**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 June 30, 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**<br>**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 August 1, 2023, there were 64,741,096 shares of the registrant's common stock outstanding.

**LIQUIDIA CORPORATION**



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 Corporation ("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 or any future patent litigation with United Therapeutics or any other third party; (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"); and (iv) the timing and our ability to obtain and maintain regulatory approval for L606, an investigational, liposomal formulation of treprostinil that we licensed from Pharmosa Biopharm Inc. ("Pharmosa"); and (iv) our ability to continue operations as a going concern without obtaining additional funding;
- our ability to predict, foresee, and effectively address or mitigate future developments resulting from health epidemics, such as 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 treprostinil 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 Smiths 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 treprostinil injection, Smiths Medical's CADD Legacy and CADD-Solis infusion pumps used for the intravenous administration of Sandoz's generic treprostinil injection, the infusion pump that we are developing with Sandoz and Mainbridge for the subcutaneous administration of Sandoz's generic treprostinil injection, Plastiape's RS00 Model 8 dry powder inhaler, which we plan to use for the administration of YUTREPIA and any devices used for the administration of L606;
- 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, the litigation arising from United Therapeutics' claim that we and a former employee misappropriated trade secrets from United Therapeutics and any future litigation with United Therapeutics or any other third party;
- the effects on our company or our subsidiaries 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 on Form 10-Q 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 on Form 10-Q. 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)**

| | June 30, 2023 | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 88,196 | $ 93,283 |
| Accounts receivable, net | 4,095 | 5,017 |
| Prepaid expenses and other current assets | 601 | 1,511 |
| Total current assets | 92,892 | 99,811 |
| Property, plant and equipment, net | 4,171 | 4,151 |
| Operating lease right-of-use assets, net | 1,914 | 2,101 |
| Indemnification asset, related party | 6,696 | 6,595 |
| Contract acquisition costs, net | 8,207 | 8,604 |
| Intangible asset, net | 3,554 | 3,726 |
| Goodwill | 3,903 | 3,903 |
| Other assets | 260 | 307 |
| Total assets | $ 121,597 | $ 129,198 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,918 | $ 2,197 |
| Accrued expenses and other current liabilities | 14,767 | 5,522 |
| Revenue interest financing payable, current | 1,741 | — |
| Operating lease liabilities, current | 965 | 900 |
| Finance lease liabilities, current | 104 | 181 |
| Total current liabilities | 19,495 | 8,800 |
| Litigation finance payable | 6,695 | 6,594 |
| Revenue interest financing payable, noncurrent | 31,799 | — |
| Operating lease liabilities, noncurrent | 2,833 | 3,332 |
| Finance lease liabilities, noncurrent | 118 | 171 |
| Long-term debt | — | 19,879 |
| Total liabilities | 60,940 | 38,776 |
| Commitments and contingencies (Note 13) | | |
| Stockholders' equity: | | |
| Preferred stock — 10,000,000 shares authorized, none outstanding | — | — |
| Common stock — $0.001 par value, 100,000,000 and 80,000,000 shares authorized as of June 30, 2023 and December 31, 2022, respectively, 64,740,382 and 64,517,912 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively | 65 | 64 |
| Additional paid-in capital | 446,450 | 440,954 |
| Accumulated deficit | (385,858) | (350,596) |
| Total stockholders' equity | 60,657 | 90,422 |
| Total liabilities and stockholders' equity | $ 121,597 | $ 129,198 |

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)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Revenue | $ 4,786 | $ 3,918 | $ 9,279 | $ 7,410 |
| Costs and expenses: | | | | |
| Cost of revenue | 671 | 731 | 1,325 | 1,425 |
| Research and development | 17,695 | 5,219 | 22,973 | 9,947 |
| General and administrative | 9,245 | 6,938 | 17,038 | 19,480 |
| Total costs and expenses | 27,611 | 12,888 | 41,336 | 30,852 |
| Loss from operations | (22,825) | (8,970) | (32,057) | (23,442) |
| Other income (expense): | | | | |
| Interest income | 734 | 65 | 1,656 | 69 |
| Interest expense | (1,426) | (542) | (2,550) | (1,020) |
| Loss on extinguishment of debt | — | — | (2,311) | (997) |
| Total other expense, net | (692) | (477) | (3,205) | (1,948) |
| Net loss and comprehensive loss | $ (23,517) | $ (9,447) | $ (35,262) | $ (25,390) |
| Net loss per common share, basic and diluted | $ (0.36) | $ (0.15) | $ (0.54) | $ (0.44) |
| Weighted average common shares outstanding, basic and diluted | 64,788,482 | 62,179,305 | 64,722,818 | 57,349,129 |

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 |
|---|---|---|---|---|---|
| **Balance as of December 31, 2022** | 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) |
| **Balance as of March 31, 2023** | 64,710,444 | $ 65 | $ 443,919 | $ (362,341) | $ 81,643 |
| Issuance of common stock upon exercise of stock options | 10,173 | — | 32 | — | 32 |
| Issuance of common stock upon vesting of restricted stock units | 19,765 | — | — | — | — |
| Stock-based compensation | — | — | 2,499 | — | 2,499 |
| Net loss | — | — | — | (23,517) | (23,517) |
| **Balance as of June 30, 2023** | 64,740,382 | $ 65 | $ 446,450 | $ (385,858) | $ 60,657 |

| | Common Stock Shares | Common Stock Amount | Additional Paid in Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|
| **Balance as of December 31, 2021** | 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) |
| **Balance as of March 31, 2022** | 53,054,158 | $ 53 | $ 380,860 | $ (325,524) | $ 55,389 |
| Issuance of common stock upon exercise of stock options | 364 | — | 1 | — | 1 |
| Issuance of common stock upon vesting of restricted stock units | 17,496 | — | — | — | — |
| Sale of common stock, net | 11,274,510 | 11 | 54,450 | — | 54,461 |
| Stock-based compensation | — | — | 1,703 | — | 1,703 |
| Net loss | — | — | — | (9,447) | (9,447) |
| **Balance as of June 30, 2022** | 64,346,528 | $ 64 | $ 437,014 | $ (334,971) | $ 102,107 |

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

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2023 | 2022 |
| **Operating activities** | | |
| Net loss | $ (35,262) | $ (25,390) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Acquired in-process research and development | 10,000 | — |
| Stock-based compensation | 5,051 | 5,832 |
| Depreciation and amortization | 1,158 | 1,953 |
| Non-cash lease expense | 187 | 146 |
| Loss (gain) on disposal of property and equipment | (2) | 1 |
| Loss on extinguishment of debt | 2,311 | 997 |
| Non-cash interest expense (income) | 2,376 | 109 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | 922 | (763) |
| Prepaid expenses and other current assets | 760 | (115) |
| Other noncurrent assets | 47 | 4 |
| Accounts payable | (380) | 111 |
| Accrued expenses and other current liabilities | (755) | (721) |
| Operating lease liabilities | (434) | (375) |
| Net cash used in operating activities | (14,021) | (18,211) |
| **Investing activities** | | |
| Purchases of property, plant and equipment | (609) | (7) |
| Proceeds from the sale of property, plant and equipment | 2 | 5 |
| Net cash used in investing activities | (607) | (2) |
| **Financing activities** | | |
| 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) | — |
| Payments on revenue interest financing liability | (500) | — |
| Proceeds from issuance of long-term debt with warrants, net | — | 19,767 |
| Principal payments on finance leases | (130) | (160) |
| Receipts from litigation financing | 101 | 369 |
| Proceeds from sale of common stock, net of underwriting fees and commissions | — | 54,461 |
| Proceeds from issuance of common stock under stock incentive plans | 446 | 622 |
| Net cash provided by financing activities | 9,541 | 64,559 |
| Net increase (decrease) in cash and cash equivalents | (5,087) | 46,346 |
| Cash and cash equivalents, beginning of period | 93,283 | 57,494 |
| Cash and cash equivalents, end of period | $ 88,196 | $ 103,840 |
| **Supplemental disclosure of cash flow information** | | |
| Cash paid for interest | $ 360 | $ 650 |
| Cash paid for operating lease liabilities | $ 637 | $ 619 |
| Non-cash increase in indemnification asset through accounts payable | $ 101 | $ 231 |

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 treprostinil injection ("Treprostinil Injection") in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil 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 Treprostinil 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 treprostinil designed with PRINT to improve the therapeutic profile of treprostinil 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 an amendment to our NDA to treat patients with pulmonary hypertension and interstitial lung disease (PH-ILD) upon the expiration of regulatory exclusivity in March 2024. We filed an amendment to our NDA to include PH-ILD as a labelled indication on July 24, 2023.

