motion for summary judgment with respect to all of the claims brought by Sandoz and Liquidia PAH against United Therapeutics. At the same time, Sandoz filed a motion for summary judgment with respect to the breach of contract claim. In March 2022, the Court issued an order granting partial summary judgment to United Therapeutics with respect to the antitrust and unfair competition claims, denying summary judgment to United Therapeutics with respect to the breach of contract claim, and granting partial summary judgment to Sandoz with respect to the breach of contract claim. The RareGen Litigation will now proceed to a trial to determine the amount of damages due from United Therapeutics to Sandoz with respect to the breach of contract claim. The Court has expressed a goal of holding a three-day bench trial to be scheduled for the summer of 2023.

Under the Promotion Agreement, all proceeds from the litigation will be divided evenly between Sandoz and Liquidia PAH. Under the litigation finance agreements that Liquidia PAH has entered into with Henderson and PBM, any net proceeds received by Liquidia PAH with respect to the RareGen Litigation will be divided between Henderson and PBM.

The Company may become subject to additional legal proceedings and claims arising in connection with the normal course of our business. In the opinion of management, except as disclosed herein, there are currently no claims that would have a material adverse effect on our financial position, results of operations or cash flows.

#### **Item 1A. Risk Factors.**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes thereto, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and the information contained under the heading “Cautionary Note Regarding Forward-Looking Statements” before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. We may update these risk factors in our periodic and other filings with the SEC.*

The following is a summary of the principal risk factors described in this section:

- We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. The future viability of our company may depend on our ability to raise additional capital to finance our future operations.
- We have a history of losses and our future profitability remains uncertain.
- We are primarily dependent on the success of our product candidate, YUTREPIA, for which we received tentative approval from the FDA in November 2021, and this product candidate may fail to receive final marketing approval (in a timely manner or at all) or may not be commercialized successfully.
- United Therapeutics has initiated a lawsuit against us in which it has claimed that YUTREPIA is infringing three of its patents and a separate lawsuit against us that we and a former United Therapeutics employee, who later joined us as an employee, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. The judge in the patent lawsuit entered a final judgment finding that one of the three asserted United Therapeutics’ patents is both valid and infringed and ordering that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the infringed patent, which will be in 2027. While the PTAB found that this same patent was unpatentable, the PTAB’s decision with respect to the patent will not override the court’s order unless and until the decision of the PTAB is affirmed on appeal. These lawsuits may result in our company being delayed in its efforts to commercialize YUTREPIA.
- Liquidia PAH does not hold the FDA regulatory approval for Treprostinil Injection, the RG Cartridge or pumps used to administer Treprostinil Injection and is dependent on Sandoz, Chengdu and the pump manufacturers to manufacture and supply Treprostinil Injection, the RG Cartridge and pumps used to administer Treprostinil Injection, respectively, in compliance with FDA requirements, and is more broadly dependent on their FDA and healthcare compliance relative to Treprostinil Injection, the RG Cartridge and the pumps used to administer Treprostinil Injection, respectively.
- Treprostinil Injection is presently administered subcutaneously via Smith Medical’s CADD-MS 3 infusion pump. Smith Medical no longer manufactures the CADD-MS 3 infusion pump and has no obligation to service or maintain CADD-MS 3 infusion pumps after January 1, 2025. Should components of the CADD-MS 3 pump become unavailable, Smith Medical’s ability to service and maintain such pumps may terminate earlier than anticipated. For instance, during 2022 we became aware of a potential shortage of a critical component of the CADD-MS 3 infusion pump that may cause the number of CADD-MS 3 infusion pumps available for the administration of Treprostinil Injection to be depleted prior to January 1, 2025. In the event the specialty pharmacies are unable to access sufficient quantities of operable pumps or in the event we are

unable to identify or develop a new pump prior to the current pumps becoming unavailable, the commercial success of Treprostinil Injection may be adversely affected.

- Sales of Treprostinil Injection are dependent on market acceptance of generic treprostinil for parenteral administration and the medical devices used for administration of Treprostinil Injection, including the Smiths Medical infusion pumps, any future pumps that we develop, and the RG Cartridge, by patients, health care providers and by third-party payors, while interactions with these persons and entities are subject to compliance requirements. The commercial success of Treprostinil Injection may also be impacted by increasing generic competition which may result in declining prices for Treprostinil Injection.
- We expect that we will need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates or indications which may be more profitable than YUTREPIA or for which there may be a greater likelihood of success.
- We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively, including if one or more such products have a superior product profile to YUTREPIA.
- Our financing facility with HCR contains milestones that must be achieved in order to draw down on the facility, and failure to achieve these milestones may result in our having insufficient financing for our existing business plan. Our financing facility with HCR also contains operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in HCR taking possession and disposing of any collateral.
- Our products may not achieve market acceptance.
- Our product candidates are based on our proprietary, novel technology, PRINT, which has not been used to manufacture any products that have been previously approved by the FDA, making it difficult to predict the time and cost of development and of subsequently obtaining final regulatory approval.
- Our business and operations may be adversely affected by the effects of health epidemics, including the continued spread of the COVID-19 global pandemic.
- We may not be able to build a commercial operation, including establishing and maintaining marketing and sales capabilities or entering into agreements with third parties to market and sell our drug products.
- We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of YUTREPIA. In the event of any disruption in these supplies, our ability to develop and commercialize, and the timeline for commercialization of, YUTREPIA may be adversely affected.
- We rely on third parties to conduct our preclinical studies and clinical trials.
- We may become involved in litigation to protect our intellectual property, to enforce our intellectual property rights or to defend against claims of intellectual property infringement by third parties, which could be expensive, time-consuming and may not be successful.
- We depend on skilled labor, and our business and prospects may be adversely affected if we lose the services of our skilled personnel, including those in senior management, or are unable to attract new skilled personnel.
- We expect that the market price of our common stock may be volatile, and you may lose all or part of your investment.
- As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting and any failure to do so may adversely affect investor confidence in us and, as a result, the trading price of our shares.

## **Risks Related to our Financial Position and Need for Additional Capital**

***We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. The future viability of our company may depend on our ability to raise additional capital to finance our future operations.***

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the impact of the COVID-19 pandemic, and the ability to secure additional capital to fund operations. We expect to incur significant expenses and may incur significant operating losses for the foreseeable future as we advance product candidates through clinical trials, seek regulatory approval and pursue commercialization of any approved product candidates. In addition, if we obtain marketing approval for any of our product candidates, we would incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. These efforts require significant amounts of capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if our development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales. The future viability of our company may depend on our ability to raise additional capital to finance our future operations. We may seek additional funding through public or private financings, debt financing or collaboration. Our inability to obtain funding, if and when needed, would have a negative impact on our financial condition and ability to pursue our business strategies.

***We have a history of losses and our future profitability remains uncertain.***

We have incurred net losses of \$11.7 million during the three months ended March 31, 2023 and \$41.0 million and \$34.6 million during the years ended December 31, 2022 and 2021, respectively. We also had negative operating cash flows for each of these periods. As of March 31, 2023, we had an accumulated deficit of \$362.3 million.

Since our incorporation, we have invested heavily in the development of our product candidates and technologies, as well as in recruiting management and scientific personnel. To date, we have not commenced the commercialization of our product candidates and all of our revenue has been derived from up-front fees and milestone payments made to us in connection with licensing and collaboration arrangements we have entered into and the Promotion Agreement, under which we share in the profit derived from the sale of Trepstinil Injection in the United States. These up-front fees and milestone payments have been, and combined with revenue generated from Trepstinil Injection may continue to be, insufficient to match our operating expenses. We expect to continue to devote substantial financial and other resources to the clinical development of our product candidates and, as a result, must generate significant revenue to achieve and maintain profitability or raise additional capital to fund clinical development. We may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow.

***We expect that we may need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates or indications which may be more profitable than YUTREPIA or for which there may be a greater likelihood of success.***

We anticipate that we may need to raise additional funds to meet our future funding requirements for the continued research, development and commercialization of our product candidates and technology. In the event that funds generated from our operations are insufficient to fund our future growth, we may raise additional funds through the issuance of equity or debt securities or by borrowing from banks or other financial institutions. We cannot assure you that we will be able to obtain such additional financing on terms that are acceptable to us, or at all. Global and local economic conditions could negatively affect our ability to raise funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing, even if obtained, may be accompanied by restrictive covenants that may, among others, limit our ability to

pay dividends or require us to seek consent for payment of dividends, or restrict our freedom to operate our business by requiring consent for certain actions.

If we conclude that we require additional financing and fail to obtain it on terms that are favorable to us, we will not be able to implement our growth plans, and we may be required to significantly curtail, delay or discontinue one or more of our research, development or manufacturing programs or the commercialization of any approved product. Furthermore, if we fail to obtain additional financing on terms that are acceptable to us, we may forgo or delay the pursuit of opportunities presented by other potential product candidates or indications that may later prove to have greater commercial potential than the product candidates and indications that we have chosen to pursue.

***Our financing facility with HCR contains milestones that must be achieved in order to draw down on our financing facility and operating and financial covenants that restrict our business and financing activities, and is subject to acceleration in specified circumstances, which may result in HCR taking possession and disposing of any collateral.***

Our financing facility with HCR contains restrictions that limit our flexibility in operating our business. Under the terms of the RIFA, HCR has agreed to pay us an aggregate investment amount of up to \$100.0 million (the “Investment Amount”). Under the terms of the RIFA, \$32.5 million of the Investment Amount was funded at the initial closing, an additional \$7.5 million of the Investment Amount will be funded fifteen business days after a request made by the us to HCR to fund our acquisition of rights, whether in the form of an acquisition, license, joint venture or similar transaction, to a clinical stage or commercial stage biopharmaceutical product to diagnose, prevent, or treat pulmonary hypertension, an additional \$35.0 million of the Investment Amount will be funded fifteen business days after the earlier of regulatory approval of YUTREPIA or a favorable determination relating to the asserted patents in the ongoing patent litigation with United Therapeutics Corporation, and the remaining \$25.0 million of the Investment Amount will be funded fifteen business days after the mutual agreement of HCR and us to fund such amount. In the event we do not achieve the milestones necessary to trigger the second or third tranches of the Investment Amount or in the event we and HCR do not mutually agree to the funding of the fourth tranche of the Investment Amount, we will be unable to draw the full amount of the Investment Amount. In addition, under the terms of the RIFA, we may not, among other actions, without the prior written consent of HCR, (a) pay any dividends or make any other distribution or payment or redeem, retire or purchase any capital stock, except in certain prescribed circumstances, (b) create, incur, assume, or be liable with respect to any indebtedness except certain permitted indebtedness, or make or permit any payment on any indebtedness, except under certain limited circumstances, or (c) make any sale, transfer, out-license, lease or other disposition of any property or any economic interest, other than certain limited exceptions. Additionally, we are required (i) during the period from January 1, 2024 through December 31, 2024, to maintain at all times a minimum cash balance of \$7.5 million, and (ii) during all periods after December 31, 2024, to maintain at all times a minimum cash balance of \$15.0 million. Our obligations under the RIFA are collateralized by all of our assets and property, subject to limited exceptions.

If we breach certain of our covenants in the RIFA and are unable to cure such breach within the prescribed period or are not granted waivers in relation to such breach, it may constitute an event of default under the RIFA, giving HCR the right to require us to repay the then outstanding obligations immediately, and HCR could, among other things, foreclose on the collateral granted to them to collateralize such indebtedness, which includes our intellectual property, if we are unable to pay the outstanding debt immediately.

***Our management has broad discretion in using the net proceeds from our financing facility with HCR and prior equity offerings and may not use them effectively.***

We are using the net proceeds of our financing facility with HCR, our April 2022 public equity offering and prior public and private equity offerings to support the development and commercialization of YUTREPIA, including the potential commercial launch of YUTREPIA in the event of final FDA approval, the commercialization of Treprostinil Injection, the development and servicing of pumps for the administration of Treprostinil Injection, one or more strategic transactions, preclinical pipeline activities, the development and commercialization of any products acquired or developed and for general corporate purposes. Our management has broad discretion in the application of such proceeds and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our equity. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, diminish cash flows available to service our obligations to HCR, cause the value of our

equity to decline and delay the development of our product candidates. Pending their use, we may invest such proceeds in short-term, investment-grade, interest-bearing securities, which may not yield favorable returns.

***Our ability to use our net operating loss carry forwards and certain other tax attributes may be limited.***

Under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), if a corporation undergoes an “ownership change”, generally defined as a greater than 50.0% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. With our April 2022 public equity offering, our 2021 private placement, the closing of the RareGen acquisition in November 2020, our July 2020 public equity offering, our December 2019 private placement, issuances under our prior at-the-market facility, our March 2019 follow-on equity offering and our July 2018 initial public offering, as well as other past transactions, we may have already triggered an “ownership change” limitation. We have not completed a formal study to determine if any “ownership changes” within the meaning of IRC Section 382 have occurred. If “ownership changes” within the meaning of Section 382 of the Code have occurred, and if we earn net taxable income, our ability to use our net operating loss carryforwards and research and development tax credits generated since inception to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

***Recently enacted tax reform legislation in the U.S., changes to existing tax laws, or challenges to our tax positions could adversely affect our business and financial condition.***

In recent years, various tax legislations were signed into law. On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law, making significant changes to the Internal Revenue Code.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted in response to the COVID-19 pandemic. Certain provisions of the CARES Act amend or suspend certain provisions of the Tax Act. For example, the tax relief measures under the CARES Act for businesses include a five-year net operating loss carryback, suspension of annual deduction limitation of 80% of taxable income from net operating losses generated in a tax year beginning after December 31, 2017, changes in the deductibility of interest, acceleration of alternative minimum tax credit refunds, payroll tax relief, and a technical correction to allow accelerated deductions for qualified improvement property. On June 15, 2020, Assembly Bill 85 was passed in California which suspended the use of net operating losses and limited the use of credits for certain corporations. Changes to existing federal and state tax laws could adversely impact our business, results of operations and financial position as the impact of recent tax legislation is uncertain.

In addition, U.S. federal, state and local tax laws are extremely complex and subject to various interpretations. Although we believe that our tax estimates and positions are reasonable, there can be no assurance that our tax positions will not be challenged by relevant tax authorities. If the relevant tax authorities assess additional taxes on us, this could result in adjustments to, or impact the timing or amount of, taxable income, deductions or other tax allocations, which may adversely affect our results of operations and financial position.

***We are a late-stage clinical biopharmaceutical company with no approved products and no historical revenue from the sale of our own products, which may make it difficult for you to evaluate our business, financial condition and prospects.***

We are a late-stage clinical biopharmaceutical company with no history of commercial operations upon which you can evaluate our prospects other than the activities we have undertaken with respect to the Promotion Agreement with Sandoz. Drug product development involves a substantial degree of uncertainty. Our operations to date have been limited to engaging in promotional and nonpromotional activities under the Promotion Agreement with Sandoz, developing our PRINT technology, undertaking preclinical studies and clinical trials for our product candidates and collaborating with pharmaceutical companies, including GSK, to expand the applications for our PRINT technology

through licensing as well as joint product development arrangements. We have not obtained final marketing approval for any of our product candidates and, accordingly, have not demonstrated an ability to generate revenue from our own pharmaceutical products or successfully overcome the risks and uncertainties frequently encountered by companies undertaking drug product development. Consequently, your ability to assess our business, financial condition and prospects may be significantly limited. Further, the net losses that we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Other unanticipated costs may also arise.

***Liquidia PAH does not hold the FDA regulatory approval for Treprostinil Injection and is dependent on Sandoz to manufacture and supply Treprostinil Injection in compliance with FDA requirements, and is more broadly dependent on Sandoz's FDA and healthcare compliance relative to Treprostinil Injection.***

Sandoz holds the FDA approval (the ANDA) for and controls Treprostinil Injection and is responsible among other things for the compliant manufacture, distribution, labeling, and advertising of Treprostinil Injection. Our role is one of a specialized service provider to Sandoz. As a result, we are dependent on Sandoz to manufacture and supply Treprostinil Injection, and dependent on Sandoz for the continued FDA compliance of Treprostinil Injection. We do not have control over Sandoz's compliance with laws and regulations applicable to drug manufacturers and ANDA holders (for example, applicable current good manufacturing practices (GMPs); FDA labeling, promotional labeling, and advertising requirements; pharmacovigilance and adverse event reporting; and other ongoing FDA reporting and submission requirements), nor over its compliance with healthcare compliance and fraud, waste, and abuse laws, or similar regulatory requirements and other laws and regulations, such as those related to environmental health and safety matters. In addition, we have no control over the ability of Sandoz to maintain adequate quality control, quality assurance and qualified personnel, or other personnel with roles related to the regulatory compliance of Treprostinil Injection and its labeling, promotion, and advertising or of Sandoz's activities in relation to government healthcare programs. If the FDA or a comparable foreign regulatory authority finds deficiencies with the manufacture or quality assurance of Treprostinil Injection or identifies safety or efficacy concerns related to Treprostinil Injection, or if Sandoz otherwise is unable to comply with applicable laws, regulations and standards, Sandoz's ability to manufacture, sell and supply Treprostinil Injection could be limited.

Sandoz's ability to consistently manufacture and supply Treprostinil Injection in a timely manner may also be interrupted by production shortages or other supply interruptions, including as a result of the ongoing COVID-19 pandemic. Our share of net profits under the Promotion Agreement is reduced by certain manufacturing costs and other write-offs related to Sandoz's inability to sell Treprostinil Injection, including in the event that Treprostinil Injection expires prior to sale. Currently, Treprostinil Injection expires 24 months after the date of manufacture.

***Sales of Treprostinil Injection are dependent on market acceptance of generic treprostinil for parenteral administration by patients, health care providers and by third-party payors, while interactions with these persons and entities are subject to compliance requirements. The commercial success of Treprostinil Injection may also be impacted by increasing generic competition which may result in declining prices for Treprostinil Injection.***

Our ability to sell Treprostinil Injection is dependent on market acceptance of generic treprostinil for parenteral administration by patients, health care providers and by third-party payors. If Treprostinil Injection does not achieve an adequate level of acceptance, we may not generate sufficient revenue to offset our cost of revenue.

At the same time, arrangements with healthcare providers, physicians, third-party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business or financial arrangements and relationships.

The degree of market acceptance of Treprostinil Injection will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to offer Treprostinil Injection for sale at competitive prices (generic drug prices, after initial generic entry, have been observed to decline with the entrance of additional generic competition);
- the convenience and ease of administration compared to alternative treatments;

- product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning;
- the willingness of the target patient population to try new treatments, including the generic version of a brand, and of physicians to prescribe such treatments;
- our ability to hire and retain sales and marketing personnel and their ability to support Sandoz under the Promotion Agreement;
- the strength of Sandoz's manufacturing and distribution support;
- the requirement by third-party payors to use generic tadalafil for parenteral administration in place of Remodulin;
- the availability of third-party coverage and adequate reimbursement for Tadalafil Injection;
- the prevalence and severity of any side effects;
- any restrictions on the use of Tadalafil Injection together with other medications;
- our and Sandoz's ability to maintain relationships with the specialty pharmacies; and
- the services provided by specialty pharmacies related to use of Tadalafil Injection.

Our business may also be impacted by the need to maintain compliant operations (including oversight and monitoring of personnel and our activities) in relation to interactions with the persons and parties noted above, relative to FDA and healthcare law requirements, and with consideration of government and industry compliance best practices.

***Medical devices, which we do not control, are necessary for the administration of Tadalafil Injection.***

In order for Tadalafil Injection to be administered to patients, patients must use certain other medical equipment, including pumps, cartridges and infusion sets. We do not manufacture or control such medical equipment, which is manufactured by third parties and owned and dispensed by specialty pharmacies, hospitals or other third parties. Our ability to serve patients is dependent upon the ability of specialty pharmacies to maintain sufficient inventory of such medical equipment to provide to patients. If manufacturers cease to manufacture or support medical equipment or if specialty pharmacies are unable to obtain or maintain sufficient inventories of such medical equipment, our sales may be adversely impacted.

We have worked with Chengdu to develop the RG Cartridge, which received FDA 510(k) clearance in March 2021. The ability of patients to administer Tadalafil Injection through subcutaneous injection is dependent on the continued availability of the RG Cartridge. Our ability to sell the Tadalafil Injection for subcutaneous administration is dependent on market acceptance of the RG Cartridge by patients, health care providers and by third-party payors. If the RG Cartridge does not achieve an adequate level of acceptance or if the RG Cartridge experiences any quality problems, recalls or other adverse events, our ability to provide Tadalafil Injection to patients who receive Tadalafil through subcutaneous injection will be limited. The degree of market acceptance of the RG Cartridge will depend on a number of factors, including:

- the efficacy, safety, quality and potential advantages or disadvantages compared to alternative cartridges;
- Chengdu's ability to offer the RG Cartridge for sale at competitive prices;
- the strength of Chengdu's manufacturing and distribution support; and
- Chengdu's ability to maintain regulatory approvals necessary to manufacture and sell the RG Cartridge in the United States.

In addition, to administer Tadalafil Injection through subcutaneous injection, patients currently must use the CADD-MS 3 infusion pump manufactured by Smiths Medical. Smiths Medical no longer manufactures the CADD-MS 3 infusion pump and, under our Settlement Agreement with Smiths Medical, they are no longer obligated to support the CADD-MS 3 infusion pump after January 1, 2025. Moreover, in the event components of the CADD-MS 3 infusion pump become unavailable prior to January 1, 2025, Smiths Medical may be unable to service pumps that require a replacement of such components. For instance, during 2022 we became aware of a shortage of a critical component of the CADD-MS 3 infusion pump that has caused the number of CADD-MS 3 infusion pumps available for the administration of Tadalafil Injection to be limited. Due to this limitation in the availability of pumps, specialty pharmacies are not currently placing new patients on to subcutaneous Tadalafil Injection therapy in order to preserve

the available pumps for those patients already receiving subcutaneous administration of Treprostinil Injection. We are working with Smiths Medical and Sandoz in an effort to resolve this shortage of critical components for the CADD-MS 3. However, if we are unable to identify a solution to this shortage, the number of patients that can receive subcutaneous administration of Treprostinil Injection will continue to be constrained, which would continue to adversely affect sales of Treprostinil Injection. Also, to administer Treprostinil Injection intravenously, patients currently use infusion pumps manufactured by Smiths Medical.

We are seeking to work with third parties to develop or procure other pumps that can be used to administer Treprostinil Injection in the future. For example, we have entered into an agreement with Sandoz and Mainbridge to develop a new pump that can be used to administer Treprostinil Injection in the future. Such pumps will require FDA 510(k) clearance before they can be sold. There is no guarantee that we or our partners will receive FDA 510(k) clearance for any such pumps or, even if they do receive FDA 510(k) clearance for any such pumps, that they will do so in a timely manner. If we are unable to identify, develop and obtain any required FDA clearance for new pumps for the subcutaneous and intravenous administration of Treprostinil Injection prior to the unavailability of the CADD-MS 3, we may no longer be able to serve patients with Treprostinil Injection through the applicable route of administration.

Failure by us or third parties to successfully develop or supply the medical equipment or to obtain or maintain regulatory approval or clearance of such medical equipment could negatively impact the market acceptance of and sales of Treprostinil Injection.

***We maintain our cash at financial institutions, often in balances that exceed federally insured limits.***

Our cash is held in non-interest-bearing and interest-bearing accounts may exceed the Federal Deposit Insurance Corporation (“FDIC”) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. For example, the FDIC took control of Silicon Valley Bank (“SVB”), where we previously held all of our cash and cash equivalents, on March 10, 2023. The Federal Reserve subsequently announced that account holders would be made whole, and we were able to move substantially all of our cash and cash equivalents to another financial institution. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders’ access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash and cash equivalents could have an adverse effect on our ability to pay our operational expenses or make other payments, which could adversely affect our business.

**Risks Related to the Commercialization of our Product Candidates and Generic Treprostinil Injection**

***United Therapeutics has initiated lawsuits against us in which it claims that YUTREPIA is infringing three of its patents and that we have misappropriated United Therapeutics’ trade secrets, which may result in our company being delayed in its efforts to commercialize YUTREPIA.***

We are developing YUTREPIA under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. Accordingly, under the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act, we were required to, in the NDA for YUTREPIA, certify that patents listed in the Orange Book for Tyvaso are invalid, unenforceable or will not be infringed by the manufacture, use or sale of YUTREPIA. Two of these patents are U.S. Patent No. 9,604,901 (the “‘901 Patent”), entitled “Process to Prepare Treprostinil, the Active Ingredient in Remodulin®”, and U.S. Patent No. 9,593,066 (the “‘066 Patent”), entitled “Process to Prepare Treprostinil, the Active Ingredient in Remodulin®”, both of which are owned by United Therapeutics. A notice of the paragraph IV certification was required to be provided to United Therapeutics as the owner of the patents that are the subject of the certification to which the NDA for YUTREPIA refers. In June 2020, United Therapeutics, as the holder of such patents, asserted a patent challenge directed to the ‘901 Patent and the ‘066 Patent by filing a complaint against us in the U.S. District Court for the District of Delaware (Case No. 1:20-cv-00755-RGA) (the “Hatch-Waxman Litigation”).

In July 2020, the U.S. Patent and Trademark Office (the USPTO) issued U.S. Patent No. 10,716,793 (the “‘793 Patent”), entitled “Treprostinil Administration by Inhalation”, to United Therapeutics. In July 2020, United Therapeutics filed an

amended complaint in the Hatch-Waxman Litigation asserting infringement of the '793 Patent by the practice of YUTREPIA.

In June 2021, the Court held a claim construction hearing. Based on the Court's construction of the claim terms, United Therapeutics filed a stipulation of partial judgment with respect to the '901 Patent in December 2021 under which United Therapeutics agreed to the entry of judgment of our non-infringement of the '901 Patent. United Therapeutics did not appeal the Court's construction of the claim terms of the '901 Patent.

Trial proceedings in the Hatch-Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Hatch-Waxman Litigation, issued an opinion that claims 1, 2, 3, 6 and 9 of the '066 Patent were invalid, that the remaining asserted claims of the '066 Patent were not infringed by us, and that all of the asserted claims of the '793 Patent were both valid and infringed by us, based on the arguments we presented in the Hatch-Waxman Litigation. In September 2022, Judge Andrews entered a final judgment in the Hatch-Waxman Litigation that incorporated the findings from his opinion and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent, which will be in 2027. Both we and United Therapeutics have appealed Judge Andrews' decision to the United States Court of Appeals for the Federal Circuit. The appeal remains pending and oral argument was held on May 3, 2023.

In September 2022, following entry of final judgment, we filed a motion requesting that Judge Andrews stay enforcement of the order delaying the effective date of any final approval by the FDA of YUTREPIA until the expiration of the '793 Patent. Briefing on the motion for stay of enforcement is complete, and the motion remains pending with the Court.

In March 2020, we filed two petitions for *inter partes* review with the Patent Trial and Appeal Board (PTAB) of the USPTO. One petition was for *inter partes* review of the '901 Patent, seeking a determination that the claims in the '901 Patent are invalid, and a second petition is for *inter partes* review of the '066 Patent, seeking a determination that the claims in the '066 Patent are invalid. In October 2020, the PTAB instituted an *inter partes* review of the '901 Patent and concurrently denied institution on the '066 Patent, stating that the '066 petition has not established a reasonable likelihood that it would prevail in showing that at least one of the challenged claims is unpatentable. In October 2021, the PTAB issued a final written decision concluding that seven of the claims in the '901 patent were unpatentable, leaving only the narrower dependent claims 6 and 7, both of which require actual storage at ambient temperature of treprostinil sodium. In November 2021, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '901 patent. The rehearing request was denied in June 2022. In August 2022, United Therapeutics appealed the decision of the PTAB with respect to the '901 Patent to the United States Court of Appeals for the Federal Circuit. The appeal remains pending.

In January 2021, we filed a petition with the PTAB for *inter partes* review of the '793 Patent, seeking a determination that the claims in the '793 Patent are invalid. In August 2021, the PTAB instituted an *inter partes* review of the '793 Patent, finding that we had demonstrated a reasonable likelihood that we would prevail with respect to showing that at least one challenged claim of the '793 Patent is unpatentable as obvious over the combination of certain prior art cited by us in our petition to the PTAB. In July 2022, the PTAB ruled in our favor, concluding that based on the preponderance of the evidence, all the claims of the '793 Patent have been shown to be unpatentable. In August 2022, United Therapeutics submitted a rehearing request with respect to the PTAB's decision in the *inter partes* review of the '793 Patent. The rehearing request was denied in February 2023. In April 2023, United Therapeutics appealed the decision of the PTAB with respect to the '793 Patent to the United States Court of Appeals for the Federal Circuit. The appeal remains pending. The PTAB's decision with respect to the '793 Patent will not override Judge Andrews' order in the Hatch-Waxman Litigation that YUTREPIA may not be approved due to infringement of the '793 Patent unless and until the decision of the PTAB is affirmed on appeal.

In December 2021, United Therapeutics filed a complaint in the Superior Court in Durham County, North Carolina, alleging that we and a former United Therapeutics employee, who later joined us as an employee many years after terminating his employment with United Therapeutics, conspired to misappropriate certain trade secrets of United Therapeutics and engaged in unfair or deceptive trade practices. In January 2022, our co-defendant in the lawsuit removed the lawsuit to the United States District Court for the Middle District of North Carolina. Subsequently, in

January 2022, United Therapeutics filed an amended complaint eliminating their claim under the federal Defend Trade Secrets Act and a motion seeking to have the case remanded to North Carolina state court. In April 2022, the Court granted United Therapeutics' motion to have the case remanded to North Carolina state court. In May 2022, we filed a motion to dismiss all of the claims made by United Therapeutics in the trade secret lawsuit. The motion was denied by the Court in October 2022. Discovery in the case is ongoing.

As a result of this litigation and the order by Judge Andrews in the Hatch-Waxman Litigation, we may be subject to significant delay and incur substantial additional costs in litigation before we are able to commercialize YUTREPIA, if at all. If we are unable to either have Judge Andrews' decision with respect to the '793 Patent overturned on appeal or obtain an affirmance of Judge Andrews' decision with respect to the '066 Patent or the PTAB's decision with respect to the '793 Patent upon appeal, we may be unable to commercialize YUTREPIA until the expiration of those patents, which could materially harm our business.

Success in the lawsuits or *inter partes* review proceedings with respect to some patents or some claims in a given patent does not mean that we will be similarly successful upon appeal of those decisions. In addition, success with respect to a given patent or patent claim in one proceeding does not mean we will be similarly successful with respect to that same patent or patent claim in another proceeding.

If, after the appeals process has been completed, we are found to infringe, misappropriate or otherwise violate any United Therapeutics' intellectual property rights, we could be required to obtain a license from United Therapeutics to continue developing and marketing YUTREPIA. However, we may not be able to obtain any required license on commercially reasonable terms or at all. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or to have misappropriated a trade secret of United Therapeutics. In addition, we may be forced to redesign YUTREPIA to avoid infringement.

***We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively.***

We face significant competition from industry players worldwide, including large multi-national pharmaceutical companies, other emerging or smaller pharmaceutical companies, as well as universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as a larger research and development staff and more experience in manufacturing and marketing, than we do. As a result, these companies may obtain marketing approval for their product candidates more quickly than we are able to and/or be more successful in commercializing their products, including generic tadalafil products, than us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large, established companies. We may also face competition as a result of advances in the commercial applicability of new technologies and greater availability of capital for investment in such technologies. Our competitors may also invest heavily in the discovery and development of novel drug products that could make our product candidates less competitive or may file FDA citizen petitions which may delay the approval process for our product candidates. Furthermore, our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, pharmaceutical products that are easier to develop, more effective or less costly than any product candidates that we are currently developing or that we may develop. Our competitors may also succeed in asserting existing patents or developing new patents, including patents that may issue from patent applications that are currently being pursued by United Therapeutics, to which we do not have a license in an attempt to prevent us from marketing our products. These competitors may also compete with us in recruiting and retaining qualified sales personnel.

Any new drug product that competes with a prior approved drug product must demonstrate advantages in safety, efficacy, tolerability or convenience in order to overcome price competition and to be commercially successful. Our products, if and when approved, are expected to face competition from drug products that are already on the market, as well as those in our competitors' development pipelines. We expect that our lead program, YUTREPIA, an inhaled tadalafil therapy for the treatment of PAH, will face competition from the following inhaled tadalafil therapies that are either currently marketed or in clinical development:

- Tyvaso, marketed by United Therapeutics, has been approved for the treatment of PAH in the United States since 2009. Tyvaso is the reference listed drug in our NDA for YUTREPIA. Following patent litigation, United Therapeutics and Watson Pharmaceuticals reached a settlement whereby Watson Pharmaceuticals will be permitted to enter the market with a generic version of Tyvaso beginning on January 1, 2026. In April 2021, United Therapeutics announced that Tyvaso was approved by FDA to include treatment of patients with PH-ILD.
- Ventavis®, marketed by Actelion, a division of Johnson & Johnson, has been approved for the treatment of PAH in the United States since 2004.
- Tyvaso DPI, licensed from MannKind by United Therapeutics, is a dry-powder formulation of treprostinil that was approved for the treatment of PAH and PH-ILD in the United States in May 2022. There is a possibility that the FDA could grant three years of market exclusivity to Tyvaso DPI as an inhaled dry-powder formulation of treprostinil that could delay the final approval of YUTREPIA until said exclusivity expires.
- Treprostinil Palmitil Inhalation Powder (TPIP), is a dry-powder formulation of a treprostinil prodrug being developed by Insmed. Insmed announced the completion of an initial Phase 1 study in February 2021 which demonstrated that TPIP was generally safe and well tolerated, with a pharmacokinetic profile that supports once-daily dosing. Insmed initiated Phase 2 trials studying patients diagnosed with PAH and PH-ILD in May 2021 and December 2022, respectively. If the TPIP clinical program is successful in demonstrating less frequent dosing with similar efficacy and safety to YUTREPIA and Tyvaso DPI, then TPIP has the potential to be viewed as a more attractive option and may take market share rapidly.
- L606 is a nebulized, liposomal formulation of treprostinil for treatment of PAH being developed by Pharmosa Biopharm Inc. (“Pharmosa”). In 2021, Pharmosa initiated a Phase 3 open-label study to evaluate the safety and tolerability of L606 in subjects with PAH that have been stabilized on Tyvaso. The intended product profile seeks to reduce the daily dosing frequency of treprostinil.

In addition to these other inhaled treprostinil therapies, we expect that YUTREPIA will also face competition from other treprostinil-based drugs, including Orenitram, which is administered orally, and Remodulin, which is administered parenterally, both of which are marketed by United Therapeutics. Branded pharmaceutical companies such as United Therapeutics continue to defend their products vigorously through, among other actions, life cycle management, marketing agreements with third-party payors, pharmacy benefits managers and generic manufacturers. These actions add increased competition in the generic pharmaceutical industry, including competition for Treprostinil Injection.

Additionally, even though Sandoz launched the first-to-file fully substitutable generic treprostinil for parenteral administration in March 2019 that is sold primarily through the specialty pharmacies, Teva Pharmaceutical Industries Ltd. launched a generic treprostinil for parenteral administration in October 2019 that is sold primarily through a specialty pharmacy and to hospitals, Par Pharmaceutical, Inc. launched a generic treprostinil for parenteral administration after receiving approval in September 2019 that is sold primarily to hospitals, Dr. Reddy’s Laboratories Inc. launched a generic treprostinil for parenteral administration in April 2023, and Alembic received approval in February 2021 for generic treprostinil for parenteral administration. Such increased competition may result in a smaller than expected commercial opportunity for us.

Generic drug prices may, and often do, decline, sometimes dramatically, especially as additional generic pharmaceutical companies (including low-cost generic producers outside of the United States) receive approvals and enter the market for a given product. The goals established under the Generic Drug User Fee Act, and increased funding of the FDA’s Office of Generic Drugs, have led to more and faster generic approvals, and consequently increased competition for generic products. The FDA has stated that it has established new steps to enhance competition, promote access and lower drug prices and is approving record-breaking numbers of generic applications. The FDA’s changes may benefit our competitors. Our ability to sell Treprostinil Injection and earn revenue is affected by the number of companies selling competitive products, including new market entrants, and the timing of their approvals.

In addition to treprostinil-based therapies, other classes of therapeutic agents for the treatment of PAH include the following:

- ***IP-agonists***, such as selexipag, marketed by Actelion, and ralinepeg, licensed from Arena Pharmaceuticals, Inc. by United Therapeutics, which is currently in clinical development;
- ***Endothelin receptor antagonists***, such as bosentan and macitentan, both marketed by Actelion, and ambrisentan, marketed by Gilead. Generic version of bosentan and ambrisentan are currently available.
- ***PDE-5 inhibitors***, such as tadalafil, marketed by United Therapeutics, and sildenafil, marketed by Pfizer Inc. Generic versions of both tadalafil and sildenafil are currently available.
- ***Soluble guanylate cyclase (sGC) stimulator***, such as riociguat marketed by Bayer.

We are also aware of several other agents in clinical development that are exploring mechanisms of action which, if approved, could impact the standard of care for treating PAH in the United States, including programs from Merck & Co. Inc., Gossamer Bio, Inc., Aerovate Therapeutics, Inc., Aerami Therapeutics Inc., Tenax Therapeutics, Inc. and Sumitovant Biopharma Ltd, among others. For example, Merck & Co's injectable sotatercept is an investigational, potential first-in-class molecule that targets the proliferation of cells in the pulmonary arterial wall and is being reviewed by the FDA for approval in 2023. If approved, it is possible that it may be used prior to prostacyclin therapies, which may have an adverse effect on the market potential for YUTREPIA.

There are a number of competitors seeking marketing approval and/or regulatory exclusivity with respect to products that are or would be competitive to our product candidate. Thus, we face the risk that one of our competitors will be granted marketing approval and/or regulatory exclusivity before we are able to obtain FDA approval for our product candidate. In that case, as stated above, there is the possibility that such a competitor would be able to prevent us from obtaining approval of and marketing our product candidate until the expiration of the competitor's term of FDA regulatory exclusivity, which could be a term of three years for so-called New Clinical Study exclusivity, or could conceivably be for longer periods of time if the competitor is successful in being granted other forms of FDA regulatory exclusivity which might include, for example, Orphan Disease Designation exclusivity (seven years), New Chemical Entity exclusivity (five years), or Pediatric exclusivity (six months beyond other existing exclusivities or patent terms). In addition, if one of our competitors is granted marketing approval before we are able to obtain FDA approval for our product candidate, as was the case with respect to the approval of United Therapeutics' Tyvaso DPI product, such competitors will be able to detail and market their products before we are able to do so, which may place us at a competitive disadvantage in the marketplace.

United Therapeutics has been granted New Clinical Study exclusivity for Tyvaso through March 31, 2024 for the indication of treatment of PH-ILD to improve exercise ability. Until the expiration of this exclusivity, we will be unable to receive FDA approval for YUTREPIA for the indication of treatment of PH-ILD to improve exercise ability. Because United Therapeutics is also the sponsor of the NDA for Tyvaso DPI, the regulatory exclusivity granted to United Therapeutics with respect to Tyvaso did not limit the indications for which the FDA approved Tyvaso DPI. Thus, even if YUTREPIA is approved, Tyvaso DPI will have a broader label than the initial label for YUTREPIA. If YUTREPIA has a narrower label than other competitive products, it may affect our ability to compete with such products.

The ability of competitors to utilize other regulatory incentive programs could also expedite their FDA review and approval timeline, which could result in their products reaching the market before our product candidate, and which could create further potential implications on exclusivity as noted above. For example, when a Priority Review Voucher (PRV) is redeemed in connection with an NDA, the FDA's goal review period would generally be expedited to six months, although this timeframe is not guaranteed.

If we are unable to maintain our competitive position, our business and prospects will be materially and adversely affected.

***Our products may not achieve market acceptance.***

We are currently focused on developing drug products that can be approved under abbreviated regulatory pathways in the United States, such as the 505(b)(2) regulatory pathway, which allows us to rely on existing knowledge of the safety and efficacy of the relevant reference listed drugs to support our applications for approval in the United States. While we believe that it will be less difficult for us to convince physicians, patients and other members of the medical community to accept and use our drug products as compared to entirely new drugs, our drug products may nonetheless fail to gain sufficient market acceptance by physicians, patients, other healthcare providers and third-party payors. If any of our drug products fail to achieve sufficient market acceptance, we may not be able to generate sufficient revenue to become profitable. The degree of market acceptance of our drug products, if and when they are approved for commercial sale, will depend on a number of factors, including but not limited to:

- the timing of our receipt of marketing approvals, the terms of such approvals and the countries in which such approvals are obtained;
- the safety, efficacy, reliability and ease of administration of our drug products;
- the prevalence and severity of undesirable side effects and adverse events;
- the extent of the limitations or warnings required by the FDA or comparable regulatory authorities in other countries to be contained in the labeling of our drug products;
- the clinical indications for which our drug products are approved;
- the availability and perceived advantages of alternative therapies;
- any publicity related to our drug products or those of our competitors;
- the quality and price of competing drug products;
- our ability to obtain third-party payor coverage and sufficient reimbursement;
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage; and
- the selling efforts and commitment of our commercialization collaborators.