We are also developing L606, an investigational, liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer, which we licensed from Pharmosa. L606 is currently being evaluated in an open-label study in the United States for treatment of PAH with a planned pivotal study for the treatment of PH-ILD.

### 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 believes 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.

**Recent Events**

***License Agreement with Pharmosa Biopharm***

In June 2023, we entered into a License Agreement with Pharmosa Biopharm Inc (“Pharmosa”) pursuant to which we were granted an exclusive license in North America to develop and commercialize L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a clinical trial for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD), and a non-exclusive license for the manufacture, development and use (but not commercialization) of such licensed product in most countries outside North America (the “Pharmosa License Agreement”).

Under the terms of the Pharmosa License Agreement, we will be responsible for development, regulatory and commercial activities of L606 in North America. Pharmosa will manufacture clinical and commercial supplies of the liposomal formulation through its global supply chain and support us in establishing a redundant global supply chain. In consideration for these exclusive rights, we paid Pharmosa an upfront license fee of $10 million and will pay Pharmosa potential development milestone payments tied to PAH and PH-ILD indications of up to $30 million, potential sales milestones of up to $185 million and two tiers of low, double-digit royalties on net sales of L606. Pharmosa will also receive a $10 million milestone payment for each additional indication approved after PAH and PH-ILD and each additional product approved under the license. We also retain the first right to negotiate for development and commercialization of L606 in Europe and other territories should Pharmosa seek a partner, subject to satisfaction of certain conditions as set forth in the Pharmosa License Agreement.

Concurrently with the execution of the Pharmosa License Agreement, we also entered into an Asset Transfer Agreement with Pharmosa pursuant to which Pharmosa will transfer its physical materials so that we can perform the necessary actions contemplated under the Pharmosa License Agreement.

***Second and Third Amendments to Revenue Interest Financing Agreement***

In June 2023 and July 2023, we entered into a Second Amendment and Third Amendment, respectively, to the Revenue Interest Financing Agreement (“RIFA”) with HealthCare Royalty Partners IV, L.P. (“HCR”), pursuant to which HCR moved $2.5 million from the fourth tranche to the second tranche such that HCR would fund a total of $10.0 million of the Investment Amount (as defined in the RIFA) under the second tranche. The $10.0 million was funded on July 27, 2023 and was used for the upfront license fee due to Pharmosa in connection with the transactions contemplated by the Pharmosa License Agreement. In addition, pursuant to the amendments, the third tranche of $35.0 million and fourth tranche of $22.5 million will now be funded only upon the mutual agreement of both HCR and us.

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

**Basis of Presentation**

The unaudited interim condensed consolidated financial statements as of June 30, 2023 and for the three and six months ended June 30, 2023 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 and six months ended June 30, 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 2022 Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (the "2022 Annual Report on Form 10-K").

***Going Concern***

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.

Since inception, we have incurred recurring losses, including a net loss of $35.3 million for the six months ended June 30, 2023 and we had an accumulated deficit of $385.9 million as of June 30, 2023. 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. Additionally, the RIFA contains minimum cash covenants 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. These conditions raise substantial doubt regarding our ability to continue as a going concern within one year after the date these consolidated condensed financial statements are issued.

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 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 have based these estimates on assumptions that may differ from actual results, and we could use our available resources sooner than expected. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates. If we conclude that we require additional funding but are unable to obtain such 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, or we may be unable to continue operations.

***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 six months ended June 30, 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 six months ended June 30, 2023, there were no newly adopted accounting pronouncements that had a material impact on our condensed consolidated financial statements. As of June 30, 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 June 30, 2023 and December 31, 2022. As of June 30, 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.

As of June 30, 2023, we concluded there were no events or changes in circumstances which indicated that the carrying amount of goodwill was not recoverable. We completed our annual impairment test as of July 1, 2023 and concluded that no impairments had occurred.

***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.

***Research and Development Expense***

Research and development costs are expensed as incurred and include direct costs incurred to third parties related to the salaries of, and stock-based compensation for, personnel involved in research and development activities, contractor fees, administrative expenses and allocations of research-related overhead costs. Administrative expenses and research-related overhead costs included in research and development expense consist of allocations of facility and equipment lease charges, depreciation and amortization of assets and insurance directly related to research and development activities. In-process research and development assets with no future alternative use acquired are expensed under the in accordance with ASC 730, *Research and Development.*

***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 share excludes the following common stock equivalent shares:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Stock Options | 9,506,827 | 7,131,419 | 9,454,756 | 7,093,120 |
| Restricted Stock Units | 1,773,919 | 401,035 | 1,682,701 | 383,307 |
| Warrants | 450,000 | 450,000 | 450,000 | 440,331 |
| Total | 11,730,746 | 7,982,454 | 11,587,457 | 7,916,758 |

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 as 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. The following table presents the placement in the fair value hierarchy of financial assets and liabilities measured at fair value as of June 30, 2023 and December 31, 2022:

| June 30, 2023 | 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) | $ 82,270 | $ — | $ — | $ 82,270 |

| 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) | $ 92,283 | $ — | $ — | $ 92,283 |

Money market funds are included in cash and cash equivalents on our 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:

| | June 30, 2023 | December 31, 2022 |
|---|---|---|
| Lab and build-to-suit equipment | $ 6,603 | $ 6,257 |
| Office equipment | 19 | 19 |
| Furniture and fixtures | 134 | 134 |
| Computer equipment | 457 | 291 |
| Leasehold improvements | 11,409 | 11,409 |
| Construction-in-progress | 252 | 155 |
| Total property, plant and equipment | 18,874 | 18,265 |
| Accumulated depreciation and amortization | (14,703) | (14,114) |
| Property, plant and equipment, net | $ 4,171 | $ 4,151 |

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 June 30, 2023 and 2022, respectively, and of $0.6 million and $0.8 million for the six months ended June 30, 2023 and 2022, respectively.

**4. Contract Acquisition Costs and Intangible Asset**

Contract acquisition costs and intangible asset are summarized as follows:

| | June 30, 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 | $ (4,773) | $ 8,207 | $ 12,980 | $ (4,376) | $ 8,604 |
| Intangible asset | $ 5,620 | $ (2,066) | $ 3,554 | $ 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 June 30, 2023 and 2022, respectively, and of $0.4 million and $0.8 million for the six months ended June 30, 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 June 30, 2023 and 2022, respectively, and of $0.2 million and $0.3 million for the six months ended June 30, 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 August 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 June 30, 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 June 30, 2024.

**6. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following:

| | June 30, 2023 | December 31, 2022 |
|---|---|---|
| Accrued compensation | $ 2,191 | $ 2,862 |
| Accrued research and development expenses | 1,181 | 1,757 |
| Accrued upfront license fee | 10,000 | — |
| Accrued other expenses | 1,395 | 903 |
| Total accrued expenses and other current liabilities | $ 14,767 | $ 5,522 |

**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 six months ended June 30, 2023 and 2022, no warrants to purchase shares of common stock were exercised.