If our drug products, if and when approved, fail to receive a sufficient level of market acceptance, our ability to generate revenue from sales of our drug products will be limited, and our business and results of operations may be materially and adversely affected.

***We may not be able to build a commercial operation, including establishing and maintaining marketing and sales capabilities or entering into agreements with third parties to market and sell our drug products.***

In order to market and sell any of our drug products, if and when approved, we will be required to build our marketing and sales capabilities with respect to such products. With the acquisition of Liquidia PAH, we acquired a sales force to market generic tadalafil in accordance with the Promotion Agreement. We cannot assure you that we will be successful in further building our marketing and sales capabilities or be able to do so in a cost-effective manner. In addition, we may enter into collaboration arrangements with third parties to market our drug products. We may face significant competition for collaborators. In addition, collaboration arrangements may be time-consuming to negotiate and document. We cannot assure you that we will be able to negotiate collaborations for the marketing and sales of our drug products on acceptable terms, or at all. Even if we do enter into such collaborations, we cannot assure you that our collaborators will be successful in commercializing our products. If we or our collaborators are unable to successfully commercialize our drug products, whether in the United States or elsewhere, our business and results of operations may be materially and adversely affected.

As we seek to establish a commercial operation with respect to YUTREPIA in anticipation of potential approval from the FDA, we also continue to evaluate additional drug candidates. There can be no assurance that we will be able to successfully manage the balance of our research and development operations with our commercial activities. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by companies balancing development of product candidates, which can include problems such as unanticipated issues relating to clinical trials and receipt of approvals from the FDA and foreign regulatory bodies, with commercialization efforts, which include problems relating to managing manufacturing and supply, reimbursement, marketing problems, and other additional costs.

There are risks involved with building and expanding our sales, marketing, and other commercialization capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any drug launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may impact our efforts to commercialize our drug candidates on our own and generate product revenues include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel over a large geographic area;
- the costs and time associated with the initial and ongoing training of sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- understanding and training relevant personnel on the limitations on, and the transparency and reporting requirements applicable to, remuneration provided to actual and potential referral sources;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- the inability of sales personnel to obtain access to physicians or to effectively promote any future drugs;
- our ability to appropriately market, detail and distribute products in light of healthcare provider facility closures, quarantine, travel restrictions and other governmental restrictions caused by COVID-19;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- any distribution and use restrictions imposed by the FDA or to which we agree;
- liability for sales and marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- our ability to maintain a healthcare compliance program including effective mechanisms for compliance monitoring; and
- unforeseen costs and expenses associated with creating a sales and marketing organization.

In the future, we may choose to participate in sales activities with collaborators for some of our drug candidates. However, there are also risks with entering into these types of arrangements with third parties to perform sales, marketing and distribution services. For example, we may not be able to enter into such arrangements on terms that are favorable to us. Our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any drug candidates that we develop ourselves. In addition, we likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drug candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

***We may be exposed to claims and may not be able to obtain or maintain adequate product liability insurance.***

Our business is exposed to the risk of product liability and other liability risks that are inherent in the development, manufacture, clinical testing and marketing of pharmaceutical products. These risks exist even if a product is approved for commercial sale by the FDA or comparable regulatory authorities in other countries and manufactured in licensed facilities. Our current product candidate, YUTREPIA, and Treprostinil Injection are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products could result in injury to a patient or even death.

Claims that are successfully brought against us could have a material and adverse effect on our financial condition and results of operations. Further, even if we are successful in defending claims brought against us, our reputation could suffer. Regardless of merit or eventual outcome, product liability claims may also result in, among others:

- a decreased demand for our products;
- a withdrawal or recall of our products from the market;
- a withdrawal of participants from our ongoing clinical trials;
- the distraction of our management's attention from our core business activities to defend such claims;
- additional costs to us; and
- a loss of revenue.

Our insurance may not provide adequate coverage against our potential liabilities. Furthermore, we, our collaborators or our licensees may not be able to obtain or maintain insurance on acceptable terms, or at all. In addition, our collaborators or licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient assets to satisfy any product liability claims. To the extent that they are uninsured or uninsurable, claims or losses that may be suffered by us, our collaborators or our licensees may have a material and adverse effect on our financial condition and results of operations.

### **Risks Related to the Development and Regulatory Approval of our Product Candidates**

*We are primarily dependent on the success of our product candidate, YUTREPIA, for which we received tentative approval from the FDA in November 2021, and this product candidate may fail to receive final marketing approval (in a timely manner or at all) or may not be commercialized successfully.*

We do not have any products approved for marketing in any jurisdiction and we have never generated any revenue from sales of our own products. Our ability to generate revenue from sales of our own products and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of our product candidates. We expect that a substantial portion of our efforts and expenditure over the next few years will be devoted to our product candidate, YUTREPIA, a proprietary inhaled dry powder formulation of treprostinil for the treatment of pulmonary arterial hypertension (PAH).

We received tentative approval of our NDA for YUTREPIA in November 2021. However, our receipt of tentative approval does not mean that we will receive final approval of our NDA for YUTREPIA in a timely manner or at all. Expectations related to final FDA approval and projected product launch timelines are impacted by ongoing Hatch-Waxman Litigation following a lawsuit filed by United Therapeutics in June 2020. As a result of Judge Andrews' order in the Hatch-Waxman Litigation, the FDA may not issue a final approval for the YUTREPIA NDA until 2027 unless either Judge Andrews' decision with respect to the '793 Patent is reversed on appeal or the PTAB's decision with respect to the '793 Patent is affirmed on appeal. In addition, a drug product that is granted tentative approval, like YUTREPIA, may be subject to additional review before final approval, particularly if tentative approval was granted more than three years before the earliest lawful approval date. The FDA's tentative approval of YUTREPIA was based on information available to FDA at the time of the tentative approval letter (i.e., information in the application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to FDA's attention. A new drug product may not be marketed until the date of final approval.

Expectations for YUTREPIA also may be impacted by competing products, including Tyvaso® DPI. *See Item 1A. Risk Factors - We face significant competition from large pharmaceutical companies, among others, in developing our products and in gaining regulatory approval to bring them to market in time to achieve commercial success, and our operating results will suffer if we are unable to compete effectively.*

We cannot assure you that we will receive final marketing approval for YUTREPIA. The FDA or comparable regulatory authorities in other countries may delay, limit or deny final approval of our product candidate for various reasons. For example, such authorities may disagree with the design, scope or implementation of our clinical trials, or with our

interpretation of data from our preclinical studies or clinical trials. Further, there are numerous FDA personnel assigned to review different aspects of an NDA, and uncertainties can be presented by their ability to exercise judgment and discretion during the review process. During the course of review prior to final approval, the FDA may request or require additional preclinical, clinical, chemistry, manufacturing, and control (CMC) or other data and information, and the development and information may be time-consuming and expensive. Status as a combination product, as is the case for YUTREPIA, may complicate or delay the FDA review process. Product candidates that the FDA deems to be combination products, such as YUTREPIA, or that otherwise rely on innovative drug delivery systems, may face additional challenges, risks and delays in the product development and regulatory approval process. Additionally, the FDA could delay approval of YUTREPIA even if approvable after completing its review. For example, if a competing product comprised of an inhaled dry-powder formulation of treprostinil, such as Tyvaso DPI, is granted three years of market exclusivity, that could delay the final approval of YUTREPIA until said exclusivity expires. Moreover, the applicable requirements for approval may differ from country to country.

If we successfully obtain marketing approval for YUTREPIA, we cannot assure you that it will be commercialized in a timely manner or successfully, or at all. For example, YUTREPIA may not achieve a sufficient level of market acceptance, or we may not be able to effectively build our marketing and sales capabilities or scale our manufacturing operations to meet commercial demand. The successful commercialization of YUTREPIA will also, in part, depend on factors that are beyond our control. Therefore, we may not generate significant revenue from the sale of such product, even if approved. Any delay or setback we face in the commercialization of YUTREPIA may have a material and adverse effect on our business and prospects, which will adversely affect your investment in our company.

***Our preclinical studies and clinical trials may not be successful and delays in such preclinical studies or clinical trials may cause our costs to increase and significantly impair our ability to commercialize our product candidates. Results of previous clinical trials or interim results of ongoing clinical trials may not be predictive of future results.***

Before we are able to commercialize our drug products, we are required to undertake extensive preclinical studies and clinical trials to demonstrate that our drug products are safe and effective for their intended uses. However, we cannot assure you that our drug products will, in preclinical studies and clinical trials, demonstrate safety and efficacy as necessary to obtain marketing approval. Due to the nature of drug product development, many product candidates, especially those in early stages of development, may be terminated during development. Although we believe we have completed clinical development for YUTREPIA, we have not yet obtained final approval for or commercialized any of our own product candidates and as a result do not have a track record of successfully bringing our own product candidates to market. Furthermore, YUTREPIA has, to date, been tested only in relatively small study populations and, accordingly, the results from our earlier clinical trials may be less reliable than results achieved in larger clinical trials, if required. Additionally, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary and interim results of a clinical trial do not necessarily predict final results.

Preclinical studies and clinical trials may fail due to factors such as flaws in trial design, dose selection and patient enrollment criteria. The results of preclinical studies and early clinical trials may not be indicative of the results of subsequent clinical trials. Product candidates may, in later stages of clinical testing, fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and earlier clinical trials. Moreover, there may be significant variability in safety or efficacy results between different trials of the same product candidate due to factors including, but not limited to, changes in trial protocols, differences in the composition of the patient population, adherence to the dosing regimen and other trial protocols and amendments to protocols and the rate of drop-out among patients in a clinical trial. If our preclinical studies or clinical trials are not successful and we are unable to bring our product candidates to market as a result, our business and prospects may be materially and adversely affected.

Furthermore, conducting preclinical studies and clinical trials is a costly and time-consuming process. The length of time required to conduct the required studies and trials may vary substantially according to the type, complexity, novelty and intended use of the product candidate. A single clinical trial may take up to several years to complete. Moreover, our preclinical studies and clinical trials may be delayed or halted due to various factors, including, among others:

- delays in raising the funding necessary to initiate or continue a clinical trial;
- delays in manufacturing sufficient quantities of product candidates for clinical trials;

- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- delays in obtaining institutional review board approval at clinical trial sites;
- delays in recruiting suitable patients to participate in a clinical trial;
- delays in patients' completion of clinical trials or their post-treatment follow-up;
- regulatory authorities' interpretation of our preclinical and clinical data; and
- unforeseen safety issues, including a high and unacceptable severity, or prevalence, of undesirable side effects or adverse events caused by our product candidates or similar drug products or product candidates.

If our preclinical studies or clinical trials are delayed, the commercialization of our product candidates will be delayed and, as a result, we may incur substantial additional costs or not be able to recoup our investment in the development of our product candidates, which would have a material and adverse effect on our business.

***Clinical trials and data analysis can be expensive, time-consuming and difficult to design and implement. If we are unsuccessful in obtaining regulatory approval for our products, or any required clinical studies of our products do not provide positive results, we may be required to delay or abandon development of such products, which would have a material adverse impact on our business.***

Continuing product development requires additional and extensive clinical testing. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We cannot provide any assurance or certainty regarding when we might receive regulatory approval for our products, including YUTREPIA. Furthermore, failure can occur at any stage of the process, and we could encounter problems that cause us to abandon an NDA filed with the FDA or repeat clinical trials. The commencement and completion of clinical trials for any current or future development product candidate may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols or amendments to our protocols.

In addition, the FDA or an independent institutional review board (IRB) may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. Although clinical data is an essential part of NDA filings, NDAs must also contain a range of additional data including CMC data to meet FDA standards for approval. In the event we do not ultimately receive final regulatory approval for YUTREPIA, we may be required to terminate development of our only product candidate.

***The marketing approval processes of the FDA and comparable regulatory authorities in other countries are unpredictable and our product candidates may be subject to multiple rounds of review or may not receive marketing approval.***

Pursuing marketing approval for a pharmaceutical product candidate (for example, through the NDA process) is an extensive, lengthy, expensive and inherently uncertain process. We cannot assure you that any of our product candidates

will receive marketing approval. Regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including, but not limited to, the following:

- the FDA or comparable regulatory authorities may, for a variety of reasons, take the view that the data collected from our preclinical and clinical trials and human factors testing, or data that we otherwise submit or reference to support an application, are not sufficient to support approval of a product candidate;
- the FDA or comparable regulatory authorities in other countries may ultimately conclude that our manufacturing processes or facilities or those of our third-party manufacturers do not sufficiently demonstrate compliance with cGMP to support approval of a product candidate, or that the drug CMC data or device biocompatibility data for our product candidates otherwise do not support approval;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable regulatory authorities in other countries that our product candidate is safe and effective for its proposed indication, or that its clinical and other benefits outweigh its safety risks;
- the approval policies of the FDA or comparable regulatory authorities in other countries may change in a manner that renders our data insufficient for approval.

Even if we obtain marketing approval, the FDA or comparable regulatory authorities in other countries may approve our product candidates for fewer or more limited indications than those for which we requested approval or may include safety warnings or other restrictions that may negatively impact the commercial viability of our product candidates. Likewise, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or other studies or the conduct of an expensive REMS, which could significantly reduce the potential for commercial success or viability of our product candidates. We also may not be able to find acceptable collaborators to manufacture our drug products, if and when approved, in commercial quantities and at acceptable prices, or at all.

***We may encounter difficulties in enrolling patients in our clinical trials.***

We may not be able to commence or complete clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials.

Patient enrollment may be affected by, among others:

- the severity of the disease under investigation;
- the design of the clinical trial protocol and amendments to a protocol;
- the size and nature of the patient population;
- eligibility criteria for the clinical trial in question;
- the perceived risks and benefits of the product candidate under clinical testing, including a high and unacceptable severity, or prevalence, of undesirable side effects or adverse events caused by our product candidates or similar products or product candidates;
- the existing body of safety and efficacy data in respect of the product candidate under clinical testing;
- the proximity of patients to clinical trial sites;
- the number and nature of competing therapies and clinical trials; and
- other environmental factors such as the ongoing COVID-19 pandemic or other natural or unforeseen disasters.

Any negative results we may report in clinical trials of our product candidates may also make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate.

We expect that if we initiate, as we are currently contemplating, a clinical trial of YUTREPIA in pediatric patients, we may encounter difficulties enrolling patients in such a trial because of the limited number of pediatric patients with this disease. Furthermore, we are aware of a number of therapies for PAH that are being developed or that are already

available on the market, and we expect to face competition from these investigational drugs or approved drugs for potential subjects in our clinical trials, which may delay enrollment in our planned clinical trials.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays, or both. We may, as a result of such delays or failures, be unable to carry out our clinical trials as planned or within the timeframe that we expect or at all, and our business and prospects may be materially and adversely affected as a result.

***Product candidates that the FDA deems to be combination products, such as YUTREPIA, or that otherwise rely on innovative drug delivery systems, may face additional challenges, risks and delays in the product development and regulatory approval process.***

The FDA has indicated that it considers YUTREPIA, which is delivered by a DPI, to be a drug-device combination product. Accordingly, the DPI was evaluated as part of our NDA filing. When evaluating products that utilize a specific drug delivery system or device, the FDA will evaluate the characteristics of that delivery system and its functionality, as well as the potential for undesirable interactions between the drug and the delivery system, including the potential to negatively impact the safety or effectiveness of the drug. The FDA review process can be more complicated for combination products, and may result in delays, particularly if novel delivery systems are involved. We rely on third parties for the design and manufacture of the delivery systems for our products, including the DPI for YUTREPIA, and in some cases for the right to refer to their data on file with the FDA or other regulators. Quality or design concerns with the delivery system, or commercial disputes with these third parties, could delay or prevent regulatory approval and commercialization of our product candidates.

***We are pursuing the FDA 505(b)(2) pathway for our current product candidates. If we are unable to rely on the 505(b)(2) regulatory pathway to apply for marketing approval of our product candidates in the United States, seeking approval of these product candidates through the 505(b)(1) NDA pathway would require full reports of investigations of safety and effectiveness, and the process of obtaining marketing approval for our product candidates would likely be significantly longer and more costly.***

We are currently focused on developing drug products that can be approved under abbreviated regulatory pathways in the United States, such as the 505(b)(2) regulatory pathway, which permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us for a particular product candidate, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for a product candidate by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. We have pursued this pathway for our current product candidate, YUTREPIA. Even if the FDA allows us to rely on the 505(b)(2) regulatory pathway for a given product candidate, we cannot assure you that marketing approval will be obtained in a timely manner, or at all.

The FDA may require us to perform additional clinical trials to support any change from the reference listed drug, which could be time-consuming and substantially delay our receipt of marketing approval. Also, as has been the experience of others in our industry, our competitors may file citizens' petitions with the FDA to contest approval of our NDA, which may delay or even prevent the FDA from approving any NDA that we submit under the 505(b)(2) regulatory pathway. If an FDA decision or action relative to our product candidate, or the FDA's interpretation of Section 505(b)(2) more generally, is successfully challenged, it could result in delays or even prevent the FDA from approving a 505(b)(2) application for our product candidates. Even if we are able to utilize the 505(b)(2) regulatory pathway, a drug approved via this pathway may be subject to the same post-approval limitations, conditions and requirements as any other drug.

In addition, we may face Hatch-Waxman litigation in relation to our NDAs submitted under the 505(b)(2) regulatory pathway, which may further delay or prevent the approval of our product candidates. The pharmaceutical industry is highly competitive, and 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a 505(b)(2) NDA. If the previously approved drugs referenced in an applicant's 505(b)(2) NDA are protected by patent(s) listed in the Orange Book, the 505(b)(2) applicant is required to make a claim after filing its NDA that each such patent is invalid, unenforceable or will not be infringed.

The patent holder may thereafter bring suit for patent infringement, which will trigger a mandatory 30-month delay (or the shorter of dismissal of the lawsuit or expiration of the patent(s)) in approval of the 505(b)(2) NDA application. In addition, in the event the court in any such lawsuit finds that any claims of any of the asserted patents are both valid and infringed, the court would likely issue an injunction prohibiting approval of the product at issue until the expiration of the patent(s) found to have been infringed. For example, the YUTREPIA NDA was filed under the 505(b)(2) regulatory pathway with Tyvaso as the reference listed drug. Under the Hatch-Waxman Act, as a result of the litigation commenced by United Therapeutics in June 2020, the FDA was automatically precluded from approving the YUTREPIA NDA for up to 30 months. In August 2022, prior to the expiration of the 30-month stay, the Court found that the asserted claims of one of the patents, the '793 Patent, were both valid and infringed by the Company and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent. As a result of the Court's order, the FDA may not issue a final approval for the YUTREPIA NDA until the expiration of the '793 Patent unless either the Court's decision with respect to the '793 Patent is reversed on appeal or the PTAB's decision, invalidating the '793 Patent, is affirmed on appeal.

It is also not uncommon for a manufacturer of an approved product, such as United Therapeutics, to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

If the FDA determines that any of our product candidates do not qualify for the 505(b)(2) regulatory pathway, we would need to reconsider our plans and might not be able to commercialize our product candidates in a cost-efficient manner, or at all. If we were to pursue approval under the 505(b)(1) NDA pathway, we would be subject to more extensive requirements and risks such as conducting additional clinical trials, providing additional data and information or meeting additional standards for marketing approval. As a result, the time and financial resources required to obtain marketing approval for our product candidates would likely increase substantially and further complications and risks associated with our product candidates may arise. Also, new competing products may reach the market faster than ours, which may materially and adversely affect our competitive position, business and prospects.

***We may be unable to continually develop a pipeline of product candidates, which could affect our business and prospects.***

A key element of our long-term strategy is to continually develop a pipeline of product candidates by developing proprietary innovations to FDA-approved drug products using our PRINT technology. If we are unable to identify off-patent drug products for which we can develop proprietary innovations using our PRINT technology or otherwise expand our product candidate pipeline, whether through licensed or co-development opportunities, and obtain marketing approval for such product candidates within the timeframes that we anticipate, or at all, our business and prospects may be materially and adversely affected.