Outstanding warrants consisted of the following as of June 30, 2023:

| | Number of warrants | Exercise Price | Expiration Date |
|---|---|---|---|
| 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 June 30, 2023, 209,087 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 June 30, 2023, a total of 669,576 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 June 30, 2023, a total of 21,650 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 June 30, 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 six months ended June 30, 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:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| **By Expense Category:** | **2023** | **2022** | **2023** | **2022** |
| Research and development | $ 578 | $ 337 | $ 1,159 | $ 720 |
| General and administrative | 1,921 | 1,310 | 3,892 | 5,112 |
| Total stock-based compensation expense | $ 2,499 | $ 1,647 | $ 5,051 | $ 5,832 |

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 June 30, 2023 | |
|---|---|---|
| | **Unamortized Expense** | **Weighted Average Remaining Recognition Period (Years)** |
| Stock options | $ 18,455 | 2.7 |
| Restricted stock units | $ 9,634 | 3.4 |

**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:

| | Six Months Ended June 30, | |
|---|---|---|
| | **2023** | **2022** |
| Expected dividend yield | — | — |
| Risk-free interest rate | 3.46% - 3.99% | 1.46% - 2.34% |
| Expected volatility | 91% - 95% | 90% - 93% |
| Expected life (years) | 5.8 - 6.1 | 5.8 - 6.1 |

The weighted average fair value for options granted during the six months ended June 30, 2023 and 2022 was $5.09 and $4.19 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:

| | Six Months Ended June 30, | |
|---|---|---|
| | 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 six months ended June 30, 2023:

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Contractual Term (in years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| **Outstanding as of December 31, 2022** | 8,398,262 | $ 4.49 | | |
| Granted | 1,373,746 | 6.56 | | |
| Exercised | (31,620) | 3.50 | | |
| Cancelled | (145,554) | 5.58 | | |
| **Outstanding as of June 30, 2023** | 9,594,834 | $ 4.77 | 8.2 | $ 30,939 |
| Exercisable as of June 30, 2023 | 4,817,133 | $ 4.34 | 7.6 | $ 18,171 |
| Vested and expected to vest as of June 30, 2023 | 9,264,881 | $ 4.77 | 8.2 | $ 29,949 |

The aggregate intrinsic value of stock options in the table above represents the difference between the $7.85 closing price of our common stock as of June 30, 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 June 30, 2023 and changes during the six months ended June 30, 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 | (109,569) | 6.00 |
| Forfeited | (56,034) | 6.22 |
| Unvested as of June 30, 2023 | 1,725,289 | $ 6.30 |

**9. Revenue From Contracts With Customers**

In August 2018, we entered into a Promotion Agreement with Sandoz under which 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 June 30, 2023, a $0.5 million refund liability is offset against accounts receivable from Sandoz related to expected refund amounts. Approximately 99% of revenue during three and six months ended June 30, 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 are 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 June 30, 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:

| | | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|---|
| | Classification | 2023 | 2022 | 2023 | 2022 |
| Operating lease cost: | | | | | |
| Fixed lease cost | Research and development | $ 175 | $ 175 | $ 351 | $ 351 |
| Fixed lease cost | General and administrative | 20 | 20 | 39 | 39 |
| Finance lease cost: | | | | | |
| Amortization of lease assets | Research and development | 22 | 36 | 52 | 74 |
| Interest on lease liabilities | Interest expense | 4 | 9 | 9 | 19 |
| Total Lease Cost | | $ 221 | $ 240 | $ 451 | $ 483 |

The weighted average remaining lease term and discount rates as of June 30, 2023 were as follows:

| | |
|---|---|
| Weighted average remaining lease term (years): | |
| Operating leases | 3.3 |
| Finance leases | 1.8 |
| 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 June 30, 2023 were as follows:

| Year ending December 31: | Operating Leases | Finance Leases | Total |
|---|---|---|---|
| 2023 (six months remaining) | $ 646 | $ 57 | $ 703 |
| 2024 | 1,317 | 115 | 1,432 |
| 2025 | 1,356 | 64 | 1,420 |
| 2026 | 1,158 | — | 1,158 |
| Total minimum lease payments | 4,477 | 236 | 4,713 |
| Less: interest | (679) | (14) | (693) |
| Present value of lease liabilities | $ 3,798 | $ 222 | $ 4,020 |

**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”) in four tranches. On January 27, 2023, $32.5 million of the Investment Amount was funded from the first tranche, $22.2 million of which was used to satisfy our existing obligations under the A&R SVB LSA (see Note 12).

On June 28, 2023 and July 27, 2023, we entered into the Second Amendment to the RIFA and Third Amendment to the RIFA, respectively, pursuant to which HCR moved $2.5 million from the fourth tranche to the second tranche such that HCR would fund a total of $10.0 million of the Investment Amount under the second tranche. The second tranche was funded on July 27, 2023. Additional tranches of $35.0 million (the “Third Investment Amount”) and $22.5 million (the “Fourth Investment Amount”) of the Investment Amount will be funded fifteen business days after the mutual agreement of HCR and us to fund such amounts.

As consideration for the Investment Amount and pursuant to the RIFA, we have agreed to pay HCR either quarterly fixed payments or a tiered royalty on our annual net revenue after the first commercial sale of YUTREPIA (the “Revenue Interests”) depending on whether the Third Investment Amount has been funded. The applicable tiered percentage will range from 3.60% to 10.28% on the first $250 million on annual net revenue, 1.44% to 4.11% on the next $250 million in annual net revenue, and 0.36% to 1.03% 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 Third Investment Amount has not been funded 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, or the occurrence of any 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 and six months ended June 30, 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 six months ended June 30, 2023:

| | June 30, 2023 |
|---|---|
| Balance as of January 27, 2023 closing | $ 32,500 |
| Issuance costs | (836) |
| Non-cash interest expense | 2,328 |
| Amortization of issuance costs | 48 |
| Payments | (500) |
| Balance as of June 30, 2023 | $ 33,540 |
| Less: current portion of revenue interest financing payable | (1,741) |
| Long-term portion of revenue interest financing payable | $ 31,799 |

**12. Long-Term Debt**

Long-term debt consisted of the following:

| | Maturity Date | June 30, 2023 | December 31, 2022 |
|---|---|---|---|
| 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 six months ended June 30, 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 six months ended June 30, 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**

**Pharmosa License Agreement and Asset Transfer Agreement**

In June 2023, we entered into a License Agreement with Pharmosa Biopharm Inc ("Pharmosa") pursuant to which we were granted an exclusive license in North America to develop and commercialize L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a clinical trial for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD), and a non-exclusive license for the manufacture, development and use (but not commercialization) of such licensed product in most countries outside North America (the "Pharmosa License Agreement").

Under the terms of the Pharmosa License Agreement, we will be responsible for development, regulatory and commercial activities of L606 in North America. Pharmosa will manufacture clinical and commercial supplies of the liposomal formulation through its global supply chain and support us in establishing a redundant global supply chain. In consideration for these exclusive rights, we will pay Pharmosa an upfront license fee of $10 million and will pay Pharmosa potential development milestone payments tied to PAH and PH-ILD indications of up to $30 million, potential sales milestones of up to $185 million and two tiers of low, double-digit royalties on net sales of L606. Pharmosa will also receive a $10 million milestone payment for each additional indication approved after PAH and PH-ILD and each additional product approved under the license. We also retain the first right to negotiate for development and commercialization of L606 in Europe and other territories should Pharmosa seek a partner, subject to satisfaction of certain conditions as set forth in the Pharmosa License Agreement.

Concurrently with the execution of the Pharmosa License Agreement, we also entered into an Asset Transfer Agreement with Pharmosa pursuant to which Pharmosa will transfer its inventory of physical materials.

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

In December 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.

**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 June 30, 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.

On July 14, 2023, we entered into an Amended and Restated Commercial Manufacturing Services and Supply Agreement with Lonza Tampa LLC ("Lonza") (the "CSA"). Lonza is our sole supplier for encapsulation and packaging services for YUTREPIA. Pursuant to the terms of the CSA, we will deliver bulk treprostinil powder, manufactured using our proprietary PRINT® technology, and Lonza will encapsulate and package it. The CSA is effective upon signing and will be in effect for an initial term of 5 years from receipt of regulatory approval of YUTREPIA by the FDA ("Regulatory Approval") absent termination by either party in accordance with the terms of the CSA. We may terminate the CSA upon 60 days' written notice to Lonza in the event that the application for regulatory approval is rejected by the FDA and such FDA decision is not caused by the fault of the Company (the "Termination for FDA Rejection"). Lonza may terminate the CSA upon 120 days written notice if we do not receive regulatory approval by December 31, 2024 (the "Termination for FDA Delay"). Upon any Termination for FDA Rejection or Termination for FDA Delay, we would reimburse Lonza for 50% of its documented out-of-pocket expenditures for any capital equipment that is purchased by Lonza after the effective date of the Agreement to perform the services for us, not to exceed $2.5 million in the aggregate.

We are required to provide Lonza with quarterly forecasts of our expected production requirements for the following 24 month period, the first twelve months of which is considered a binding, firm order. We are required to purchase certain minimum annual order quantities, which may be adjusted by us after the thirteenth month after receipt of regulatory approval (as defined in the CSA). The CSA provides for tiered pricing depending upon the batch size ordered. As of June 30, 2023, we have non-cancelable commitments with Lonza Tampa LLC for product manufacturing costs of approximately $4.3 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. As of June 30, 2023, we have incurred and paid $1.3 million of the annual minimum purchase commitment. 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 formulation 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 did not file an appeal with respect to 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 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 appealed Judge Andrews' decision to the United States Court of Appeals for the Federal Circuit. On July 24, 2023, the United States Court of Appeals for the Federal Circuit affirmed Judge Andrews' decision with respect to both the '066 patent and the '793 patent.

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 3ml Medication Cartridge (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 had

expressed a goal of holding a three-day bench trial to be scheduled for the summer of 2023. However, no trial date has been set.

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.

**15. Subsequent Events**

On July 27, 2023, HCR funded us $10.0 million of the Investment Amount from the second tranche of the RIFA, the entire amount of which was used to pay the amount due to Pharmosa at June 30, 2023 for the $10.0 upfront license fee under the Pharmosa License Agreement.

**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 and six months ended June 30, 2023 as compared to the three and six months ended June 30, 2022. Also refer to our Annual Report on Form 10-K for the fiscal 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 treprostinil injection ("Treprostinil Injection") in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil 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 Treprostinil 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 treprostinil designed with PRINT to improve the therapeutic profile of treprostinil 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 an amendment to our NDA to treat patients with pulmonary hypertension and interstitial lung disease (PH-ILD) upon the expiration of regulatory exclusivity in March 2024. We filed an amendment to our NDA to add PH-ILD to the label on July 24, 2023.

We are also currently developing L606, an investigational, liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer, which we licensed from Pharmosa. L606 is currently being evaluated in an open-label study in the United States for treatment of PAH with a planned pivotal study for the treatment of PH-ILD.

Since our inception, we have incurred significant operating losses. Our net loss was $35.3 million for the six months ended June 30, 2023 and $41.0 million and $34.6 million for the years ended December 31, 2022 and 2021, respectively. As of June 30, 2023, we had an accumulated deficit of $385.9 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**

***License Agreement with Pharmosa Biopharm***

In June 2023, we entered into a License Agreement with Pharmosa Biopharm Inc ("Pharmosa") pursuant to which we were granted an exclusive license in North America to develop and commercialize L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a clinical trial for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD), and a non-exclusive license for the manufacture, development and use (but not commercialization) of such licensed product in most countries outside North America (the "Pharmosa License Agreement").

Under the terms of the Pharmosa License Agreement, we will be responsible for development, regulatory and commercial activities of L606 in North America. Pharmosa will manufacture clinical and commercial supplies of the liposomal formulation through its global supply chain and support us in establishing a redundant global supply chain. In consideration for these exclusive rights, we paid Pharmosa an upfront license fee of $10 million and will pay Pharmosa potential development milestone payments tied to PAH and PH-ILD indications of up to $30 million, potential sales milestones of up to $185 million and two tiers of low, double-digit royalties on net sales of L606. Pharmosa will also receive a $10 million milestone payment for each additional indication approved after PAH and PH-ILD and each additional product approved under the license. We also retain the first right to negotiate for development and commercialization of L606 in Europe and other territories should Pharmosa seek a partner, subject to satisfaction of certain conditions as set forth in the Pharmosa License Agreement.

Concurrently with the execution of the Pharmosa License Agreement, we also entered into an Asset Transfer Agreement with Pharmosa pursuant to which Pharmosa will transfer its inventory of physical materials so that we and Pharmosa can perform the necessary actions contemplated under the Pharmosa License Agreement.

***Second and Third Amendments to Revenue Interest Financing Agreement***

In June 2023 and July 2023, we entered into a Second Amendment and Third Amendment, respectively, to the Revenue Interest Financing Agreement ("RIFA") with HealthCare Royalty Partners IV, L.P. ( "HCR"), pursuant to which HCR moved $2.5 million from the fourth tranche to the second tranche such that HCR would fund a total of $10.0 million of the Investment Amount (as defined in the RIFA) under the second tranche. The $10.0 million was funded on July 27, 2023 and was used for the upfront license fee due to Pharmosa in connection with the transactions contemplated by the Pharmosa License Agreement. Under these amendments, we agreed with HCR that all further funding under the RIFA will be by mutual agreement of both HCR and us.

**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 will increase as we expand manufacturing activities and initiate new 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 and Six Months Ended June 30, 2023 compared with the Three and Six Months Ended June 30, 2022***

The following table summarizes the results of our operations for the three and six months ended June 30, 2023 and 2022, together with the changes in those items in dollars and as a percentage (in thousands, except for percentages):

| | Three Months Ended June 30, | | $ | % | Six Months Ended June 30, | | $ | % |
|---|---|---|---|---|---|---|---|---|
| | 2023 | 2022 | Change | Change | 2023 | 2022 | Change | Change |
| Revenue | $ 4,786 | $ 3,918 | $ 868 | 22 % | $ 9,279 | $ 7,410 | $ 1,869 | 25 % |
| Costs and expenses: | | | | | | | | |
| Cost of revenue | 671 | 731 | (60) | (8)% | 1,325 | 1,425 | (100) | (7)% |
| Research and development | 17,695 | 5,219 | 12,476 | 239 % | 22,973 | 9,947 | 13,026 | 131 % |
| General and administrative | 9,245 | 6,938 | 2,307 | 33 % | 17,038 | 19,480 | (2,442) | (13)% |
| Total costs and expenses | 27,611 | 12,888 | 14,723 | 114 % | 41,336 | 30,852 | 10,484 | 34 % |
| Loss from operations | (22,825) | (8,970) | (13,855) | 154 % | (32,057) | (23,442) | (8,615) | 37 % |
| Other income (expense): | | | | | | | | |
| Interest income | 734 | 65 | 669 | 1,029 % | 1,656 | 69 | 1,587 | 2,300 % |
| Interest expense | (1,426) | (542) | (884) | 163 % | (2,550) | (1,020) | (1,530) | 150 % |
| Loss on extinguishment of debt | — | — | — | * % | (2,311) | (997) | (1,314) | 132 % |
| Total other expense, net | (692) | (477) | (215) | 45 % | (3,205) | (1,948) | (1,257) | 65 % |
| Net loss and comprehensive loss | $ (23,517) | $ (9,447) | $ (14,070) | 149 % | $ (35,262) | $ (25,390) | $ (9,872) | 39 % |

* Not meaningful

**Revenue**

Revenue was $4.8 million for the three months ended June 30, 2023, compared to $3.9 million for the three months ended June 30, 2022. Revenue related primarily to the Promotion Agreement. The increase of $0.9 million was primarily due to favorable gross-to-net chargeback and rebate adjustments.