***We have conducted, and may in the future conduct, clinical trials for our product candidates outside the United States and the FDA may not accept data from such trials.***

Although the FDA may accept data from clinical trials conducted outside the United States in support of safety and efficacy claims for our product candidates, if not conducted under an IND, this is subject to certain conditions set out in 21 C.F.R. § 312.120. For example, in order for the FDA to accept data from such a foreign clinical trial, the study must have been conducted in accordance with Good Clinical Practice (GCP) including review and approval by an independent ethics committee and obtaining the informed consent from subjects of the clinical trials. The FDA must also be able to validate the data from the study through an onsite inspection if the agency deems it necessary. In addition, foreign clinical data submitted to support FDA applications should be applicable to the U.S. population and U.S. medical practice. Other factors that may affect the acceptance of foreign clinical data include differences in clinical conditions, study populations or regulatory requirements between the United States and the foreign country.

## **Risks Related to Our Dependence on Third Parties**

***We depend on third parties for clinical and commercial supplies, including single suppliers for the active ingredient, the device, encapsulation and packaging of YUTREPIA.***

We depend on third-party suppliers for clinical and commercial supplies for the supply of materials and components necessary for clinical and commercial production of YUTREPIA, including the active pharmaceutical ingredients which are used in our product candidates. These supplies may not always be available to us at the standards we require or on terms acceptable to us, or at all, and we may not be able to locate alternative suppliers in a timely manner, or at all. If we are unable to obtain necessary clinical or commercial supplies, our manufacturing operations and clinical trials and the clinical trials of our collaborators may be delayed or disrupted and our business and prospects may be materially and adversely affected as a result.

For example, we currently rely on a sole supplier for treprostinil, the active pharmaceutical ingredient of YUTREPIA, which sources treprostinil from a manufacturer in South Korea, with whom we have a long-term supply agreement. If our supplier is unable to supply treprostinil to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, or if it ceases its relationship with us, we may not be able to obtain alternative supplies of treprostinil from other suppliers on acceptable terms, in a timely manner, or at all. We also rely on a sole supplier for encapsulation and packaging services, with whom we have a long-term contract. Furthermore, YUTREPIA is administered using the RS00 Model 8 DPI, which is manufactured by Plastiape, which is located in Italy. We purchase our RS00 Model 8 DPI supply pursuant to purchase orders and do not have a long-term contract with Plastiape. In the event of any prolonged disruption to our supply of treprostinil, the encapsulation and packaging services, or the manufacture and supply of RS00 Model 8 DPI, our ability to develop and commercialize, and the timeline for commercialization of, YUTREPIA may be adversely affected.

We also rely upon Chengdu for the manufacture and supply of RG Cartridges for the subcutaneous administration of Treprostinil Injection and upon Smiths Medical for ongoing servicing and support of the CADD-MS 3, CADD Legacy and CADD-Solis infusion pumps. In the event of any disruption to our supply of RG Cartridges or any disruption in the availability of parts or servicing for the CADD-MS 3, CADD Legacy and CADD-Solis infusion pumps, sales of Treprostinil Injection may be adversely affected.

In addition, we are relying upon Mainbridge for the development of new pumps for the subcutaneous administration of Treprostinil Injection. In the event of any failure of Mainbridge to successfully develop such a pump, sales of Treprostinil Injection may be adversely affected.

Additionally, in December 2019, a novel strain of COVID-19 was reported to have surfaced in Wuhan, China and continues to be a global pandemic as of the date of this Quarterly Report on Form 10-Q. The full impact of the COVID-19 pandemic is unknown and continues to evolve. South Korea, the country from which our supplier sources treprostinil, Italy, the country in which Plastiape is headquartered, and China, the country in which Chengdu is located, have had significant outbreaks of this disease, which, in the case of Italy and China, led to lockdowns of all or portions of the entire country. The extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development and commercialization of our products and product candidates will depend on the severity, location and duration of the spread of the pandemic, and the actions undertaken to contain it or treat its ongoing effects.

***If we are unable to establish or maintain licensing and collaboration arrangements with other pharmaceutical companies on acceptable terms, or at all, we may not be able to develop and commercialize additional product candidates using our PRINT technology.***

We have collaborated, and may consider collaborating, with, among others, pharmaceutical companies to expand the applications for our PRINT technology through licensing as well as joint product development arrangements. In addition, if we are able to obtain marketing approval for our product candidates from regulatory authorities, we may enter into strategic relationships with collaborators for the commercialization of such products.

Collaboration and licensing arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish collaboration or other alternative arrangements should we so choose to enter into such arrangements. In addition, the terms of any collaboration or other arrangements that we may enter into may not be favorable to us or may restrict our ability to enter into further collaboration or other arrangements with third parties. For example, collaboration agreements may contain exclusivity arrangements which limit our ability to work with other pharmaceutical companies to expand the applications for our PRINT technology, as is the case in our collaboration agreement with GSK which restricts our ability to use PRINT for inhaled applications with respect to certain identified compounds.

If we are unable to establish licensing and collaboration arrangements or the terms of such agreements we enter into are unfavorable to us or restrict our ability to work with other pharmaceutical companies, we may not be able to expand the applications for our PRINT technology or commercialize our products, if and when approved, and our business and prospects may be materially and adversely affected.

***Our collaboration and licensing arrangements may not be successful.***

Our collaboration and licensing arrangements, as well as any future collaboration and licensing arrangements that we may enter into, may not be successful. The success of our collaboration and licensing arrangements will depend heavily on the efforts and activities of our collaborators, which are not within our control. We may, in the course of our collaboration and licensing arrangements, be subject to numerous risks, including, but not limited to, the following:

- our collaborators may have significant discretion in determining the efforts and resources that they will contribute;
- our collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing. For example, in July 2018, GSK notified us of its decision to discontinue development of the inhaled antiviral for viral exacerbations in COPD after completion of its related Phase 1 clinical trial and we do not believe that GSK is currently advancing any program under our collaboration;
- our collaborators may independently, or in conjunction with others, develop products that compete directly or indirectly with our product candidates;
- we may grant exclusive rights to our collaborators that would restrict us from collaborating with others. For example, we are currently subject to certain restrictions with regard to our ability to enter into collaboration arrangements to use PRINT for the development of inhaled therapeutics using certain identified compounds pursuant to our collaboration with GSK;
- our collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and our collaborators, which may cause a delay in or the termination of our research, development or commercialization activities;
- our collaboration and licensing arrangements may be terminated, and if terminated, may result in our need for additional capital to pursue further drug product development or commercialization. For example, our development and licensing agreement with G&W Laboratories, Inc., was mutually terminated in April 2018;
- our collaborators may own or co-own certain intellectual property arising from our collaboration and licensing arrangements with them, which may restrict our ability to develop or commercialize such intellectual property; and
- our collaborators may alter the strategic direction of their business or may undergo a change of control or management, which may affect the success of our collaboration arrangements with them.

## **Risks Related to our Intellectual Property**

*We may be subject to claims from third parties that our products infringe their intellectual property rights.*

The pharmaceutical industry has experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay any introduction of new drug products or related technologies by, among others, establishing intellectual property rights over their drug products or technologies and aggressively enforcing these rights against potential new entrants into the market. We expect that we and other industry participants will be increasingly subject to infringement claims as the number of competitors and drug products grows.

Our commercial success depends in large part upon our ability to develop, manufacture, market and sell our drug products or product candidates without infringing on the patents or other proprietary rights of third parties. It is not always clear to industry participants, including us, what the scope of a patent covers. Due to the large number of patents in issue and patent applications filed in our industry, there is a risk that third parties will claim that our products or technologies infringe their intellectual property rights.

Claims for infringement of intellectual property which are brought against us, whether with or without merit, and which are generally uninsurable, could result in time-consuming and costly litigation, diverting our management's attention from our core business and reducing the resources available for our drug product development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being issued. We also may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Uncertainties resulting from the initiation and continuation of litigation or other proceedings could also have a material and adverse effect on our ability to compete in the market. Third parties making claims against us could obtain injunctive or other equitable relief against us, which could prevent us from further developing or commercializing our product candidates.

In particular, under the Hatch-Waxman Act, the owner of patents listed on the Orange Book and referenced by an NDA applicant may bring patent infringement suit against the NDA applicant after receipt of the NDA applicant's notice of paragraph IV certification. For example, in June 2020, United Therapeutics asserted a patent challenge directed to the Orange Book listed patents for Tyvaso by filing a complaint against us in the U.S. District Court for the District of Delaware, thereby triggering an automatic 30-month regulatory stay on final approval of the NDA for YUTREPIA. As a result of United Therapeutics' patent challenge, the FDA was prohibited from approving the NDA for YUTREPIA until the expiration of the 30-month stay. In August 2022, prior to the expiration of the 30-month stay, the Court found that the asserted claims of one of the patents, the '793 Patent, were both valid and infringed by the Company and ordered that the effective date of any final approval by the FDA of YUTREPIA shall be a date which is not earlier than the expiration date of the '793 Patent. As a result of the Court's order, the FDA may not issue a final approval for the YUTREPIA NDA until the expiration of the '793 Patent unless either the Court's decision with respect to the '793 Patent is reversed on appeal or the PTAB's decision, invalidating the '793 Patent, is affirmed on appeal. Accordingly, we may be subject to significant delay and incur substantial costs in litigation before we are able to commercialize YUTREPIA, if at all.

In the event of a successful infringement claim against us, including an infringement claim filed in response to a paragraph IV certification, we may be required to pay damages, cease the development or commercialization of our drug products or product candidates, re-engineer or redevelop our drug products or product candidates or enter into royalty or licensing agreements, any of which could have a material and adverse impact on our business, financial condition and results of operations. Any effort to re-engineer or redevelop our products would require additional monies and time to be expended and may not ultimately be successful.

Infringement claims may be brought against us in the future, and we cannot assure you that we will prevail in any ensuing litigation given the complex technical issues and inherent uncertainties involved in intellectual property litigation. Our competitors may have substantially greater resources than we do and may be able to sustain the costs of such litigation more effectively than we can.

***Our commercial success depends largely on our ability to protect our intellectual property.***

Our commercial success depends, in large part, on our ability to obtain and maintain patent protection and trade secret protection in the United States and elsewhere in respect of our product candidates and PRINT technology. If we fail to adequately protect our intellectual property rights, our competitors may be able to erode, negate or preempt any competitive advantage we may have. To protect our competitive position, we have filed and will continue to file for patents in the United States and elsewhere in respect of our product candidates and PRINT technology. The process of identifying patentable subject matter and filing a patent application is expensive and time-consuming. We cannot assure you that we will be able to file the necessary or desirable patent applications at a reasonable cost, in a timely manner, or at all. Further, since certain patent applications are confidential until patents are issued, third parties may have filed patent applications for subject matters covered by our pending patent applications without us being aware of such applications, and our patent applications may not have priority over patent applications of others. In addition, we cannot assure you that our pending patent applications will result in patents being obtained. Once published, all patent applications and publications throughout the world, including our own, become prior art to our new patent applications and may prevent patents from being obtained or interfere with the scope of patent protection that might be obtained. The standards that patent offices in different jurisdictions use to grant patents are not always applied predictably or uniformly and may change from time to time.

Even if we have been or are able to obtain patent protection for our product candidates or PRINT technology, if the scope of such patent protection is not sufficiently broad, we may not be able to rely on such patent protection to prevent third parties from developing or commercializing product candidates or technology that may copy our product candidates or technology. The enforceability of patents in the pharmaceutical industry involves complex legal and scientific questions and can be uncertain. Accordingly, we cannot assure you that third parties will not successfully challenge the validity, enforceability or scope of our patents. A successful challenge to our patents may lead to generic versions of our drug products being launched before the expiry of our patents or otherwise limit our ability to stop others from using or commercializing similar or identical products and technology. A successful challenge to our patents may also reduce the duration of the patent protection of our drug products or technology. In addition, we cannot assure you that we will be able to detect unauthorized use or take appropriate, adequate and timely actions to enforce our intellectual property rights. If we are unable to adequately protect our intellectual property, our business, competitive position and prospects may be materially and adversely affected.

Even if our patents or patent applications are unchallenged, they may not adequately protect our intellectual property or prevent third parties from designing around our patents or other intellectual property rights. If the patent applications we file or may file do not lead to patents being granted or if the scope of any of our patent applications is challenged, we may face difficulties in developing our product candidates, companies may be dissuaded from collaborating with us, and our ability to commercialize our product candidates may be materially and adversely affected. We are unable to predict which of our patent applications will lead to patents or assure you that any of our patents will not be found invalid or unenforceable or challenged by third parties. The patents of others may prevent the commercialization of product candidates incorporating our technology. In addition, given the amount of time required for the development, clinical testing and regulatory review of new product candidates, any patents protecting our product candidates may expire before or shortly after such product candidates might become approved for commercialization.

Moreover, the issuance of a patent is not conclusive as to the inventorship of the patented subject matter, or its scope, validity or enforceability. We cannot assure you that all of the potentially relevant prior art, that is, any evidence that an invention is already known, relating to our patents and patent applications, has been found. If such prior art exists, it may be used to invalidate a patent or may prevent a patent from being issued.

In addition, we, our collaborators or our licensees may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. As a result, we may miss potential opportunities to seek patent protection or strengthen our patent position.

***If we are unable to protect our trade secrets, the value of our PRINT technology and product candidates may be negatively impacted, which would have a material and adverse effect on our competitive position and prospects.***

In addition to patent protection, we rely on trade secret protection to protect certain aspects of our intellectual property. While we require parties who have access to any portion of our trade secrets, such as our employees, consultants, advisers, CROs, CMOs, collaborators and other third parties, to enter into non-disclosure and confidentiality agreements with us, we cannot assure you that these parties will not disclose our proprietary information, including our trade secrets, in breach of their contractual obligations. Enforcing a claim that a party has illegally disclosed or misappropriated a trade secret is difficult, costly and time-consuming, and we may not be successful in doing so. If the steps we have taken to protect our trade secrets are deemed by the adjudicating court to be inadequate, we may not be able to obtain adequate recourse against a party for misappropriating our trade secrets.

Trade secrets can be difficult to protect as they may, over time, be independently discovered by our competitors or otherwise become known despite our trade secret protection. If any of our trade secrets were to be lawfully obtained or independently developed by our competitors, we would have no right to prevent such competitors, or those to whom they communicate such technology or information, from using that technology or information to compete with us. Such competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights.

If our trade secrets were to be disclosed to or independently developed by our competitors, our competitors may be able to exploit our PRINT technology to develop competing product candidates, and the value of our PRINT technology and our product candidates may be negatively impacted. This would have a material and adverse effect on our competitive position and prospects.

***We rely on licenses to intellectual property that are owned by third parties.***

We have entered and may, in the future, enter into license agreements with third parties to license the rights to use their technologies in our research, development and commercialization activities. License agreements generally impose various diligence, milestone payments, royalty, insurance and other obligations on us, and if we fail to comply with these obligations, our licensors may have the right to terminate these license agreements. Termination of these license agreements or the reduction or elimination of our licensed rights or the exclusivity of our licensed rights may have an adverse impact on, among others, our ability to develop and commercialize our product candidates. We cannot assure you that we will be able to negotiate new or reinstated licenses on commercially acceptable terms, or at all.

In addition, we license certain patent rights for our PRINT technology from UNC under the UNC License. Under the UNC License, UNC has the right to terminate our license if we materially breach the agreement and fail to cure such breach within the stipulated time. In the event that UNC terminates our license and we have a product that relies on that license, it may bring a claim against us, and if they are successful, we may be required to compensate UNC for the unauthorized use of their patent rights through the payment of royalties.

Also, the agreements under which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented and may not be able to secure, maintain or successfully enforce necessary or desirable patent protection from those patent rights. We do not have primary control over patent prosecution and maintenance for certain of the patents we license, and therefore cannot assure you that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. We also cannot assure you that patent prosecution and maintenance activities by our licensors, if any, will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

Pursuant to the terms of some of our license agreements with third parties, some of our third-party licensors have the right, but not the obligation, in certain circumstances, to control the enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors, and we cannot assure you that we will receive such cooperation on

commercially acceptable terms, or at all. We also cannot assure you that our licensors will allocate sufficient resources or prioritize their or our enforcement of these patents or defense of these claims to protect our interests in the licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, our competitive position, business and prospects may be materially and adversely affected.

Further, licenses to intellectual property may not always be available to us on commercially acceptable terms, or at all. In the event that the licenses we rely on are not available to us on commercially acceptable terms, or at all, our ability to commercialize our PRINT technology or product candidates, and our business and prospects, may be materially and adversely affected.

***We may not be able to enforce our intellectual property rights throughout the world.***

Filing, prosecuting, enforcing and defending patents on our PRINT technology and our product candidates throughout the world may be prohibitively expensive and may not be financially or commercially feasible. In countries where we have not obtained patent protection, our competitors may be able to use our proprietary technologies to develop competing product candidates.

Also, the legal systems of non-U.S. jurisdictions may not protect intellectual property rights to the same extent or in the same manner as the laws of the United States, and we may face significant difficulty in enforcing our intellectual property rights in these jurisdictions. The legal systems of certain developing countries may not favor the enforcement of patents and other intellectual property rights. We may therefore face difficulty in stopping the infringement or misappropriation of our patents or other intellectual property rights in those countries.

***We need to protect our trademark, trade name and service mark rights to prevent competitors from taking advantage of our name recognition.***

We believe that the protection of our trademark, trade name and service mark rights, such as Liquidia, the Liquidia logo, PRINT, and YUTREPIA, is an important factor in product recognition, protecting our brand, maintaining goodwill and maintaining or increasing market share. We may expend substantial cost and effort in an attempt to register new trademarks, trade names and service marks and maintain and enforce our trademark, trade name and service mark rights. If we do not adequately protect our rights in our trademarks, trade names and service marks from infringement, any name recognition that we have developed in those trademarks could be lost or impaired.

Third parties may claim that the sale or promotion of our products, when and if approved, may infringe on the trademark, trade name and service mark rights of others. Trademark, trade name and service mark infringement problems occur frequently in connection with the sale and marketing of pharmaceutical products. If we become involved in any dispute regarding our trademark, trade name and service mark rights, regardless of whether we prevail, we could be required to engage in costly, distracting and time-consuming litigation that could harm our business. If the trademarks, trade names and service marks we use are found to infringe upon the trademarks, trade names or service marks of another company, we could be liable for damages and be forced to stop using those trademarks, trade names or service marks, and as a result, we could lose all the name recognition that has been developed in those trademarks, trade names or service marks.

**Risks Related to the Manufacturing of our Product Candidates**

***Our product candidates are based on our proprietary, novel technology, PRINT, which has not been used to manufacture any products that have been previously approved by the FDA, making it difficult to predict the time and cost of development and of subsequently obtaining final regulatory approval.***

Our future success depends on the successful development of our novel PRINT technology and products based on it, including YUTREPIA. To our knowledge, no regulatory authority has granted final approval to market or commercialize drugs made using our PRINT technology. We may never receive final approval to market and commercialize any product candidate that uses our PRINT technology.

Even if we receive final approval to market YUTREPIA, we will need to scale up our manufacturing capabilities to effectively commercialize the product. We have never completed a scale up of our PRINT manufacturing process and, if we are unable to do so in an effective and timely manner, our ability to commercialize YUTREPIA, even if it receives final FDA approval, will be adversely affected.

***Our operations are concentrated in Morrisville, North Carolina and interruptions affecting us or our suppliers due to natural disasters or other unforeseen events could materially and adversely affect our operations.***

Most of our current operations are concentrated in Morrisville, North Carolina. In addition, our inventory is warehoused in a limited number of locations. A fire, flood, hurricane, earthquake or other disaster or unforeseen event resulting in significant damage to our facilities or to inventory held by us could significantly disrupt or curtail or require us to cease our operations. It would be difficult, costly and time-consuming to transfer resources from one facility to another, to repair or replace our facility or to replace inventory in the event that it is significantly damaged. In addition, our insurance may not be sufficient to cover all of our losses and may not continue to be available to us on acceptable terms, or at all. In addition, if one of our suppliers experiences a similar disaster or unforeseen event, we could face significant loss of our inventory and significant delays in obtaining our supplies or be required to source supplies from an alternative supplier and may incur substantial costs as a result. Any significant uninsured loss, prolonged or repeated disruption to operations or inability to operate, experienced by us or by our suppliers, could materially and adversely affect our business, financial condition and results of operations.

#### **Risks Related to our Employees**

***We depend on skilled labor, and our business and prospects may be adversely affected if we lose the services of our skilled personnel, including those in senior management, or are unable to attract new skilled personnel.***

Our ability to continue our operations and manage our potential future growth depends on our ability to hire and retain suitably skilled and qualified employees, including those in senior management, in the long-term. Due to the specialized nature of our work, there is a limited supply of suitable candidates. We compete with other biotechnology and pharmaceutical companies, educational and research institutions and government entities, among others, for research, technical, clinical and sales and marketing personnel. In addition, in order to manage our potential future growth effectively, we will need to improve our financial controls and systems and, as necessary, recruit sales, marketing, managerial and finance personnel. The loss of the services of members of our sales team could seriously harm our ability to successfully implement our business strategy. If we are unable to attract and retain skilled personnel, including in particular Roger Jeffs, our Chief Executive Officer, our business and prospects may be materially and adversely affected.

#### **Risks Related to our Common Stock**

***Future sales of our common stock or securities convertible into our common stock in the public market could cause our stock price to fall.***

Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

As of May 1, 2023, 64,717,549 shares of our common stock were outstanding, of which 54,836,202 shares of common stock, or 84.7% of our outstanding shares as of May 1, 2023, are freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless held by our “affiliates,” as that term is defined in Rule 144 under the Securities Act (“Rule 144”). The resale of the remaining 9,881,347 shares held by our stockholders as of May 1, 2023 is currently prohibited or otherwise restricted as a result of securities law provisions. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act.

As of May 1, 2023, the holders of 1,887,937 shares, or 2.9%, of our outstanding shares as of May 1, 2023, have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, including the employee stock purchase plan. Once we register the offer and sale of shares for the holders of registration rights, they can be freely sold in the public market upon issuance or resale (as applicable), subject to lock-up agreements, if any.

***We expect that the market price of our common stock may be volatile, and you may lose all or part of your investment.***

The trading prices of the securities of pharmaceutical and biotechnology companies have been highly volatile. As such, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The market price for our common stock may be influenced by many factors, including:

- results of any clinical trials of any product candidate we may develop, or those of our competitors;
- the success of Sandoz's Treprostinil Injection to which we have commercial rights to pursuant to the Promotion Agreement;
- the success of Chengdu's launch of the RG Cartridge and the market acceptance of the RG Cartridge for the subcutaneous administration of Treprostinil Injection;
- whether Mainbridge is able to complete the development of a new pump for the subcutaneous administration of Treprostinil Injection and obtain FDA clearance on a timely basis or at all;
- our cash resources;
- the approvals or success of competitive products or technologies;
- potential approvals of any product candidate we may develop, including YUTREPIA, for marketing by the FDA or equivalent foreign regulatory authorities or any failure to obtain such approvals;
- our involvement in significant lawsuits, such as stockholder or patent litigation, including *inter partes* review proceedings and Hatch-Waxman litigation with originator companies or others which may hold patents, including the ongoing appeals in connection with the patents that United Therapeutics has asserted against us;
- regulatory or legal developments in the United States and other countries;
- the results of our efforts to commercialize any product candidate we may develop, including YUTREPIA in the event we receive final approval from the FDA;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

The stock market in general, and market prices for the securities of pharmaceutical companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In several recent situations when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit

against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.***

Our executive officers, directors and principal stockholders, together with their respective affiliates, beneficially owned 36.4% of our capital stock as of May 1, 2023. Accordingly, our executive officers, directors and principal stockholders have significant influence in determining the composition of our board of directors (the “Board”), and voting on all matters requiring stockholder approval, including mergers and other business combinations, and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us that you may believe are in your best interests as one of our stockholders. This in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the Board or management.

***As a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to do so may adversely affect investor confidence in us and, as a result, the trading price of our shares.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the “Sarbanes-Oxley Act”) or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement.

As required by the Sarbanes Oxley Act and commencing with the fiscal year ended December 31, 2019, we were required to furnish a report by management on, among other things, the effectiveness of our ICFR. See Item 4. Controls and Procedures for additional information.

***We are an “emerging growth company,” as defined in the JOBS Act, and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act, and we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We will take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.07 billion or more, (ii) the last day of 2023, (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and adversely affect our stock price.***

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and bylaws:

- permit the Board to issue up to 10 million shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of our Board;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent;
- create a staggered board of directors such that all members of our Board are not elected at one time;
- allow for the issuance of authorized but unissued shares of our capital stock without any further vote or action by our stockholders; and
- establish advance notice requirements for nominations for election to the Board or for proposing matters that can be acted upon at stockholders' meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law ("DGCL") which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any stockholder owning in excess of 15% of our outstanding stock for a period of three years following the date on which the stockholder obtained such 15% equity interest in us.

The terms of our authorized preferred stock selected by our Board at any point could decrease the amount of earnings and assets available for distribution to holders of our common stock or adversely affect the rights and powers, including voting rights, of holders of our common stock without any further vote or action by the stockholders. As a result, the rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued by us in the future, which could have the effect of decreasing the market price of our common stock.

Any provision of our certificate of incorporation or bylaws or Delaware corporate law that has the effect of delaying or deterring a change in control could limit opportunities for our stockholders to receive a premium for their shares of common stock, and could also affect the price that investors are willing to pay for our common stock.

***Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.***

Our certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; or (d) any action asserting a claim against us governed by the internal affairs doctrine; *provided*, that, this provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or Exchange Act. Furthermore, our bylaws designate the federal district courts of the United States as the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or our directors or officers, which may

discourage such lawsuits against us and our directors or officers. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, prospects or results of operations.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our equity securities. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of our existing RIFA with HCR preclude us, and the terms of any future debt or financing agreement may preclude us, from paying dividends. As a result, capital appreciation, if any, of our equity securities will likely be your sole source of gain for the foreseeable future.

***An impairment of our long-lived contract acquisition costs and intangible assets, including goodwill, could have a material non-cash adverse impact on our results of operations.***

In connection with the accounting for our RareGen acquisition, we have recorded significant amounts of contract acquisition costs, intangible assets, and goodwill. Under GAAP, we must assess, at least annually and potentially more frequently, whether the value of goodwill has been impaired. Contract acquisition costs and amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. The valuation of goodwill depends on a variety of factors, the success of our business, including our ability to obtain regulatory approval for YUTREPIA, global market and economic conditions, earnings growth and expected cash flows. Impairments may be caused by factors outside our control, such as actions by the FDA, increasing competitive pricing pressures, and various other factors. Significant and unanticipated changes or our inability to obtain or maintain regulatory approvals for our product candidates, including the NDA for YUTREPIA, could require a non-cash charge for impairment in a future period, which may significantly affect our results of operations in the period of such charge.

## **General Risk Factors**

### **General Risks Related to the Commercialization of our Product Candidates**

***Our business and operations may be adversely affected by the effects of health epidemics, including the continued spread of the COVID-19 global pandemic.***

Our business and operations could be adversely affected by health epidemics in regions where we have offices, manufacturing facilities, concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of clinical trial sites, contract manufacturers or suppliers and contract research organizations upon whom we rely. For example, starting in December 2019, a novel strain of the coronavirus (“COVID-19”) was reported to have surfaced in Wuhan, China and spread to multiple countries, including the U.S. and several European countries. In March 2020, the World Health Organization declared COVID-19 a global pandemic and the U.S. declared the COVID-19 pandemic a national emergency. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including state and local orders across the United States that, among other things, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings and events and ordered cessation of non-essential travel. Throughout 2020 and 2021, similar executive orders were issued by state and local governments, and states of emergency had been declared at the state and local level in most jurisdictions throughout the U.S. As recently as April 2022, ports and airports in Shanghai, China have been closed due to another outbreak of COVID-19, resulting in a lockdown of the city and disruption to export and import activities. In the U.S., many of these executive orders have been rescinded, however, we remain vigilant and continue to monitor the ongoing COVID-19 pandemic closely to determine if additional actions are required.

Remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity and our

research and development activities, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In addition, although our employees are accustomed to working remotely, changes in internal controls due to remote work arrangements may result in control deficiencies in the preparation of our financial reports, which could be material.

Such orders may also impact the availability or cost of materials, which would disrupt our supply chain and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities.

The global pandemic of COVID-19 continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of this Quarterly Report on Form 10-Q, such as the ultimate geographic spread of the disease, the severity and duration of future outbreaks (including from the spread of COVID-19 variants or mutant strains), the duration and effect of business disruptions and the short-term effects, the administration, availability and efficacy of vaccination programs and the ultimate effectiveness of travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. We expect the impact of COVID-19 on the FDA's operations will continue to evolve. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section and the "Risk Factors" sections of the documents incorporated by reference herein.

***We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, an ongoing military conflict between Russia and Ukraine, and record inflation. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine, geopolitical tensions, or record inflation.***

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. In February 2022, a full-scale military invasion of Ukraine by Russian troops began. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine has led to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions, which has contributed to record inflation globally. We are continuing to monitor inflation, the situation in Ukraine and global capital markets and assessing its potential impact on our business.

Although, to date, our business has not been materially impacted by the ongoing military conflict between Russian and Ukraine, geopolitical tensions, or record inflation, we do expect that such matters will affect our business and it is impossible to predict the extent to which our operations will be impacted in the short and long term, or the ways in which such matters may impact our business. We anticipate that increases in compensation to our employees and costs paid to vendors may similarly be greater than in past periods due to ongoing inflation. The extent and duration of the conflict in Ukraine, geopolitical tensions, record inflation and resulting market disruptions are impossible to predict but could be substantial. Any such disruptions may also magnify the impact of other risks described herein.

***If the FDA or comparable regulatory authorities in other countries approve generic versions of our product candidates, or do not grant our product candidates a sufficient period of market exclusivity before approving their generic versions, our ability to generate revenue may be adversely affected.***

Once an NDA is approved, the drug product covered will be listed as a reference listed drug in the FDA's Orange Book. In the United States, manufacturers of drug products may seek approval of generic versions of reference listed drugs through the submission of abbreviated new drug applications (ANDAs). In support of an ANDA, a generic manufacturer is generally required to show that its product has the same active pharmaceutical ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is

bioequivalent to the reference listed drug. Generic drug products may be significantly less expensive to bring to market than the reference listed drug, and companies that produce generic drug products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug product, a significant percentage of the sales of any reference listed drug may be lost to the generic drug product.

The FDA will not approve an ANDA for a generic drug product until the applicable period of market exclusivity for the reference listed drug has expired. The applicable period of market exclusivity varies depending on the type of exclusivity granted. A grant of market exclusivity is separate from the existence of patent protection and manufacturers may seek to launch generic versions of our drug products following the expiry of their respective marketing exclusivity periods, even if our drug products are still under patent protection at the relevant time.

Any competition that our product candidates may face, if and when such product candidates are approved for marketing and commercialized, from generic versions could substantially limit our ability to realize a return on our investment in the development of our product candidates and have a material and adverse effect on our business and prospects.

#### **General Risks Related to the Development and Regulatory Approval of our Product Candidates**

*Even if we obtain marketing approval for our product candidates in the United States, we or our collaborators may not obtain marketing approval for the same product candidates elsewhere.*

We may enter into strategic collaboration arrangements with third parties to commercialize our product candidates outside of the United States. In order to market any product candidate outside of the United States, we or our collaborators will be required to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be recognized or accepted by regulatory authorities in other countries, and obtaining marketing approval in one country does not mean that marketing approval will be obtained in any other country. Approval processes vary among countries and additional product testing and validation, or additional administrative review periods, may be required from one country to the next.

Seeking marketing approval in countries other than the United States could be costly and time-consuming, especially if additional preclinical studies or clinical trials are required to be conducted. We currently do not have any product candidates approved for sale in any jurisdiction, including non-U.S. markets, and we do not have experience in obtaining marketing approval in non-U.S. markets. We currently also have not identified any collaborators to market our products outside of the United States and cannot assure you that such collaborators, even if identified, will be able to successfully obtain marketing approval for our product candidates outside of the United States. If we or our collaborators fail to obtain marketing approval in non-U.S. markets, or if such approval is delayed, our target market may be reduced, and our ability to realize the full market potential of our products will be adversely affected.

#### **General Risks Related to Healthcare Regulation**

*The pharmaceutical industry is subject to a range of laws and regulations in areas including healthcare program requirements and fraud, waste, and abuse; healthcare and related marketing compliance and transparency; and privacy and data security. Our failure to comply with these laws and regulations as they are, or in the future become, applicable to us may have an adverse effect on our business.*

Healthcare providers, physicians and third-party payors often play a primary role in the recommendation and prescription of any drug products for which we may obtain marketing approval, or for which we may provide contracted promotional services to third parties. Our current and future arrangements with healthcare providers, physicians, third-party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain our business or financial arrangements and relationships through which we market, sell, or distribute drug products.

In addition, we may be subject to transparency laws and patient privacy regulation by both the federal government and the states in which we conduct our business.

The laws that may affect our ability to operate include, but are not limited to, the following examples:

- The federal Anti-Kickback Statute (AKS) prohibits, among other things, persons and entities including pharmaceutical manufacturers from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for or the purchase, lease, or order of, or the arranging for an item or service for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs.
- The federal civil and criminal false claims laws and civil monetary penalty laws impose a range of prohibitions and compliance considerations. For example, the False Claims Act (FCA) prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Claims resulting from a violation of the federal AKS constitute a false or fraudulent claim for purposes of the federal False Claims Act. Promotion that is deemed to be “off label” can be the basis of FCA exposure.
- Federal law includes provisions (established under the Health Insurance Portability and Accountability Act of 1996) addressing healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Violations of these statutes is a felony and may result in fines, imprisonment or exclusion from governmental programs.
- Privacy and data security laws may apply to our business. Under the Federal Trade Commission Act (the FTCA) Section 5(a), the FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. States may also impose requirements, for example the California Consumer Privacy Act (CCPA) created data privacy obligations for covered companies and providing privacy rights to California residents, including the right to opt out of certain disclosures of their information.
- The federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act,” requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under government healthcare programs to annually report to the Centers for Medicare and Medicaid Services (CMS) information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Payments and transfers of value made to certain other providers such as nurse practitioners and physician assistants will also need to be reported under the Sunshine Act.
- For both investigational and commercialized products, interactions with or communications directed to healthcare professionals (HCPs), patients or patient- or disease-advocates or advocacy groups, and payors, are subject to heightened scrutiny by the FDA. Relative to nonpromotional communications, for example, there are specific and limited FDA accommodations for nonpromotional, truthful and non-misleading sharing of information regarding products in development and off-label uses including dissemination of peer-reviewed reprints, support of independent continuing medical education (CME), and healthcare economic discussions with payors. In a competitive environment, a company’s communications about products in development may also be subject to heightened scrutiny.

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to items or services reimbursed by any third-party payor, including commercial insurers, and in some cases may apply regardless of payor (i.e., even for self-pay scenarios). Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report pricing and marketing information, including, among other things, information related to payments to physicians and other healthcare providers or marketing expenditures, state and local laws that require the registration of pharmaceutical sales representatives. Many of these state laws differ from each other in significant ways and may not have the same effect, and may apply more broadly or be stricter than their federal counterparts, thus complicating compliance efforts; and
- Price reporting laws require the calculation and reporting of complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursements or discounts on our drug products. Participation in such programs and compliance with their requirements may subject us to increased infrastructure costs and potentially limit our ability to price our drug products.

Ensuring that our business and business arrangements with third parties comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert management's attention from the business, even if the government ultimately finds that no violation has occurred.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws or government regulations that apply to us, we may be subject to penalties and potentially, the curtailment or restructuring of our operations as well as additional governmental reporting obligations and oversight, any of which could adversely affect our ability to operate our business and our results of operations.

#### **General Risks Related to Our Dependence on Third Parties**

##### ***We rely on third parties to conduct our preclinical studies and clinical trials.***

We currently rely on, and plan to continue to rely on, third-party contract research organizations (CROs) to monitor and manage data for our preclinical studies and clinical trials. However, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable regulatory standards and our reliance on CROs does not relieve us of our regulatory responsibilities.

The CROs on which we rely are required to comply with FDA regulations (and the regulations of comparable regulatory authorities in other countries) regarding GCP. Regulatory authorities enforce GCP standards through periodic inspections. If any of the CROs on which we rely fail to comply with the applicable GCP standards, the clinical data generated in our clinical trials may be deemed unreliable. While we have contractual agreements with these CROs, we have limited influence over their actual performance and cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical trials. A failure to comply with the applicable regulations in the conduct of the preclinical studies and clinical trials for our product candidates may require us to repeat such studies or trials, which would delay the process of obtaining marketing approval for our product candidates and have a material and adverse effect on our business and prospects.

Some of our CROs have the ability to terminate their respective agreements with us if, among others, it can be reasonably demonstrated that the safety of the patients participating in our clinical trials warrants such termination. If any of our agreements with our CROs is terminated, and if we are not able to enter into agreements with alternative CROs on acceptable terms or in a timely manner, or at all, the clinical development of our product candidates may be delayed and our development expenses could be increased.

## General Risks Related to Legal Compliance Matters

*Even if we obtain regulatory approval for a product candidate, our products and business will remain subject to ongoing regulatory obligations and review.*

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, drug supply chain security surveillance and tracking, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and comparable requirements outside of the United States. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we may receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. We will also be required to report certain adverse reactions and production problems, if any, to the FDA or other regulatory agencies and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have FDA or other regulatory agency approval. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our product candidates in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a clinical study could result in the withdrawal of marketing approval. Furthermore, any new legislation addressing drug safety issues could result in delays in product development or commercialization or increased costs to assure compliance. Foreign regulatory authorities impose similar requirements. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us or our strategic partners;
- restrict the marketing or manufacturing of our products;
- seize or detain products, or require a product recall;
- refuse to permit the import or export of our product candidates; or
- refuse to allow us to enter into government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory

compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

***Environmental, social and governance matters may impact our business and reputation.***

Governmental authorities, non-governmental organizations, customers, investors, external stakeholders and employees are increasingly sensitive to environmental, social and governance, or ESG, concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. While we strive to improve our ESG performance, we risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas, including equitable access to medicines and vaccines, product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors in our operations. If we do not meet the ESG expectations of our investors, customers and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations.

**General Risks Related to our Intellectual Property**

***We may become involved in litigation to protect our intellectual property or enforce our intellectual property rights, which could be expensive, time-consuming and may not be successful.***

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, we may engage in litigation to, among others, enforce or defend our intellectual property rights, determine the validity or scope of our intellectual property rights and those of third parties, and protect our trade secrets. Such actions may be time-consuming and costly and may divert our management's attention from our core business and reduce the resources available for our clinical development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome.

In addition, in an infringement proceeding, a court may decide that a patent owned by, or licensed to, us is invalid or unenforceable, or may refuse to stop the other party from using the technology in question on the ground that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information may be compromised by disclosure.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. While various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

We intend to seek extensions of patent terms in the United States and, if available, in other countries where we prosecute patents. In the United States, the Hatch-Waxman Act permits patent owners to request a patent term extension, based on the regulatory review period for a product, of up to five years beyond the normal expiration of the patent, which is limited to one patent claiming the approved drug product or use in an indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO, in the United States, and comparable regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or grant more limited extensions than we had

requested. In such event, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our preclinical and clinical data in their marketing approval applications with the FDA to launch their drug product earlier than might otherwise be the case.

### **General Risks Related to the Manufacturing of our Product Candidates**

***Our facilities are subject to extensive and ongoing regulatory requirements and failure to comply with these regulations may result in significant liability.***

Our company and our facilities are subject to payment of fees, registration and listing requirements, ongoing review and periodic inspections by the FDA and other regulatory authorities for compliance with quality system regulations, including the FDA's cGMP requirements. These regulations cover all aspects of the manufacturing, testing, quality control and record-keeping of our drug products. Furthermore, the facilities where our product candidates are manufactured may be subject to additional inspections by the FDA before we can obtain final marketing approval and remain subject to periodic inspection even after our product candidates have received marketing approval. Suppliers of components and materials, such as active pharmaceutical ingredients, used to manufacture our drug products are also required to comply with the applicable regulatory standards.

The manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and any contract manufacturers that we may engage in the future must comply with cGMP requirements. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and contamination controls. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Compliance with these regulatory standards often requires significant expense and effort. If we or our suppliers are unable to comply with the applicable regulatory standards or take satisfactory corrective steps in response to adverse results of an inspection, this could result in enforcement action, including, among others, the issue of a public warning letter, a shutdown of or restrictions on our or our suppliers' manufacturing operations, delays in approving our drug products and refusal to permit the import or export of our drug products. Any adverse regulatory action taken against us could subject us to significant liability and harm our business and prospects.

## Item 6. Exhibits

The exhibits listed on the Exhibit Index hereto are filed or furnished (as stated therein) as part of this Quarterly Report on Form 10-Q.

### EXHIBIT INDEX

Exhibit No.	Document
10.1*	<a href="#">Fourth Amendment to Promotion Agreement, dated as of March 10, 2023, by and between Liquidia PAH, LLC and Sandoz Inc.</a>
10.2*	<a href="#">Research License Agreement, dated as of March 31, 2023, by and between Liquidia Technologies, Inc. and Glaxo Group Limited.</a>
10.3*	<a href="#">First Amendment to Revenue Interest Financing Agreement, dated as of April 17, 2023, by and among Liquidia Technologies, Inc., Healthcare Royalty Partners IV, L.P., and HCR Collateral Management, LLC.</a>
31.1*	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act.</a>
31.2*	<a href="#">Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act.</a>
32.1**	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes- Oxley Act.</a>
32.2**	<a href="#">Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes- Oxley Act.</a>
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).

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\* Filed herewith.

\*\* Furnished herewith.

**SIGNATURES**

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 thereunto duly authorized.

DATE: May 8, 2023

**LIQUIDIA CORPORATION**

By: /s/ Roger A. Jeffs, Ph.D.

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Roger A. Jeffs, Ph.D.

Chief Executive Officer

DATE: May 8, 2023

**LIQUIDIA CORPORATION**

By: /s/ Michael Kaseta

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Michael Kaseta

Chief Financial Officer

**FOURTH AMENDMENT TO  
PROMOTION AGREEMENT**

This Fourth Amendment to Promotion Agreement (this “**Fourth Amendment**”), is entered into as of March 10, 2023 (the “**Fourth Amendment Effective Date**”) by and between Sandoz Inc. (“Sandoz”) and Liquidia PAH, LLC, formerly known as RareGen, LLC (“**RareGen**”).

**BACKGROUND**

WHEREAS, Sandoz and RareGen are parties to that certain Promotion Agreement, dated as of August 1, 2018 (the “Original Agreement”), as amended by that certain First Amendment to Promotion Agreement, dated as of May 8, 2020 (the “**First Amendment**”), that certain Second Amendment to Promotion Agreement, dated as of September 4, 2020 (the “**Second Amendment**”), and that certain Third Amendment to Promotion Agreement, dated as of November 18, 2022 (the “**Third Amendment**” and, collectively with the Original Agreement, First Amendment, Second Amendment, and Third Amendment, as they may be amended from time to time, the “**Agreement**”); and

WHEREAS, Sandoz and RareGen plan to enter into an agreement with Smiths Medical ASD, Inc. (“**Smiths**”) regarding the repair and servicing of CADD-MS 3 pumps (“**Smiths Pumps**”) for use with the Product in substantially the form attached hereto as Exhibit A (the “**Project Agreement**”);

WHEREAS, Sandoz and RareGen desire to amend the terms of the Agreement to allocate responsibility for the costs agreed to in the Project Agreement;

WHEREAS, Sandoz and RareGen and Mainbridge Health Partners LLC executed the Mainbridge Development Agreement dated December 1, 2022;

NOW, THEREFORE, in consideration of the mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, Sandoz and RareGen agree as follows:

**AGREEMENT**

1. **Definitions.** All capitalized terms used in this Amendment and not otherwise defined herein shall have the meanings assigned to them in the Agreement.

2. **Amendments.**

a. A new Section 2.4.6 is hereby added to the Agreement to read as follows:

“2.4.6 **Servicing of Smiths Pumps.**

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(a) Sandoz and RareGen agree to enter into the Project Agreement in substantially the form attached hereto, with only such changes as may be approved by both Sandoz and RareGen.

(b) Sandoz and RareGen agree to split equally the payments due from Sandoz and RareGen, collectively, to Smiths as set forth in the Project Agreement (the “**Smiths Payments**”).

Sandoz will pay the full amount of each Smiths Payment in full directly to Smiths in accordance with the terms of the Project Agreement. Following each such payment, Sandoz will deduct fifty percent (50%) of each Smiths Payment from RareGen’s portion of the Net Profits under this Agreement until the full 50% has been recouped by Sandoz.”

b. A new Section 3.4.11 is hereby added to the Agreement to read as follows:

“3.4.11 discuss and review the status of activities under the Project Agreement and any associated costs.”

c. Section 6.3 of the Agreement is hereby amended as follows:

In the first sentence of Section 6.3, “The terms and conditions of this Section 6.3 shall govern each Party’s rights and obligations with respect to Net Profits during the Term:” is deleted and replaced with “During the Term in consideration for (a) performance of the RareGen Activities, (b) for the IP and rights contributed by RareGen related to the Cartridges as set in Section 2.4.3 and (c) the exclusive rights granted in the Mainbridge Development Agreement to Sandoz and Liquidia, Sandoz will distribute a portion of the Net Profits to RareGen in accordance with the terms and conditions of this Section 6.3:” The remainder of Section 6.3 shall remain unchanged. The aforementioned amendment to Section 6.3 shall be considered effective as of January 1, 2023.

3. **Effect of Amendment.** Except as otherwise provided herein, all of the provisions of the Agreement are hereby ratified and confirmed and all the terms, conditions and provisions thereof remain in full force and effect.

4. **Governing Law.** This Amendment and any and all matters arising directly or indirectly here from shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, U.S.A. applicable to agreements made and to be performed entirely in such state, without giving effect to the conflict of law principles thereof. The Parties expressly agree that the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Amendment or any Party’s performance hereunder.

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5. **Counterparts.** This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Amendment may be executed by the exchange of faxed executed copies, certified electronic signatures or executed copies delivered by electronic mail in Adobe Portable Document Format or similar format, and such signature shall be deemed an original signature for purposes of this Amendment. The Parties agree that the electronic signatures appearing on this Amendment are the same as handwritten signatures for the purposes of validity, enforceability and admissibility pursuant to the Electronic Signatures in Global and National Commerce (ESIGN) Act of 2000 and Uniform Electronic Transactions Act (UETA) model law or similar applicable laws.

[Signature page follows.]

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IN WITNESS WHEREOF, the Parties have executed this Fourth Amendment as of the Fourth Amendment Effective Date.

**SANDOZ:**

SANDOZ INC.

By: /s/ Timothy de Gavre  
Name: Timothy de Gavre  
Title: VP, Chief Commercial Officer US

**RAREGEN:**

LIQUIDIA PAH, LLC

By: /s/ Scott Moomaw  
Name: Scott Moomaw  
Title: Senior Vice President, Commercial

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**RESEARCH LICENSE AGREEMENT**

This **RESEARCH LICENSE AGREEMENT** (the “**Agreement**”) is entered into as of March 31, 2023 (the “**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**”), and **GLAXO GROUP LIMITED**, a company organized and existing under the laws of England and having an office and place of business at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 ONN, United Kingdom (“**GSK**”). Liquidia and GSK are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

**RECITALS**

**WHEREAS**, Liquidia controls certain technology for the formulation and/or delivery of small molecule, diagnostic, or biologic constructs, generally known as its PRINT platform technology, including PRINT particles, particle formulations, and PRINT processing technology;

**WHEREAS**, GSK wishes to conduct research regarding certain molecules owned or controlled by GSK using certain of Liquidia’s intellectual property;

**WHEREAS**, Liquidia and GSK entered into an Inhaled Collaboration and Option Agreement, dated June 15, 2012, which agreement was amended by Amendment 1 to the Inhaled Collaboration and Option Agreement, dated May 13, 2015, Second Amendment to the Inhaled Collaboration and Option Agreement, dated November 19, 2015, Amendment No. 3 to the Inhaled Collaboration and Option Agreement, dated June 24, 2019 and an Addendum to the Inhaled Collaboration and Option Agreement, dated August 30, 2017 (collectively, the “**Prior Inhaled Agreement**”);

**WHEREAS**, the Parties desire to terminate the Prior Inhaled Agreement and replace it with a license granted by Liquidia to GSK under certain of Liquidia’s intellectual property on the terms and conditions set forth herein.

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants and conditions contained in this Agreement, the Parties agree as follows:

**ARTICLE 1  
DEFINITIONS**

Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized, shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

**1.1** “**Acquiror**” has the meaning set forth in Section 10.5(a).

**1.2** “**Affiliate**” means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms

“controlled by” or “under common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more (or such lesser percentage which is the maximum allowed to be owned by a person, corporation, partnership or other entity in a particular jurisdiction) of the voting stock of such entity, or by contract or otherwise.

**1.3** “**Agreement**” has the meaning set forth in the preamble.

**1.4** “**Arising PRINT Improvements**” means any and all PRINT Improvements made or generated by or on behalf of GSK or its Affiliates in its exercise of the license granted to GSK in Section 2.1.

**1.5** “**Bankruptcy Code**” has the meaning set forth in Section 7.4.

**1.6** “**Business Day**” means a day on which banking institutions in London, England and New York, New York are open for business, but excluding the nine (9) consecutive calendar days beginning on December 24th and continuing through January 1st of each calendar year during the Term, and all Saturdays and Sundays.

**1.7** “**Change of Control**” means the occurrence of any of the following: (a) a Party enters into a merger, consolidation, stock sale or sale or transfer of all or substantially all of its assets to which this Agreement relates, or other similar transaction or series of transactions with a Third Party; or (b) any transaction or series of related transactions in which any Third Party or group of Third Parties acquires beneficial ownership of securities of a Party representing more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a Third Party in a particular jurisdiction) of the combined voting power of the then outstanding securities of such Party. Notwithstanding the foregoing, a stock sale to underwriters of a public offering of a Party’s capital stock or a stock sale to Third Parties solely for the purpose of financing or a transaction solely to change the domicile of a Party shall not constitute a Change of Control.

**1.8** “**Claims**” has the meaning set forth in Section 5.1.

**1.9** “**Competing Program**” has the meaning set forth in Section 2.2(b).

**1.10** “**Confidential Information**” of a Party means (a) any and all Know-How of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, or electronic form and (b) any information that constituted “Confidential Information” under the Prior Inhaled Agreement.

**1.11** “**Control**” means, with respect to any material, Know-How, Patent or other intellectual property right, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement) to such material, Know-How, Patent or other intellectual property right and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

**1.12** “**CPR**” has the meaning set forth in Section 8.3.

- 1.13 “**Dollar**” means a U.S. dollar, and “\$” shall be interpreted accordingly.
- 1.14 “**Effective Date**” has the meaning set forth in the preamble.
- 1.15 “**Executive Officer**” means, with respect to Liquidia, its Chief Executive Officer, with respect to GSK, its Vice President of Alliance Management, or in each case, such Executive Officer’s designee, provided such designee is at a Vice President level or above.
- 1.16 “**FD&C Act**” means the U.S. Federal Food, Drug and Cosmetic Act, as amended, and applicable regulations promulgated thereunder by the FDA.
- 1.17 “**FDA**” means the U.S. Food and Drug Administration or any successor entity.
- 1.18 “**Field**” means the treatment of any human disease or condition in pulmonary tissues or cells, the brain or any other extra-pulmonary tissues, in each case via the inhaled route topically via the lung or nasal mucosa. The foregoing notwithstanding, the Field excludes the use of any Liquidia Respiratory Product.
- 1.19 “**General Biological Effects**” means biological effect(s) that are not solely applicable within the Field and that result from either (a) the shape and/or uniformity of size of particles contained within PRINT Material or (b) the particle surface characteristics, particle modulus, and/or particle charge, only if and to the extent biological effect(s) are due to the association of such characteristics with the shape and/or uniformity of size of particles contained within PRINT Material, and cannot be achieved with a technology other than PRINT. For clarity, General Biological Effects does not include biological effects attributable to (i) components of PRINT Materials other than the particles themselves, such as excipients and polymers, or (ii) the overall formulation of the composition of particles comprising PRINT Materials.
- 1.20 “**Governmental Authority**” means any multi-national, supra-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).
- 1.21 “**GSK Arising IP**” has the meaning set forth in Section 3.2.
- 1.22 “**GSK Indemnitees**” has the meaning set forth in Section 5.1.
- 1.23 “**GSK Molecules**” means any or all molecules owned or Controlled by GSK.
- 1.24 “**GSK Retained Exclusivity Term**” means the period of time between the Effective Date and the date that the last to expire US patent within Liquidia Patents expires.
- 1.25 “**GSK Retained Products**” means those products listed in Exhibit B hereto, with the same formulation, composition, dosing and other chemical or biological characteristics as such products, in each case as described as of the Effective Date in the approved package insert therefor.
- 1.26 “**ICC**” has the meaning set forth in Section 8.4.

- 1.27 “**Indemnified Party**” has the meaning set forth in Section 5.3.
- 1.28 “**Indemnifying Party**” has the meaning set forth in Section 5.3.
- 1.29 “**Infringement**” has the meaning set forth in Section 3.6(a).
- 1.30 “**Joint Arising IP**” has the meaning set forth in Section 3.2.
- 1.31 “**Know-How**” means any and all data and test data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from non-clinical studies), results, inventions (whether or not patentable), technology, business or financial information or information of any other type, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, and expertise.
- 1.32 “**Laws**” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, supranational, state, provincial, county, city or other political subdivision.
- 1.33 “**Legal Requirement**” has the meaning set forth in Section 6.1(c).
- 1.34 “**Liquidia Arising IP**” has the meaning set forth in Section 3.2.
- 1.35 “**Liquidia Indemnitees**” has the meaning set forth in Section 5.2.
- 1.36 “**Liquidia Know-How**” means all Know-How Controlled by Liquidia or its Affiliates as of the Effective Date that is generally applicable to PRINT, PRINT Material or PRINT Tooling, and for clarity excludes any such Know-How that specifically applies to a given molecule that has not previously been disclosed to GSK or its Affiliates prior to the Effective Date.
- 1.37 “**Liquidia Patents**” means the Patents set forth in Exhibit A attached hereto.
- 1.38 “**Liquidia Respiratory Product**” means a dry powder inhaled treprostinil product directed to the treatment or prevention of pulmonary hypertension developed using PRINT.
- 1.39 “**Liquidia Technology**” means the Arising PRINT Improvements, Liquidia Know-How and Liquidia Patents.
- 1.40 “**Losses**” has the meaning set forth in Section 5.1.
- 1.41 “**Party**” or “**Parties**” has the meaning set forth in the preamble.
- 1.42 “**Patents**” means (a) pending patent applications, issued patents, utility models and designs; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (c) extensions, renewals or restorations of any of the foregoing by

existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

**1.43 “Permitted Contractor”** means any Third Party contractor that has entered into a written agreement with GSK or its Affiliates to perform services for GSK where such written agreement is consistent with the terms and conditions of this Agreement applicable to the services to be provided by such Third Party contractor.

**1.44 “PRINT”** means Liquidia’s proprietary micro or nano-fabrication process for producing particles and particles on a film of a predetermined size, shape and composition (generally known as PRINT® (Particle Replication In Nonwetting Template)), including all processes, systems and materials (including using molds but excluding making molds) for producing such particles and all Liquidia proprietary substances used in making any such particles. For the avoidance of doubt, PRINT does not include the particles or the particle formulations or PRINT Material generated using PRINT, or the PRINT Tooling.

**1.45 “PRINT Improvements”** means (a) any improvements or modifications to General Biological Effects; and/or (b) any Know-How which constitutes an improvement or modification of PRINT or PRINT Tooling, in each case of (a) and (b) which is made or generated by or on behalf of GSK, its Affiliates or sublicensees (for clarity, including any Third Party manufacturer) under this Agreement, as well as any Patents claiming or covering any of the foregoing.

**1.46 “PRINT Material”** means a particle or a group of particles that is developed, manufactured or otherwise produced using PRINT and PRINT Tooling or otherwise developed, manufactured or produced using any Liquidia Technology whether such particle or group of particles is developed, manufactured or produced by Liquidia or GSK, or their Affiliates or sublicensees. For clarity, “particle(s)” may refer to the composition of the particles, including excipients that prevent degradation or provide stabilization to the particle(s).

**1.47 “PRINT Tooling”** means the Liquidia proprietary information, trade secrets, materials and substrates for fabricating the patterned drums (including the patterned drums themselves) and molds (excluding the molds themselves) that enable PRINT. For the avoidance of doubt, PRINT Tooling does not include the particles or any particle formulation, PRINT Material or PRINT.

**1.48 “Public Statement”** has the meaning set forth in Section 6.4(c).

**1.49 “Releasees”** has the meaning set forth in Section 9.2.

**1.50 “Term”** has the meaning set forth in Section 7.1.

**1.51 “Territory”** means the whole world.

**1.52 “Third Party”** means any entity other than Liquidia or GSK or their respective Affiliates.

**1.53 “UNC License Agreement”** means the Amended and Restated License Agreement between Liquidia and The University of North Carolina at Chapel Hill (“UNC”), dated December 15, 2008, as amended.

**1.54** “U.S.” means the United States of America, including all possessions and territories thereof.

**1.55** “Valid Claim” means a claim of any issued and unexpired Patent included within Liquidia Patents, which claim has not been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.

**1.56 Interpretation.** In this Agreement, unless otherwise specified:

(a) “includes” and “including” shall mean respectively includes without limitation and including without limitation;

(b) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(c) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear; and

(d) the Exhibits and other attachments form part of the operative provision of this Agreement and references to this Agreement shall include references to the Exhibits and attachments.

## **ARTICLE 2 LICENSES**

**2.1 License Under Liquidia Technology.** Liquidia hereby grants to GSK a non-exclusive, non-sublicensable (except to its Affiliates and Permitted Contractors as set forth in Section 2.3), royalty-free license under Liquidia Technology for the sole purpose of conducting pre-clinical research and pre-clinical development on GSK Molecules in the Field and in the Territory. For clarity, the foregoing license does not include the right to make or have made any PRINT Material or other materials, to conduct a clinical trial, or to commercialize products. Promptly following designation of a GSK Molecule as a development candidate in accordance with GSK’s customary internal policies, GSK shall notify Liquidia in writing of the identity of such GSK Molecule for which GSK plans to exercise its license under this Section 2.1. GSK acknowledges that any technology transfer or manufacturing activities by Liquidia, if any, would be subject to the negotiation and execution of a separate agreement between GSK and Liquidia covering such activities. The Parties acknowledge the practical difficulty of policing the use of Liquidia Know-How in the unaided memory of GSK or its Affiliates and its and their officers, directors, employees and agents, and as such, to the extent that such Liquidia Know-How is retained in the unaided memory of any officers, directors, employees and agents of GSK or its Affiliates after the termination or expiration of this Agreement, Liquidia agrees that GSK or its Affiliates may continue to use such retained Know-How for the sole purpose of conducting pre-clinical research and pre-clinical development on GSK Molecules in the Field and in the Territory; *provided, however*, that such officer, director, employee or agent has not intentionally memorized such Liquidia Know-How for use after the termination or expiration of this Agreement.

## **2.2 Liquidia Retained Rights; Limitations Regarding Certain Inhaled Products.**

(a) Except as expressly set forth in Section 2.2(b), Liquidia retains all rights not expressly granted to GSK in Section 2.1, including, but not limited to, the following: (i) the non-exclusive right to practice and license the Liquidia Technology in the Field and in the Territory; and (ii) the exclusive right to practice and license the Liquidia Technology outside of the Field and otherwise outside the scope of the rights granted to GSK in this Agreement.

(b) In consideration for GSK's agreement to terminate the Prior Inhaled Agreement, unless contrary to applicable law, during the GSK Retained Exclusivity Term, Liquidia shall not, either alone or in conjunction with a Third Party, clinically develop or commercialize any GSK Retained Product in the Field in the Territory if any such development or commercialization would be covered or claimed by a Liquidia Patent or use Arising PRINT Improvements (a "**Competing Program**"). Notwithstanding the foregoing in this Section 2.2(b), in the event that, during the GSK Retained Exclusivity Term, Liquidia undergoes a Change of Control and such Acquiror of Liquidia or its Affiliates has, immediately prior to the consummation of such transaction, a Competing Program that would violate this Section 2.2(b) and was not otherwise licensed or authorized by Liquidia or its Affiliates prior to consummation of the Change of Control, then Liquidia shall notify GSK in writing of such program within sixty (60) days after the consummation of such transaction, and such Acquiror and its Affiliates will have the right to continue to conduct such Competing Program; provided that such Acquiror and its Affiliates do not use PRINT or PRINT Tooling in connection with such Competing Program during the GSK Retained Exclusivity Term. The restriction set forth in this Section 2.2(b) is reasonably limited in time and scope and necessary for the Parties to be able to provide each other with access to technology that may benefit consumers with innovative products.