Revenue was $9.3 million for the six months ended June 30, 2023, compared to $7.4 million for the six months ended June 30, 2022. Revenue related primarily to the Promotion Agreement. The increase of $1.9 million was primarily due to favorable gross-to-net chargeback and rebate adjustments and increased quantities.

**Cost of Revenue**

Cost of revenue was $0.7 million for both the three months ended June 30, 2023 and 2022. Cost of revenue related to the Promotion Agreement as noted above.

Cost of revenue was $1.3 million for the six months ended June 30, 2023, compared to $1.4 million for the six months ended June 30, 2022. Cost of revenue related to the Promotion Agreement as noted above.

**Research and Development Expenses**

Research and development expenses were $17.7 million for the three months ended June 30, 2023, compared to $5.2 million for the three months ended June 30, 2022. The increase of $12.5 million or 239% was primarily due to a $10.0 million upfront license fee due to Pharmosa for the exclusive license in North America to develop and commercialize L606. Additionally, there was a $2.2 million increase in expenses related to our YUTREPIA program driven by higher manufacturing and supply costs.

Research and development expenses were $23.0 million for the six months ended June 30, 2023, compared to $9.9 million for the six months ended June 30, 2022. The increase of $13.1 million or 131% was primarily due to a $10.0 million upfront license fee due to Pharmosa for the exclusive license in North America to develop and commercialize L606. Additionally, there was a $2.2 million increase in expenses related to our YUTREPIA program driven by higher manufacturing and supply costs and a $0.7 million increase in consulting and personnel expenses in preparation for the potential commercialization of YUTREPIA.

**General and Administrative Expenses**

General and administrative expenses were $9.2 million for the three months ended June 30, 2023, compared to $6.9 million for the three months ended June 30, 2022. The increase of $2.3 million or 33% was primarily due to a $1.3 million increase in consulting and personnel expenses in preparation for the potential commercialization of YUTREPIA, a $0.7 million increase in legal fees related to our ongoing YUTREPIA-related litigation, and a $0.6 million increase in stock-based compensation expense.

General and administrative expenses were $17.0 million for the six months ended June 30, 2023, compared to $19.5 million for the six months ended June 30, 2022. The decrease of $2.5 million or 13% was primarily due to a $3.3 million decrease in legal fees related to our ongoing YUTREPIA-related litigation and a $1.2 million decrease in stock-based compensation expense driven by an option modification charge recorded in 2022. These decreases were offset by a $2.2 million increase in consulting and personnel expenses in preparation for the potential commercialization of YUTREPIA.

**Other Income (Expense)**

Total other expense, net was $0.7 million for the three months ended June 30, 2023, compared with $0.5 million for the three months ended June 30, 2022.We incurred a $0.9 million increase in interest expense attributable to the higher borrowings under the RIFA as compared to balances outstanding under the A&R SVB LSA and a $0.7 million increase in interest income attributable to higher money market yields.

Total other expense, net was $3.2 million for the six months ended June 30, 2023, compared with $1.9 million for the six months ended June 30, 2022. The six months ended June 30, 2023 included a $2.3 million loss on extinguishment of debt related to repayment of the A&R SVB LSA in January 2023. The six months ended June 30, 2022 included a $1.0 million loss on extinguishment of debt related to the refinance of our long-term debt with SVB in January 2022. We also incurred a $1.5 million increase in interest expense attributable to the higher borrowings under the RIFA as compared to balances outstanding under the A&R SVB LSA and a $1.6 million increase in interest income attributable to higher money market yields.

**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 June 30, 2023 and December 31, 2022, we had cash and cash equivalents of $88.2 million and $93.3 million, respectively. As of June 30, 2023, we had stockholders' equity of $60.7 million and an accumulated deficit of $385.9 million.

In January 2023, we entered into a Revenue Interest Financing Agreement (the "RIFA") with HealthCare Royalty Partners IV, L.P. ("HCR"), as amended, pursuant to which 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. An additional $10.0 million of the Investment Amount was funded on July 27, 2023 (the "Second Tranche Amount"), which was used to fund payment of the $10.0 million upfront license fee due under the Pharmosa License Agreement. See Note 11 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, investing in research and development efforts for our YUTREPIA and L606 programs, and expanding our corporate infrastructure. 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 we are unable to access the contingent Investment Amounts from the RIFA or generate meaningful YUTREPIA product revenue by the second quarter of 2024, we will require additional capital. See Note 2 to the consolidated condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for information regarding the Company's ability to continue as a going concern.

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, or we may be unable to continue operations.

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:

| | Six Months Ended June 30, | |
|---|---|---|
| | 2023 | 2022 |
| Net cash provided by (used in): | | |
| Operating activities | $ (14,021) | $ (18,211) |
| Investing activities | (607) | (2) |
| Financing activities | 9,541 | 64,559 |
| Net increase (decrease) in cash and cash equivalents | $ (5,087) | $ 46,346 |

***Operating Activities***

Net cash used in operating activities decreased $4.2 million to $14.0 million for the six months ended June 30, 2023 compared to $18.2 million for the six months ended June 30, 2022. The decrease was primarily due to $2.2 million lower net loss adjusted for non-cash items and favorable working capital changes of $2.0 million.

***Investing Activities***

Net cash used in investing activities was $0.6 million for the six months ended June 30, 2023 and primarily related to property, plant and equipment purchases.

***Financing activities***

Net cash provided by financing activities was $9.5 million during the six months ended June 30, 2023, compared to $64.6 million during the six months ended June 30, 2022. During the six months ended June 30, 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. This inflow was offset by $0.5 million in payments on the revenue interest financing payable. During the six months ended June 30, 2022, we received $54.5 million net proceeds from the Offering which closed on April 18, 2022, $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 $0.4 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), the 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 June 30, 2023.

In December 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.

In June 2023, we entered into a License Agreement with Pharmosa Biopharm Inc ("Pharmosa") pursuant to which we were granted an exclusive license in North America to develop and commercialize L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a clinical trial for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD), and a non-exclusive license for the manufacture, development and use (but not commercialization) of such licensed product in most countries outside North America. In consideration for these exclusive rights, we will pay Pharmosa potential development milestone payments tied to PAH and PH-ILD indications of up to $30 million, potential sales milestones of up to $185 million and two tiers of low, double-digit royalties on net sales of L606. Pharmosa will also receive a $10 million milestone payment for each additional indication approved after PAH and PH-ILD and each additional product approved under the license.

*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.