**2.3 Sublicense Rights.** GSK shall have the right to grant sublicenses of the licenses granted in Section 2.1 solely to its Affiliates (for so long as such entity remains an Affiliate) and Permitted Contractors. GSK shall remain responsible for all of its sublicensees' activities and any and all failures by its sublicensees to comply with the applicable terms of this Agreement. Except as set forth in the preceding sentence, GSK shall not have any right to grant sublicenses of the licenses granted in Section 2.1. GSK shall promptly notify Liquidia of any sublicense to a Permitted Contractor pursuant to this Section 2.3. Each such sublicense agreement shall be consistent with the terms and conditions of this Agreement and shall include the following terms and conditions:

(i) the sublicensee shall be bound by and subject to all applicable terms and conditions of this Agreement in the same manner and to the same extent as GSK is bound thereby; and

(ii) GSK and Liquidia shall have the same rights, ownership and/or licenses to all PRINT Improvements generated by such sublicensee to the same extent as if such PRINT Improvements were generated by GSK.

**2.4 No Implied Licenses.** Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any option, license or other right to any intellectual property right of such Party. Neither Party shall, nor permit any of its Affiliates or sublicensees to, practice any intellectual property rights licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

**2.5 UNC License.** GSK acknowledges and agrees that it has received an unredacted copy of the UNC License. GSK acknowledges that this Agreement is subject to the terms and conditions set forth in the UNC License and that, to the extent any action taken by GSK under the license granted in Section 2.1 creates any financial obligation for Liquidia under the UNC License, GSK shall pay to Liquidia an amount equal to any amounts due from Liquidia to UNC under the UNC License with respect thereto.

### **ARTICLE 3 INTELLECTUAL PROPERTY MATTERS**

**3.1 Ownership of Existing IP.** Each Party shall own and retain all rights, title, and interest in and to all inventions, discoveries and other subject matter (including Know-How) together with all intellectual property rights therein which are owned or Controlled by such Party as of the Effective Date or which are invented or acquired by or on behalf of such Party independent of this Agreement.

**3.2 Ownership of Arising IP.** Inventorship of inventions made during the course of the performance of activities or exercise of rights under this Agreement will be determined in accordance with United States patent Laws for determining inventorship. GSK shall solely own all right, title and interest in and to all inventions, discoveries and other subject matter (including Know-How) created solely by or on behalf of GSK or its Affiliates in the performance of activities or the exercise of rights under this Agreement together with all intellectual property rights therein, but excluding in each case all Arising PRINT Improvements (“**GSK Arising IP**”). Liquidia will solely own all right, title and interest in and to (a) inventions, discoveries and other subject matter (including Know-How) created solely by or on behalf of Liquidia or its Affiliates in the performance of activities or the exercise of rights under this Agreement together with all intellectual property rights therein and (b) all Arising PRINT Improvements, in each case together with all intellectual property rights therein (“**Liquidia Arising IP**”). The Parties shall jointly own all Know-How invented jointly by GSK or its Affiliates and Liquidia or its Affiliates together with all intellectual property rights therein, but excluding in each case all Arising PRINT Improvements (“**Joint Arising IP**”). GSK hereby assigns to Liquidia all its right, title, and interest in and to all Arising PRINT Improvements. GSK shall, at Liquidia’s cost, execute and deliver to Liquidia a deed(s) of such assignment, in a form proposed by Liquidia and mutually agreeable by GSK and will take whatever actions reasonably necessary, to effect such assignment.

**3.3 Disclosure of Know-How.** (a) Each Party shall promptly disclose to the other Party all Joint Arising IP of which it is aware and (b) GSK shall, as soon as reasonably practical following a Disclosure Time (as defined below), disclose to Liquidia all Arising PRINT Improvements, in each case of (a) and (b), including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing the inventions to the extent necessary or useful for the preparation, filing and maintenance of a Patent covering or claiming such Joint Arising IP or Arising PRINT Improvements. “**Disclosure Time**” means (i) when GSK seeks a license to obtain additional rights to the Liquidia Technology beyond those rights described in Section 2.1, or (ii) upon Liquidia’s reasonable request if Liquidia believes that GSK has disclosed to Liquidia, to a third party or publicly the existence of an Arising PRINT Improvement.

**3.4 Prosecution of Patents.** Liquidia shall have the sole right, but not obligation, to prepare, file, prosecute and maintain, at its cost, all Liquidia Patents and any Patents claiming or covering Liquidia Arising IP. GSK shall have the sole right, but not obligation, to prepare, file, prosecute and maintain, at its cost, all Patents claiming or covering GSK Arising IP. The Parties shall discuss in good faith the Patent prosecution strategy for any Patent claiming or covering any Joint Arising IP, including which Party shall lead prosecution thereof, information sharing rights, and any cost sharing in connection therewith.

#### **ARTICLE 4 REPRESENTATIONS AND WARRANTIES; COVENANTS**

**4.1 Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party as follows:

**(a) Corporate Existence.** As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated.

**(b) Corporate Power, Authority and Binding Agreement.** As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

**4.2 Disclaimer.** Each Party understands that the Liquidia Technology is the subject of ongoing research and development and that Liquidia cannot assure the safety or usefulness of the Liquidia Technology. In addition, Liquidia (and GSK to the extent GSK assigns any Arising PRINT Improvements to Liquidia) make no warranties except as set forth in this Article 4 concerning the Liquidia Technology. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

#### **ARTICLE 5 INDEMNIFICATION**

**5.1 Indemnification by Liquidia.** Liquidia shall defend, indemnify, and hold GSK and its Affiliates and their respective officers, directors, employees, and agents (the “**GSK Indemnitees**”) harmless from and against any and all liabilities, damages, losses, costs and expenses including the reasonable fees of attorneys (collectively, “**Losses**”), arising out of or resulting from any Third Party suits, claims, actions, proceedings or demands (“**Claims**”) to the extent that such Claims arise out of, are based on, or result from: (a) the breach of any of Liquidia’s obligations under this

Agreement, including Liquidia's representations and warranties set forth herein; (b) the willful misconduct or grossly negligent acts of Liquidia, its Affiliates, sublicensees, subcontractors, or the officers, directors, employees, or agents of Liquidia or its Affiliates; or (c) any breach by Liquidia or its Affiliates of the UNC License Agreement not attributable to an act or omission of GSK or its Affiliates, or their respective subcontractors or sublicensees. The foregoing indemnity obligation shall not apply to the extent that (i) the GSK Indemnitees fail to comply with the indemnification procedures set forth in Section 5.3 and Liquidia's defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim that arises from, is based on, or results from any activity set forth in Section 5.2 for which GSK is obligated to indemnify the Liquidia Indemnitees.

**5.2 Indemnification by GSK.** GSK shall defend, indemnify, and hold Liquidia and its Affiliates and their respective officers, directors, employees, and agents (the "**Liquidia Indemnitees**") harmless from and against any and all Losses arising out of or resulting from any Claims to the extent that such Claims arise out of, are based on, or result from: (a) the research, or other use of GSK Molecules; (b) the breach of any of GSK's obligations under this Agreement, including GSK's representations and warranties set forth herein; or (c) the willful misconduct or grossly negligent acts of GSK, its Affiliates or its or their sublicensees or subcontractors, or the officers, directors, employees, or agents of GSK or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the Liquidia Indemnitees fail to comply with the indemnification procedures set forth in Section 5.3 and GSK's defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity set forth in Section 5.1 for which Liquidia is obligated to indemnify the GSK Indemnitees.

**5.3 Indemnification Procedures.** The Party claiming indemnity under this Article 5 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, that the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 5.

**5.4 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES (INCLUDING ANY LOSS OF PROFITS, EARNINGS, GOODWILL, SAVINGS OR BUSINESS SUFFERED BY LIQUIDIA OR GSK) ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY

OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 5.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 5.1 OR 5.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 6.

**5.5 Insurance.** Each Party shall procure and maintain insurance, or in GSK's case, self-insure, consistent with normal business practices of prudent companies similarly situated at all times during the Term of this Agreement. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 5. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance.

## **ARTICLE 6 CONFIDENTIALITY**

**6.1 Confidentiality.** Each Party agrees that, during the Term and for a period of five (5) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by the other Party, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

- (a) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the other Party;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;
- (d) was disclosed to the receiving Party or its Affiliate on a non-confidential basis by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or
- (e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application or use of the other Party's Confidential Information, as evidenced by written records made contemporaneous with such discovery or development and kept in the ordinary course of business, or other similar documentary proof of actual knowledge by the receiving Party.

**6.2 Authorized Disclosure.** Notwithstanding the obligations set forth in Section 6.1, a Party may disclose the other Party's Confidential Information to the extent:

(a) such disclosure is reasonably necessary (i) for the filing or prosecuting Patents as contemplated by this Agreement; (ii) to comply with the requirements of Governmental Authorities with respect to obtaining and maintaining regulatory approval of a product; or (iii) for prosecuting or defending litigation as contemplated by this Agreement;

(b) such disclosure is reasonably necessary to its employees, agents, consultants, contractors, licensees or sublicensees on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement;

(c) such disclosure (including the terms of this Agreement) is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, licensee or other financial or commercial partner for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; provided that in connection with such disclosure, such Party shall inform each Third Party to whom Confidential Information is disclosed of the confidential nature of such Confidential Information and cause each such Third Party to treat such Confidential Information as confidential; or

(d) such disclosure is reasonably necessary to comply with applicable Laws, including regulations promulgated by applicable security exchanges, court order, administrative subpoena or order.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 6.2(a) or 6.2(d), such Party shall promptly notify the other Party such required disclosure and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

**6.3 Technical Publication.** Neither Party may publish any information or material relating to GSK's exercise of its license hereunder without the other Party's prior consent not to be unreasonably withheld, conditioned or delayed; *provided*, that upon Liquidia's request, GSK shall remove from any proposed publication any Liquidia Know-How or Confidential Information of Liquidia.

#### **6.4 Publicity; Terms of this Agreement.**

(a) The Parties agree that the terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 6.4.

(b) On or after the Effective Date, Liquidia shall have the right to issue a public announcement of the execution of this Agreement, in the form agreed by the Parties as of the Effective Date.

(c) Except for the public announcement described in Section 6.4(b), neither Party nor such Party's Affiliates will make any public announcements, press releases, regulatory filing or other public disclosures, written or oral, whether to the public, the press, stockholders or otherwise, concerning this Agreement or the terms or the subject matter hereof, the performance hereof or the Parties' activities hereunder, or any results or data arising hereunder (a "**Public Statement**"), except: (i) with the prior written consent of the other Party (such consent not to be unreasonably

delayed or withheld but may be conditional upon certain restrictions as to the content and/or distribution of such Public Statement to ensure consistency with GSK's policies, including GSK's standards for Scientific Engagement); or (ii) for such Public Statements, as in the opinion of the counsel for the Party intending to make such Public Statement, are required to comply with applicable Laws (including the regulations of any stock exchange) (a "**Legal Requirement**") and which in any event contain only the minimum disclosure necessary to comply with the relevant Legal Requirement.

(d) Each Party agrees to provide the other Party with a copy of any proposed Public Statement as soon as reasonably practicable under the circumstances prior to its scheduled release. Each Party shall provide the other with an advance copy of any such Public Statement at least seven (7) days prior to its scheduled release; provided, that if the Party proposing such Public Statement cannot provide the reviewing Party with seven (7) days' notice due to extraordinary circumstances, such Party will use reasonable efforts to provide the reviewing Party with the proposed Public Statement for comment at least forty-eight (48) hours before release. Each Party furthermore shall have the right to review and recommend changes to any such Public Statement and, except as otherwise required by Legal Requirement, the Party whose Public Statement has been reviewed shall remove any Confidential Information of the reviewing Party that the reviewing Party reasonably deems to be inappropriate for disclosure.

(e) In addition to the foregoing each Party agrees to give the other Party a reasonable opportunity (to the extent consistent with Legal Requirements) to review all Public Statements required by Legal Requirements to be filed with the SEC or similar body prior to submission of such filings, and will give due consideration to any reasonable comments by the non-filing Party relating to such filing, including the provisions of this Agreement for which confidential treatment should be sought.

(f) Notwithstanding anything to the contrary in this Section 6.4, once any written statement is approved for disclosure by the Parties or information is otherwise made public in accordance with this Section 6.4, either Party may make a subsequent public disclosure of the same contents of such statement in the same context as such statement without further approval of the other Party.

**6.5 Equitable Relief.** Each Party acknowledges that its breach of this Article 6 may cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated in monetary damages. Therefore, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to seek preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this Article 6 by the other Party.

## **ARTICLE 7 TERM AND TERMINATION**

**7.1 Term.** This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 7, shall remain in effect (the "**Term**") until the later of (a) the expiration of the last-to-expire Valid Claim included within the Liquidia Technology and (b) all Arising PRINT Improvements and Liquidia Know-How are in the public domain.

**7.2 Termination by GSK for Convenience.** GSK may terminate this Agreement in its entirety for any reason upon at least thirty (30) days' prior written notice to Liquidia.

**7.3 Termination for Breach.** Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party if the other Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail, fails to cure such material breach within sixty (60) days from the date of such notice.

**7.4 Termination for Bankruptcy.** Each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party upon such other Party's filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by such other Party; provided however that in the case of involuntary bankruptcy proceeding such right to terminate shall only become effective if such other Party consents to the involuntary bankruptcy or such proceeding is not dismissed within sixty (60) days after its filing. In connection therewith, all rights and licenses granted under or pursuant to any section of this Agreement are and shall otherwise be deemed to be for purposes of Section 365(n) of Title 11, United States Code (the "**Bankruptcy Code**") licenses of rights to "intellectual property" as defined in Section 101(56) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of, or complete access to, any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

**7.5 Survival.** Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: the last sentence of Section 2.1, Section 2.2(a), Section 2.4, Article 3, Section 4.2, Article 5, Article 6, this Section 7.5, Article 8, Article 9 and Article 10.

## **ARTICLE 8 DISPUTE RESOLUTION**

**8.1 Disputes.** The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 8 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

**8.2 Internal Resolution.** With respect to all disputes arising between the Parties under this Agreement, including any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute

within thirty (30) days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Executive Officers of the Parties for attempted resolution by good faith negotiations within thirty (30) days after such notice is received by or referred to the Executive Officers.

**8.3 Third Party Mediation.** Any dispute remaining unresolved after escalation to the Executive Officers pursuant to Section 8.2 shall first be submitted to mediation in accordance with the Mediation Procedure of the International Institute for Conflict Prevention and Resolution (“CPR”). Such mediation shall be attended on behalf of each Party for at least one session by a senior executive with authority to resolve the dispute and shall be held in New York City, New York. Unless otherwise agreed by the Parties, the Parties shall select a mediator from the CPR Panels of Distinguished Neutrals. Notwithstanding the foregoing, each Party has the right to pursue provisional relief from any court, such as attachment, preliminary injunction or replevin to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the dispute, prior to the commencement of, or while the Parties are engaged in, the mediation process pursuant to Section 8.5. Any dispute that cannot be resolved by mediation within sixty (60) days of notice by one Party to the other Party of the commencement of the mediation process shall be resolved by arbitration in accordance Section 8.4.

**8.4 Dispute Resolution.** If the Parties are not able to resolve a dispute referred to them under Section 8.2 and subject to mediation as set forth in Section 8.3, then subject to Section 8.5, such dispute shall be finally resolved by final and binding arbitration conducted in accordance with the terms of this Section 8.4. The arbitration will be held in New York City, New York according to Rules of Arbitration of the International Chamber of Commerce (“ICC”). The arbitration will be conducted by a single arbitrator with significant experience in the pharmaceutical industry, unless otherwise agreed by the Parties, appointed by ICC within fifteen (15) days after commencement of the arbitration in accordance with applicable ICC rules. Any arbitration herewith will be conducted in the English language. The arbitrator will be instructed not to award any punitive or special damages and will render a written decision no later than six (6) months following the selection of the arbitrator, including a basis for any damages awarded and a statement of how the damages were calculated. Any award will be promptly paid in Dollars free of any tax, deduction or offset. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 8.4. With respect to money damages, nothing contained herein will be construed to permit the arbitrator or any court or any other forum to award punitive or exemplary damages. Each Party will pay its legal fees and costs related to the arbitration (including witness and expert fees); provided, that the arbitrator shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable attorneys’ fees, costs and disbursements. All proceedings and decisions of the arbitrator shall be deemed Confidential Information of each of the Parties, and shall be subject to Article 6. From the date of submission of the dispute to the Executive Officers in Section 8.2, until such time as the dispute has become finally settled, the running of the time periods as to which a Party alleged to have breached the Agreement must cure such breach becomes suspended as to any breach that is the subject matter of the dispute. Judgment on the award so rendered will be final and may be entered in any court having jurisdiction thereof.

**8.5 Equitable Relief.** Nothing in this Article 8 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a

temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute prior to any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

**8.6 Excluded Matters.** Notwithstanding Sections 8.2 through 8.4, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent shall be submitted to a court of competent jurisdiction.

## **ARTICLE 9 PRIOR AGREEMENT**

### **9.1 Termination of Prior Inhaled Agreement.**

**(a)** Subject to Section 9.1(b), the Prior Inhaled Agreement is hereby terminated effective as of the Effective Date.

**(b)** Notwithstanding the termination of the Prior Inhaled Agreement pursuant to Section 9.1(a), the following sections of the Prior Inhaled Agreement shall survive as they relate to the time periods and activities to which the Prior Inhaled Agreement was applicable: Sections 5.3, 5.5(b), 5.6, 11.1, 11.3 (and, for clarity, such assignment obligations are not subject to, released by or otherwise affected by the first sentence of Section 9.2), 11.4 and 11.5(b) and Articles 1, 13, 14, 16, and 17.

**9.2 Release.** Each Party hereby irrevocably waives, releases and forever discharges the other Party and each of its Affiliates, predecessors, successors, present and former officers, directors, shareholders, servants, employees, workers, contractors, agents, sureties, representatives, attorneys and assigns (hereinafter, the “**Releasees**”) of and from and all actions, causes of action, claims, debts, defenses, disabilities, accounts, demands, damages, claims for indemnification, or contribution, costs, expenses, or fees whatsoever, whether arising in the United States or elsewhere, whether known or unknown, certain or speculative, arising out of any breach of contractual claim of the Prior Inhaled Agreement, or any tort or other cause of action of any kind whatsoever relating to any breach of the Prior Inhaled Agreement, prior to the date hereof. Notwithstanding the foregoing in this Section 9.2, this Agreement does not settle, release, or compromise any claim by either Party for any (a) intentional breach of confidentiality, non-use, or non-disclosure obligations under Article 14 of the Prior Inhaled Agreement, or (b) right, title, or interest in and to any Collaboration Know-How (as defined in the Prior Inhaled Agreement) to which such Party is entitled pursuant to Section 11.3 of the Prior Inhaled Agreement.

## **ARTICLE 10 MISCELLANEOUS**

**10.1 Entire Agreement; Amendment.** This Agreement, the surviving terms of the Prior Inhaled Agreement, and the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof. No subsequent alteration, amendment, change



**10.4 No Strict Construction; Headings.** This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

**10.5 Assignment.**

(a) Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other (not to be unreasonably withheld or delayed), except that a Party may make such an assignment without the other Party's consent to (i) an Affiliate (for so long as such entity remains an Affiliate) or (ii) a Third Party in connection with a Change of Control of such Party (such Third Party, an "**Acquiror**"). Any successor or assignee of rights or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 10.5 shall be null, void and of no legal effect.

(b) In the event that a Party undergoes a Change of Control, all intellectual property rights owned or otherwise controlled by the Acquiror or its Affiliates at any time (excluding the Party hereto that becomes an Affiliate of the Acquiror as a result of such transaction) shall be excluded from the licenses granted under this Agreement (including any such intellectual property owned or otherwise controlled by such Acquiror as of the date of consummation of such transaction but not acquired as a result of the transaction), except for any intellectual property rights generated or owned by the Acquiror or its Affiliates pursuant to the term of this Agreement in performing any activity under this Agreement.