On July 14, 2023, the Company entered into an Amended and Restated Commercial Manufacturing Services and Supply Agreement with Lonza Tampa LLC. Pursuant to the terms of the Agreement, Lonza provides us with manufacturing and storage services for YUTREPIA inhalation powder. We will deliver bulk treprostinil powder, manufactured using its proprietary PRINT® technology, and Lonza will encapsulate and package the Product. Under the terms of the Agreement, our minimum annual commitments and Lonza's annual minimum capacity guarantees were materially increased as compared to the Original Agreement. In connection therewith, we have agreed that upon any Termination for FDA Rejection or Termination for FDA Delay, we would reimburse Lonza for 50% of its documented out-of-pocket expenditures for any capital equipment that is purchased by Lonza after the effective date of the Agreement to perform the services for us, not to exceed $2.5 million in the aggregate. As of June 30, 2023, we had non-cancelable commitments with Lonza Tampa LLC for product manufacturing costs of approximately $4.3 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.

Concurrently with the execution of the Pharmosa License Agreement, we also entered into an Asset Transfer Agreement with Pharmosa pursuant to which Pharmosa will transfer its inventory of physical materials.

*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 $0.6 million in the remaining six 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 any product candidates.

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 June 30, 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 June 30, 2023.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended June 30, 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 formulation 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 did not file an appeal with respect to 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 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 appealed Judge Andrews' decision to the United States Court of Appeals for the Federal Circuit. On July 24, 2023, the United States Court of Appeals for the Federal Circuit affirmed Judge Andrews' decision with respect to both the '066 patent and the '793 patent.

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 had expressed a goal of holding a three-day bench trial to be scheduled for the summer of 2023. However, no trial date has been set.

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. Our net losses and significant cash used in operating activities have raised substantial doubt regarding our ability to continue as a going concern.
- We are primarily dependent on the success of our product candidates, YUTREPIA and L606, and these product candidates 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 Smiths Medical's CADD-MS 3 infusion pump. Smiths 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, Smiths 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 and/or L606 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 and/or L606.
- Our financing facility with HCR requires mutual agreement of both HCR and us in order to draw down on the facility. HCR may not agree to make additional advances pursuant to the facility. Failure to receive further funding from HCR 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 proprietary, novel technology, which have 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 COVID-19 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 and single suppliers for the drug product and device for L606. In the event of any disruption in these supplies, our ability to develop and commercialize, and the timeline for commercialization of, YUTREPIA and/or L606 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. Our net losses and significant cash used in operating activities have raised substantial doubt regarding our ability to continue as a going concern.***

We have incurred net losses of $35.3 million during the six months ended June 30, 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 June 30, 2023, we had an accumulated deficit of $385.9 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 Treprostinil Injection in the United States. These up-front fees and milestone payments have been, and combined with revenue generated from Treprostinil 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. These factors raise substantial doubt about our ability to continue as a going concern and to satisfy our estimated liquidity needs for one year from the issuance of the condensed consolidated financial statements.

***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 and/or L606 or for which there may be a greater likelihood of success.***

We anticipate that we will 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 requires mutual agreement of both HCR and us in order to draw down on our financing facility, 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 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 $10.0 million of the Investment Amount was funded in connection with our entry into a license agreement with Pharmosa, and additional tranches of $35.0 million and $22.5 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 and HCR do not mutually agree to the funding of the third and/or 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, the development of L606, 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 treprostinil for parenteral administration in place of Remodulin;
- the availability of third-party coverage and adequate reimbursement for Treprostinil Injection;
- the prevalence and severity of any side effects;
- any restrictions on the use of Treprostinil 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 Treprostinil 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 Treprostinil Injection.***

In order for Treprostinil 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 Treprostinil Injection through subcutaneous injection is dependent on the continued availability of the RG Cartridge. Our ability to sell the Treprostinil 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 Treprostinil Injection to patients who receive Treprostinil 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 Treprostinil 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 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 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 file an appeal with respect to 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 appealed Judge Andrews' decision to the United States Court of Appeals for the Federal

Circuit. On July 24, 2023, the United States Court of Appeals for the Federal Circuit affirmed Judge Andrews' decision with respect to both the '066 patent and the '793 patent.

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 obtain an affirmance of the PTAB's decision with respect to the '793 Patent upon appeal, we may be unable to commercialize YUTREPIA until the expiration of the '793 Patent, which could materially harm our business.

In connection with an amendment to our NDA filed on July 24, 2023 to add PH-ILD as an indication for YUTREPIA, a new 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. As a result, United Therapeutics may bring a new suit for patent infringement, which may trigger a new 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, if new patents are issued to United Therapeutics, including any patent issued from U.S. Patent Application Number 17/233,061, United Therapeutics may seek to assert those newly issued patents against us and may seek to enjoin the FDA from granting final approval to YUTREPIA or enjoin us from launching YUTREPIA.

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 treprostinil 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 treprostinil therapy for the treatment of PAH and PH-ILD, and L606, a nebulized, liposomal formulation of treprostinil for treatment of PAH and PH-ILD, will face competition from the following inhaled treprostinil 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. In April 2021, United Therapeutics announced that Tyvaso was approved by FDA to include treatment of patients with PH-ILD. 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.

- 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.

In addition to these other inhaled treprostinil therapies, we expect that YUTREPIA and L606 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 and/or PH-ILD 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 and/or L606.

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 candidates, 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 treprostinil 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 and develop additional drug candidates, including L606. 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 candidates, YUTREPIA and L606, 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 for the treatment of PAH, 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 PAH and PH-ILD, and L606, a nebulized, liposomal formulation of treprostinil for treatment of PAH and PH-ILD.

We received tentative approval of our NDA for YUTREPIA for the treatment of PAH 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 or that we will receive approval for other indications, such as PH-ILD. 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 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 for the treatment of PAH 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. In addition, the FDA has not yet issued any approval for YUTREPIA for the treatment of PH-ILD, which remains under review. A new drug product may not be marketed until the date of final approval.

Expectations for YUTREPIA and/or L606 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 or L606 or, even if we do receive final marketing approval, the indications for which they will be approved. 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 and L606, may complicate or delay the FDA review process. Product candidates that the FDA deems to be combination products, such as YUTREPIA and L606, 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 and/or L606 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 and/or L606, we cannot assure you that they will be commercialized in a timely manner or successfully, or at all. For example, they 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 and L606 will also, in part, depend on factors that are beyond our control. Therefore, we may not generate significant revenue from the sale of such products, even if approved. Any delay or setback we face in the commercialization of YUTREPIA and/or L606 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 and L606 have, 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 and L606. 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 and/or L606, we may be required to terminate development of these product candidates.

***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, including planned clinical trials for YUTREPIA and L606, 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 and L606, 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, and L606, which is delivered by a next generation nebulizer, to be drug-device combination products. Accordingly, the medical devices used to administer the products were, or in the case of L606 will be, 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 the nebulizer for L606, 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, and are pursuing this pathway for L606. 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 or certain types of amendments to 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 the PTAB's decision invalidating the '793 Patent is affirmed on appeal.

In connection with an amendment to our NDA filed on July 24, 2023 to add PH-ILD as an indication for YUTREPIA, a new 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. As a result, United Therapeutics may bring a new Hatch-Waxman suit for patent infringement, which may trigger a new 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, if new patents are issued to United Therapeutics, including any patent issued from U.S. Patent Application Number 17/233,061, United Therapeutics may seek to assert those newly issued patents against us.

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 products for the treatment of pulmonary hypertension and proprietary innovations to FDA-approved drug products using our PRINT technology. If we are unable to identify suitable product candidates for the treatment of pulmonary hypertension or off-patent drug products for which we can develop proprietary innovations using our PRINT technology or are otherwise unable to 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 and single suppliers for the active ingredient, bulk product manufacturing and packaging of L606.***

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 and L606, 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.

For L606, we rely upon single sources of supply for the active pharmaceutical ingredient, manufacture of bulk drug product and packaging. Some of these suppliers are located in Taiwan. Although we are working to establish a secondary supply chain outside of Taiwan, if hostilities were to break out between Taiwan and China, we may be unable to secure a supply of L606.

Additionally, in December 2019, a novel strain of COVID-19 was reported to have surfaced in Wuhan, China. 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, previously 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 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 connection with an amendment to our NDA filed on July 24, 2023 to add PH-ILD as an indication for YUTREPIA, a new 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. As a result, United Therapeutics may bring a new Hatch-Waxman suit for patent infringement, which may trigger a new 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, if new patents are issued to United Therapeutics, including any patent issued from U.S. Patent Application Number 17/233,061, United Therapeutics may seek to assert those newly issued patents against us.

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. We also license trade secrets from Pharmosa with respect to L606. 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, including YUTREPIA, 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.

Similarly, under our license agreement with Pharmosa, Pharmosa 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 Pharmosa terminates our

license and we have a product that relies on that license, including L606, it may bring a claim against us, and if they are successful, we may be required to compensate Pharmosa 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, 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, and the development of L606 using Pharmosa's proprietary liposomal technology. To our knowledge, no regulatory authority has granted final approval to market or commercialize drugs made using our PRINT technology or Pharmosa's liposomal technology. We may never receive final approval to market and commercialize any product candidate that uses our PRINT technology or Pharmosa's liposomal technology.

Even if we receive final approval to market YUTREPIA and/or L606, we will need to scale up our manufacturing capabilities to effectively commercialize the products. We have never completed a scale up of our PRINT manufacturing process or the manufacturing process for L606, and, if we are unable to do so in an effective and timely manner, our ability to commercialize these products, even if they receive 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.

In addition, for L606, we rely upon single sources of supply for the active pharmaceutical ingredient and manufacture of bulk drug that are located in Taiwan. Although we are working to establish a secondary supply chain outside of Taiwan, if hostilities were to break out between Taiwan and China, we may be unable to secure a supply of L606, which could limit our ability to continue development of L606 and 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 August 1, 2023, 64,741,096 shares of our common stock were outstanding, of which 54,859,749 shares of common stock, or 84.7% of our outstanding shares as of August 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 August 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 August 1, 2023, the holders of 1,887,937 shares, or 2.9%, of our outstanding shares as of August 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, including L606, 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 and L606, 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 and L606, 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 37.0% of our capital stock as of August 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 COVID-19 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 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 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 high 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 high 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 high 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, changes in inflation rates 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 |
|---|---|
| 3.1* | Certificate of Amendment of Certificate of Incorporation of Liquidia Corporation. |
| 10.1* | Second Amendment to Revenue Interest Financing Agreement, dated as of June 28, 2023, by and between Liquidia Technologies, Inc. and Healthcare Royalty Partners IV, L.P. |
| 10.2* | Third Amendment to Revenue Interest Financing Agreement, dated as of July 27, 2023, by and between Liquidia Technologies, Inc. and Healthcare Royalty Partners IV, L.P. |
| 10.3* | License Agreement, dated as of June 28, 2023, by and between Liquidia Technologies, Inc. and Pharmosa Biopharm Inc. |
| 10.4* | Asset Transfer Agreement, dated as of June 28, 2023, by and between Liquidia Technologies, Inc. and Pharmosa Biopharm Inc. |
| 10.5* | Supply Agreement, dated May 22, 2023, by and between Liquidia Technologies, Inc. and Plastiape SpA. |
| 10.6* | Amended and Restated Commercial Manufacturing Services and Supply Agreement, dated July 13, 2023, by and between Liquidia Technologies, Inc. and Lonza Tampa LLC. |
| 31.1* | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act. |
| 31.2* | Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act. |
| 32.1** | Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes- Oxley Act. |
| 32.2** | Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes- Oxley Act. |
| 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). |

* 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: August 10, 2023

**LIQUIDIA CORPORATION**

By: /s/ Roger A. Jeffs, Ph.D.
Roger A. Jeffs, Ph.D.
Chief Executive Officer

DATE: August 10, 2023

**LIQUIDIA CORPORATION**

By: /s/ Michael Kaseta
Michael Kaseta
Chief Financial Officer

**Exhibit 3.1**

**CERTIFICATE OF AMENDMENT TO THE CERTIFICATE OF INCORPORATION OF LIQUIDIA CORPORATION**

Liquidia Corporation, a corporation duly organized and validly existing under and by virtue of the General Corporation Law of the State of Delaware (the "Company"), does hereby certify as follows:

**FIRST**: The Certificate of Incorporation of the Company is hereby amended by deleting the first sentence of Article IV thereof in its entirety and inserting the following in lieu thereof:

"The total number of shares of all classes of stock which the Corporation shall have authority to issue is One Hundred Ten Million (110,000,000), consisting of: (a) One Hundred Million (100,000,000) shares of common stock, $0.001 par value per share ("***Common Stoc***k"), and (b) Ten Million (10,000,000) shares of Preferred Stock, $0.001 par value per share ("***Preferred Stock***")."

**SECOND:** Except as explicitly amended by the foregoing amendment, the language of Article IV of the Certificate of Incorporation shall remain unchanged.

**THIRD**: All other provisions of the Certificate of Incorporation shall remain in full force and effect.

**FOURTH**: The foregoing amendment was duly adopted in accordance with the provisions of Section 242(b) of the General Corporation Law of the State of Delaware.

**FIFTH:** That this Certificate of Amendment to the Certificate of Incorporation shall be effective upon filing.

**IN WITNESS WHEREOF**, the undersigned has duly executed this Certificate of Amendment on this 16th day of June, 2023.

**LIQUIDIA CORPORATION**

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

**Exhibit 10.1**

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

This **SECOND AMENDMENT TO THE REVENUE INTEREST FINANCING AGREEMENT**, dated as of June 28, 2023 (this "Amendment"), is entered into by and between Liquidia Technologies, Inc., a Delaware corporation (the "Company"), and Healthcare Royalty Partners IV, L.P., a Delaware limited liability partnership, as the sole Investor and Investor Representative under the Agreement (as defined below) (the "Investor Representative"), solely with respect to certain enumerated provisions in the Agreement 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, modified, or supplemented prior to the date hereof, the "Agreement"); and

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 Section 2.1(b)**. Section 2.1(b) of the Agreement is hereby amended and restated in its entirety as follows:

> "(b) the sum of Ten Million Dollars ($10,000,000) (the "Second Investment Amount") on the Second Closing Date, subject to the satisfaction of the conditions set forth in Section 8.3 and the performance of the obligations set forth in Section 8.6(c), in immediately available funds, by wire transfer to an account designated in writing by the Company to the Investor Representative prior to the Second Closing Date;"

2. **Amendment to Section 2.1(d)**. Section 2.1(d) of the Agreement is hereby amended and restated in its entirety as follows:

> "(d) the sum of Twenty-Two Million Five Hundred Thousand Dollars ($22,500,000) (the "Fourth Investment Amount") on the Fourth Closing Date, subject to the satisfaction of the conditions set forth in in Section 8.5 and the performance of the obligations set forth in Section 8.6(e), in immediately available funds by wire transfer to an account designated in writing by the Company to the Investor Representative prior to the Fourth Closing Date."

3. **Amendment to Schedule 1.1-1**. Schedule 1.1-1 of the Agreement is hereby amended and restated in its entirety as set forth on Exhibit A to this Amendment.

4. **Representations and Warranties**. To induce the Investor Representative to enter into this Amendment, each of the Company and each other member of the Company Group represents and warrants to the Investor Representative 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.

5. **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.

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

7. **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.

8. **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.

9. **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.

10. **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.