**10.6 Performance by Affiliates.** Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

**10.7 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**10.8 Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**10.9 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

**10.10 Independent Contractors.** Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

**10.11 English Language; Governing Law.** This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of Delaware, without giving effect to any choice of law principles that would require the application of the laws of a different state.

**10.12 Counterparts.** This Agreement may be executed in one (1) or more counterparts, by original, facsimile or PDF signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

{Signature page follows}

IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized officers as of the Effective Date.

**GLAXO GROUP LIMITED**

**LIQUIDIA TECHNOLOGIES, INC.**

By: /s/ Marcus Dowding

By: /s/ Roger Jeffs

Name: Marcus Dowding

Name: Roger Jeffs

Title: Authorised Signatory, Corporate Director

Title: CEO

**EXHIBIT A**  
**LIQUIDIA PATENTS**

<b>Title</b>	<b>Application No.</b>	<b>Application Date</b>	<b>Patent No</b>	<b>Jurisdiction</b>	<b>Entity with Ownership Interest</b>
METHODS AND MATERIALS FOR FABRICATING LAMINATE NANOMOLDS AND NANOPARTICLES THEREFROM	11/633763	12/4/2006	8128393	US	Liquidia Technologies, Inc.
	200780050904.3	12/4/2007	101668594	CN	
	201410061019.7	12/4/2007	103831914	CN	
	14111960.7	11/27/2014	1198474	HK	
	18112880.8	10/10/2018	PENDING	HK	
	07874162.6	12/4/2007	2117725	DE, FR, GB	
	17194942.3	10/5/2017	PENDING	EP	
	2009-540277	12/4/2007	5921798	JP	
	2012-185449	8/24/2012	5680597	JP	
	2014-180817	9/5/2014	6069272	JP	
	10-2009-7013846	12/4/2007	10-1507816	KR	
	10-2014-7011301	12/4/2007	10-1507805	KR	
	10-2014-7033229	12/4/2007	10-1557030	KR	
	13/354046	1/19/2012	8439666	US	
	13/834454	3/15/2013	8662878	US	
	14/157971	1/17/2014	8945441	US	
	14/574543	12/18/2014	9340001	US	
	15/138831	4/26/2016	9662809	US	
15/605746	5/25/2017	10717209	US		

<b>Title</b>	<b>Application No.</b>	<b>Application Date</b>	<b>Patent No</b>	<b>Jurisdiction</b>	<b>Entity with Ownership Interest</b>
NANOSTRUCTURED SURFACES FOR BIOMEDICAL/BIOMATERIAL APPLICATIONS AND PROCESSES THEREOF	12/087374	1/4/2007	8944804	US	Liquidia Technologies, Inc.
	14/572895	12/17/2014	9314548	US	
SYSTEM AND METHOD FOR PRODUCING PARTICLES AND PATTERNED FILMS	12/250461	10/13/2008	7976759	US	Liquidia Technologies, Inc.
	200880120295.9	10/13/2008	101896337	CN	
	201310435322.4	10/13/2008	103660089	CN	
	08838460.7	10/13/2008	2207670	FR, DE, IE, CH, GB	
	2648/CHENP/2010	10/13/2008	316962	IN	
	2010-529144	10/13/2008	5604301	JP	
	2014-150037	7/23/2014	5869630	JP	
	2015-224693	11/17/2015	6383343	JP	
	11100331.5	1/13/2011	1146018 B	HK	
	14109535.7	9/23/2014	1196108	HK	
	13/156147	6/8/2011	8518316	US	
	13/950447	7/25/2013	9545737	US	
DEGRADABLE COMPOUNDS AND METHODS OF USE THEREOF, PARTICULARLY WITH PARTICLE REPLICATION IN NON-WETTING-TEMPLATES	12/989315	4/24/2009	8945527	US	Liquidia Technologies, Inc. and The University of North Carolina at Chapel Hill

Title	Application No.	Application Date	Patent No	Jurisdiction	Entity with Ownership Interest
METHOD FOR PRODUCING PATTERNED MATERIALS	12/630569	12/3/2009	8444907	US	Liquidia Technologies, Inc.
	PI0923282-6	12/3/2009	PI0923282-6	BR	
	200980156363.1	12/3/2009	102301463	CN	
	201410371325	12/3/2009	104162947	CN	
	12106128.8	6/21/2012	1165612	HK	
	15104672	5/18/2015	1203901	HK	
	10-2011-7015316	12/3/2009	10-1690643	KR	
	10-2016-7035942	12/3/2009	10-1880582	KR	
	MX/a/2011/005900	12/3/2009	340875	MX	
	MX/a/2016/009492	12/3/2009	366510	MX	
	09831124.4	12/3/2009	2370998	BE, FR, DE, IE, NL, CH, GB	
	13/867413	4/22/2013	9205594	US	
14/937158	11/10/2015	9744715	US		
ENGINEERED AEROSOL PARTICLES AND ASSOCIATED METHODS	2014-182213	9/8/2014	6189807	JP	Liquidia Technologies, Inc. and The University of North Carolina at Chapel Hill
PHOTOCURABLE PERFLUOROPOLYETHERS FOR USE AS NOVEL MATERIALS IN MICROFLUIDIC DEVICES	10/572764	9/23/2004	8268446	US	The University of North Carolina at Chapel Hill, California Institute of
	2004276302	9/23/2004	2004276302	AU	
	2540035	9/23/2004	2540035	CA	
	200480034620.1	9/23/2004	200480034620	CN	
	04784924.5	9/23/2004	1694731	EP	
	08100301.6	9/23/2004	1106262	HK	
	2212/DELNP/2006	9/23/2004	261330	IN	
	2006-527164	9/23/2004	4586021	JP	
	2006/003201	9/23/2004	299945	MX	
	2006018757.6	9/23/2004	120640	SG	

<b>Title</b>	<b>Application No.</b>	<b>Application Date</b>	<b>Patent No</b>	<b>Jurisdiction</b>	<b>Entity with Ownership Interest</b>
					Technology, and North Carolina State University
METHODS FOR FABRICATING ISOLATED MICRO- AND NANOSTRUCTURES USING SOFT OR IMPRINT LITHOGRAPHY	10/583570	12/20/2004	8263129	US	The University of North Carolina at Chapel Hill
	2004318602	12/20/2004	2004318602	AU	
	PI0417848-3	12/20/2004	PI0417848-3	BR	
	2549341	12/20/2004	2549341	CA	
	2847260	12/20/2004	2847260	CA	
	200480041942.9	12/20/2004	101147239	CN	
	04821787.1	12/20/2004	1704585	EP	
	17156921.3	12/20/2004	PENDING	EP	
	07103263.7	12/20/2004	1095921	HK	
	176254	12/20/2004	176254	IL	
	245063	12/20/2004	245063	IL	
	3991/DELNP/2006	12/20/2004	316353	IN	
	2006545541	12/20/2004	6067954	JP	
	2011-104856	12/20/2004	5956116	JP	
	2014-054051	12/20/2004	6232320	JP	
	2014-161427	12/20/2004	6232352	JP	
10-2006-7012179	12/20/2004	10-1281775	KR		

<b>Title</b>	<b>Application No.</b>	<b>Application Date</b>	<b>Patent No</b>	<b>Jurisdiction</b>	<b>Entity with Ownership Interest</b>
	10-2014-7018393	12/20/2004	10-2005840	KR	
	PA/A/2006/006738	12/20/2004	266246	MX	
	200603890-5	12/20/2004	123152	SG	
	2006/04885	12/20/2004	ACCEPTANCE PROCEEDING	ZA	
	11/825469	7/6/2007	8420124	US	
	13/852683	3/28/2013	8992992	US	
	14/658386	3/16/2015	9877920	US	
	15/846827	12/19/2017	10517824	US	
	16/689733	11/20/2019	10842748	US	
	17/095301	11/11/2020	PENDING	US	
METHODS AND MATERIALS FOR FABRICATING MICROFLUIDIC DEVICES	12/063284	8/9/2006	8158728	US	The University of North Carolina at Chapel Hill and Liquidia Technologies, Inc.
	13/438431	4/3/2012	8444899	US	The University of North Carolina at Chapel Hill
NANOPARTICLE FABRICATION METHODS, SYSTEMS, AND MATERIALS	2006282042	6/19/2006	2006282042	AU	The University of North Carolina at Chapel Hill
	2611985	6/19/2006	2611985	CA	

<b>Title</b>	<b>Application No.</b>	<b>Application Date</b>	<b>Patent No</b>	<b>Jurisdiction</b>	<b>Entity with Ownership Interest</b>
	200680029884.7	6/19/2006	102016814	CN	
	MX/A/2007/016039	6/19/2006	295862	MX	
ISOLATED AND FIXED MICRO AND NANO STRUCTURES AND METHODS THEREOF	11/594023	11/7/2006	9040090	US	The University of North Carolina at Chapel Hill
	14/704047	5/5/2015	9902818	US	
HIGH FIDELITY NANO-STRUCTURES AND ARRAYS FOR PHOTOVOLTAICS AND METHODS OF MAKING THE SAME	13/787134	3/6/2013	9214590	US	The University of North Carolina at Chapel Hill
	10-2015-7002658	5/9/2007	10-1564390	KR	
NANOPARTICLE FABRICATION METHODS, SYSTEMS, AND MATERIALS	13/918322	6/11/2013	8685461	US	The University of North Carolina at Chapel Hill
NANOPARTICLE FABRICATION METHODS, SYSTEMS AND MATERIALS FOR FABRICATING ARTIFICIAL RED BLOOD CELLS	12/374182	7/27/2007	8465775	US	The University of North Carolina at Chapel Hill
	13/904517	5/24/2013	9381158	US	

<b>Title</b>	<b>Application No.</b>	<b>Application Date</b>	<b>Patent No</b>	<b>Jurisdiction</b>	<b>Entity with Ownership Interest</b>
	15/198081	6/30/2016	9724305	US	
DEGRADABLE COMPOUNDS AND METHODS OF USE THEREOF, PARTICULARLY WITH PARTICLE REPLICATION IN NON-WETTING-TEMPLATES	12/989315	4/24/2009	8945527	US	The University of North Carolina at Chapel Hill
ASYMMETRIC BIFUNCTIONAL SILYL MONOMERS AND PARTICLES THEREOF AS PRODRUGS AND DELIVERY VEHICLES FOR PHARMACEUTICAL, CHEMICAL AND BIOLOGICAL AGENTS	14/482624	9/10/2014	9457098	US	The University of North Carolina at Chapel Hill
	15/283574	10/3/2016	9913916	US	

## EXHIBIT B

### GSK RETAINED PRODUCTS

Anoro Ellipta (umeclidinium and vilanterol)  
Arnuity Ellipta (fluticasone)  
Flixotide / Flovent - Diskus / MDI (fluticasone propionate)  
Relvar/Breo (fluticasone furoate/vilanterol)  
Seretide / Advair - Diskus / MDI (salmeterol xinafoate, fluticasone propionate)  
Serevent - Diskus / MDI (salmeterol xinafoate)  
Trelegy – Ellipta (fluticasone furoate, umeclidinium, and vilanterol inhalation powder)  
Ventolin - Diskus / MDI (salbutamol)  
GSK3923868 – PI4K beta inhibitor

**FIRST AMENDMENT TO THE REVENUE INTEREST FINANCING AGREEMENT**

This **FIRST AMENDMENT TO THE REVENUE INTEREST FINANCING AGREEMENT**, dated as of April 17, 2023 (this "Amendment"), is entered into by and among Liquidia Technologies, Inc., a Delaware corporation (the "Company"), Healthcare Royalty Partners IV, L.P., a Delaware limited liability partnership (the "Investor"), and HCR Collateral Management, LLC, a Delaware limited liability company (the "Investor Representative"), and solely in its capacity as agent for, and representative of, the Investor, solely with respect to certain enumerated provisions in the Agreement (as defined below) described herein. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Agreement.

WHEREAS, the Parties entered into that certain Revenue Interest Financing Agreement, dated as of January 9, 2023 (as amended prior to the date hereof, the "Agreement");

WHEREAS, the Parties desire to effect the amendments to the Agreement contemplated by this Amendment;

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. **Amendment to Article IV.** Article IV of the Agreement is hereby amended by adding the following as Section 4.29:

“Section 4.29 Investment Company Act. No member of the Company Group is required to be registered as an “investment company” under the Investment Company Act of 1940, as amended.”

2. **Amendment to Article VII.** Article VII of the Agreement is hereby amended by adding the following as Section 7.14:

“Section 7.14 Compliance. Become required to register as an “investment company” under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Investment Amount for that purpose.”

3. **Amendment to Section 8.6(c)(ii).** Section 8.6(c)(ii) of the Agreement is hereby amended and restated in its entirety as follows:

“(ii) A certificate of a Responsible Officer of the Company (A) certifying that the information and documents provided to the Investor Representative with the Second Closing Notice are true and correct; and (B) no Bankruptcy Event with respect to any member of the Company Group and no Special Termination Event, Change of Control, Default or Event of Default has occurred and is continuing; and”

4. **Amendment to Section 8.6(d)(ii).** Section 8.6(d)(ii) of the Agreement is hereby amended and restated in its entirety as follows:

“(ii) A certificate of a Responsible Officer of each member of the Company Group (A) certifying that, (1) the information and documents provided to the Investor Representative with the Third Closing Notice are true and correct and (2) as applicable, (x) the Favorable Determination has

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occurred, (y) the Insurance Policy is in effect, or (z) the Parties have mutually agreed to the Third Investment Amount; (B) attaching copies, certified by such officer as true and complete, of documents sufficient to evidence that the event indicated with respect to clause (A) has occurred; and (C) certifying that no Bankruptcy Event with respect of its Subsidiaries and no Special Termination Event, Change of Control, Default or Event of Default has occurred and is continuing;”

5. **Representations and Warranties.** To induce the Investor Representative and the Investor to enter into this Amendment, each of the Company and each other member of the Company Group represents and warrants to the Investor Representative and the Investors that, as of the date of this Amendment, (a) the execution, delivery and performance by each Company Party of this Amendment are within each such Company Party’s power and authority, and the execution, delivery and performance of this Amendment by each Company Party have been duly authorized by each Company Party, (b) the execution and delivery of this Amendment by each Company Party will not (i) contravene, conflict with, result in a breach, violation, cancellation or termination of, constitute a default (with or without notice or lapse of time, or both) under, require prepayment under, give any Person the right to exercise any remedy (including termination, cancellation or acceleration) or obtain any additional rights under, or accelerate the maturity or performance of or payment under, in any respect, (A) any Applicable Law or any judgment, order, writ, decree, Permit or license of any Governmental Authority to which any member of the Company Group or any of their respective assets or properties may be subject or bound, (B) any term or provision of any contract, agreement, indenture, lease, license, deed, commitment, obligation or instrument to which any member of the Company Group is a party or by which any member of the Company Group or any of their respective assets or properties is bound or committed (other than a Material Contract), (C) any Material Contract or (D) any term or provision of any of the organizational documents of any member of the Company Group, except in the case of clause (A) or (B) where any such event would not reasonably be expected to result in a Material Adverse Effect or (ii) except as provided in any of the Transaction Documents to which it is party, result in or require the creation or imposition of any Lien on the Collateral (in each case other than Permitted Liens), (c) this Amendment has been duly executed and delivered by each Company Party and constitutes the legal, valid and binding obligation of each such Company Party, enforceable against each such Company Party in accordance with its respective terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or similar Applicable Laws affecting creditors’ rights generally, general equitable principles and principles of public policy, and (d) no Bankruptcy Event with respect to any member of the Company Group or any Special Termination Event, Change of Control, Default or Event of Default has occurred and is continuing.

6. **Effect on Agreement.** Upon the execution and delivery of this Amendment by the Parties, the Agreement shall be amended and/or restated as hereinabove set forth as fully and with the same effect as if the amendments made hereby were originally set forth in the Agreement, and this Amendment and the Agreement shall henceforth respectively be read, taken and construed as one and the same instrument, but such amendments shall not operate so as to render invalid or improper any action heretofore taken under the Agreement. No representation, inducement, promise, understanding, condition or warranty not set forth herein (or in Exhibits hereto or the other Transaction Documents) has been made or relied upon by either Party hereto.

7. **Agreement in Effect.** Except as specifically provided for in this Amendment, the Agreement shall remain unmodified and in full force and effect.

8. **Headings.** The headings of the Articles and Sections of this Amendment have been inserted for convenience of reference only, are not to be considered a part hereof and shall in no way modify or restrict any of the terms or provisions hereof.

9. **Other Miscellaneous Terms.** The provisions of Article XII of the Agreement (other than Section 12.6, Section 12.10 and Section 12.13 of the Agreement) shall apply *mutatis mutandis* to this Amendment, and to the Agreement as modified by this Amendment, taken together as a single agreement, reflecting the terms therein as modified hereby.

10. **Counterparts.** This Amendment may be executed in counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. This Amendment and any amendments hereto, to the extent signed and delivered by means of digital imaging and electronic mail, shall be treated in all manner and respects as an original contract and shall be considered to have the same binding legal effects as if it were the original signed version thereof delivered in person.

11. **Entire Agreement; Conflicts.** This Amendment, the Agreement and the other documents and instruments referred to herein and therein constitute the entire agreement among the Parties and supersede any prior understandings, agreements or representations by or among the Parties, written or oral, that may have related in any way to the subject matter hereof. In the event of any conflict between the terms and provisions of this Amendment and any Transaction Document, the terms and provisions of this Amendment shall control.

12. **Reaffirmation by the Company Parties.** Each Company Party party hereto hereby consents to the amendments of the Agreement effected hereby and confirms and agrees that, notwithstanding the effectiveness of this Amendment, each Transaction Document to which such Company Party is a party is, and the obligations of such Company Party contained in the Agreement, this Amendment or in any other Transaction Document to which it is a party are, and shall continue to be, in full force and effect and are hereby ratified and confirmed in all respects, in each case, as amended by this Amendment. For greater certainty and without limiting the foregoing, each Company Party hereby confirms that the security interests granted by such Company Party in favor of the Investor Representative and the Investor pursuant to the Transaction Documents in the Collateral described therein remain in full force and effect, are not released or reduced and shall continue to secure the Obligations and the Secured Obligations (as defined in the Security Agreement).

*[Remainder of page intentionally left blank.]*

**IN WITNESS WHEREOF**, the Parties have duly executed this Amendment as of the date first written above.

**THE COMPANY:**

LIQUIDIA TECHNOLOGIES, INC.

By: /s/ Roger Jeffs  
Name: Roger Jeffs  
Title: CEO

*[Signature Page to First Amendment to the Revenue Interest Financing Agreement]*

4866-7599-0618v.2

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**INVESTOR:**

HEALTHCARE ROYALTY PARTNERS IV, L.P.

By: HealthCare Royalty GP IV, LLC,  
its general partner

By: /s/ Clarke B. Futch  
Name: Clarke B. Futch  
Title: Managing Partner

**INVESTOR REPRESENTATIVE:**

HCR COLLATERAL MANAGEMENT, LLC

By: /s/ Clarke B. Futch  
Name: Clarke B. Futch  
Title: Managing Partner

*[Signature Page to First Amendment to the Revenue Interest Financing Agreement]*

Acknowledged and Agreed,

**LIQUIDIA CORPORATION**

By: /s/ Roger Jeffs  
Name: Roger Jeffs  
Title: CEO

**LIQUIDIA PAH, LLC**

By: /s/ Roger Jeffs  
Name: Roger Jeffs  
Title: CEO

*[Signature Page to First Amendment to the Revenue Interest Financing Agreement]*

4866-7599-0618v.2

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**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Roger A. Jeffs, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Liquidia Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2023

By: /s/ Roger A. Jeffs, Ph.D.  
Name: Roger A. Jeffs, Ph.D.  
Title: Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael Kaseta, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Liquidia Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2023

By: /s/ Michael Kaseta  
Name: Michael Kaseta  
Title: Chief Financial Officer  
(Principal Financial Officer)

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**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Liquidia Corporation, a Delaware corporation (the "Company"), on Form 10-Q for the three months ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Roger A. Jeffs, Ph.D., Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 8, 2023

By: /s/ Roger A. Jeffs, Ph.D.  
Name: Roger A. Jeffs, Ph.D.  
Title: Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Liquidia Corporation, a Delaware corporation (the “Company”), on Form 10-Q for the three months ended March 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Michael Kaseta, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 8, 2023

By: /s/ Michael Kaseta

Name: Michael Kaseta

Title: Chief Financial Officer  
(Principal Financial Officer)

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