11. **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 Second Amendment to the Revenue Interest Financing Agreement]*

**INVESTOR REPRESENTATIVE:**

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: Chairman & CEO

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

EXHIBIT A

APPLICABLE TIERED PERCENTAGES

[***]

**Exhibit 10.2**

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

This **THIRD AMENDMENT TO THE REVENUE INTEREST FINANCING AGREEMENT** (this "Amendment"), dated as of July 27, 2023 (the "Amendment Effective Date"), is entered into by and between Liquidia Technologies, Inc., a Delaware corporation (the "Company"), and Healthcare Royalty Partners IV, L.P., a Delaware limited liability partnership, as the sole Investor and Investor Representative under the Agreement (as defined below) (the "Investor Representative"), solely with respect to certain enumerated provisions in the Agreement 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 by the First Amendment to the Revenue Interest Financing Agreement dated as of April 17, 2023, and as amended by the Second Amendment to the Revenue Interest Finance Agreement dated as of June 28, 2023, the "Agreement"); and

WHEREAS, the Parties desire to effect the agreements, acknowledgements and 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. **Agreement to Pay Second Investment Amount**. The Investor Representative acknowledges and agrees that (a) by execution hereof it waives the requirements of Section 8.3(b) of the Agreement and (b) as of the Amendment Effective Date, it has received delivery of that certain Omnibus Responsible Officer's Certificate dated as of the Amendment Effective Date and signed by a Responsible Officer of each Company Party (the "Second Closing Certificate"), which satisfies the conditions set forth in Section 8.6(c) of the Agreement. Based on the foregoing, the Investor Representative and the Company agree that as of the Amendment Effective Date, the Company has satisfied all of its obligations for the Second Closing to occur and the Investor will make payment of the Second Investment Amount to Company on July 27, 2023.

2. **Amendments to Section 1.1**.

(a) Section 1.1 of the Agreement is hereby amended by amending and restating the following defined term in its entirety:

> " "Included Product Payment Amount" means, for each Calendar Quarter, if the Third Investment Amount has been funded, then (x) for any Calendar Quarter ending prior to January 1, 2026, an amount equal to the Applicable Tiered Percentage multiplied by the Quarterly Net Revenues for such Calendar Quarter, or (y) for any Calendar Quarter commencing on or after January 1, 2026, an amount equal to the greater of (A) the Applicable Tiered Percentage multiplied by the Quarterly Net Revenues for such Calendar Quarter and (B) Five Million Dollars ($5,000,000), until such time as the Investor Representative has received Included Product Payment Amounts for the relevant Calendar Year for which determination is being made equal to Twenty Million Dollars ($20,000,000), in which case the amount set forth in clause (ii)(y)(A) shall apply for the balance of such Calendar Year. For clarity, the Applicable Tiered Percentage used to calculate the Included Product Payment Amount for a given Calendar Quarter will be based on the aggregate Net Revenues billed or invoiced in such Calendar Quarter and all prior Calendar Quarters in the applicable Calendar Year. The Included Product Payment Amount for each Quarterly Payment

Date shall be determined in a manner consistent with the example of such calculation set forth in Exhibit C."

(b) Section 1.1 of the Agreement is hereby amended by adding the following defined term:

" "Insurance Policy" means an insurance policy in a form and substance reasonably satisfactory to Investor Representative and the Company, whereby Investor would receive an amount equal to or greater than the Third Investment Amount if an Other Determination occurs."

(c) Section 1.1 of the Agreement is hereby amended by amending and restating the following defined term in its entirety:

" "Quarterly Fixed Payments" means, with respect to any Calendar Quarter for which a payment is due under Section 3.1(a)(i), the amount equal to (a) Five Hundred Thousand Dollars ($500,000), plus (b) with respect to each Quarterly Payment Date following any Closing Date (other than the Initial Closing Date), an additional amount to reflect the increased Investment Amount on a ratable basis determined in a manner consistent with the example of such calculation set forth in Exhibit C, and plus (c) if the Third Closing Date has not occurred by June 30, 2025, Three Million Dollars ($3,000,000) as set forth in Section 3.1(a)(i). For clarity, the Quarterly Fixed Payments do not include the One-Time Fixed Payment."

(d) Section 1.1 of the Agreement is hereby amended by deleting the defined term "Third Closing Notice".

3. **Amendment to Section 3.1(a)**. Section 3.1(a) of the Agreement is hereby amended and restated in its entirety as follows:

"(a) In consideration of the Investor paying the Investment Amount hereunder, the Company shall pay the following amounts to the Investor Representative as follows:

(i) On each Quarterly Payment Date, until the earlier of (A) subject to the proviso hereto, the Third Closing Date and (B) the date on which the Investor Representative has received payments (including, without limitation, any amounts received by the Investor pursuant to the Insurance Policy, if any) equal to the Hard Cap, the Company shall pay the Quarterly Fixed Payments to the Investor Representative; provided that, if the Third Closing Date has not occurred prior to June 30, 2025, then the Company shall (1) continue the Quarterly Fixed Payments until such time as the Investor Representative has received payments (including, without limitation, any amounts received by the Investor pursuant to the Insurance Policy, if any) equal to the Hard Cap, and (2) make a one-time payment of [***] to Investor Representative no later than July 30, 2025 (the "One-Time Fixed Payment").

(ii) Following the Third Closing Date (in addition to any payments required under the proviso to Section 3.1(a)(i) in the event the Third Closing Date does not occur prior to June 30, 2025), on each Quarterly Payment Date, the Company shall pay the Included Product Payment Amount to the Investor Representative for the applicable Calendar Quarter until the earlier of (A) the date on which the Investor Representative has received payments (including, without limitation, any amounts received by the Investor pursuant to the Insurance Policy, if any) equal to the Hard Cap and (B) the Legal Maturity Date. If (1) the Investor Representative has not received payments (including, without limitation, any amounts received by the Investor pursuant to the Insurance Policy, if any) equal to the Hard

Cap by the Legal Maturity Date (after giving effect to any payments made on the Legal Maturity Date) and (2) no Special Termination Event, Change of Control, Default or Event of Default has occurred or is continuing, the Company shall pay the Special Maturity Payment Amount on the Legal Maturity Date. The Company shall have the right, at any time and from time to time, to make voluntary prepayments to the Investor Representative, and such payments shall be credited against the Hard Cap and the Under Performance Payments set forth in Section 3.1(b). This Agreement shall be in full force and effect for the duration of the Payment Term."

4. **Amendment to Section 3.1(b)(i).** The first sentence of Section 3.1(b)(i) of the Agreement is hereby amended and restated in its entirety as follows:

"(i) Following the Third Closing Date, if the Investor Representative has not received the applicable Minimum Multiple of the Investment Amount set forth below by the corresponding Reference Date set forth below, the Company shall, within thirty (30) days of the applicable Reference Date, make a cash payment to the Investor Representative equal to (i) the Minimum Multiple times the then-current Investment Amount, minus (ii) the aggregate of all payments of the Company in respect of the Total Fixed Payments, the Total Included Product Payments (including any Under Performance Payment or Generic Product Payment paid on or prior to such Reference Date) and any amounts received by the Investor pursuant to the Insurance Policy, if any, made to the Investor prior to such date (each, an "Under Performance Payment")."

5. **Amendment to Section 3.4**. Section 3.4 of the Agreement is hereby amended and restated in its entirety as follows:

"Section 3.4 Included Product Payment Reports and Record Retention. On or prior to each Quarterly Payment Date occurring after the Initial Closing Date, the Company shall deliver to the Investor Representative (i) copies of any Third Party Report for the applicable Calendar Quarter, so long as the Company is able to obtain the prior written consent of the relevant Third Party to disclose such information to the Investor Representative, (ii) following the Third Closing Date, a written report of the amount of gross sales of the Included Product in each country during the applicable Calendar Quarter, an itemized calculation of Net Sales and Other Royalty Payments on a country-by-country basis and a calculation of the amount of the Included Product Payment Amount due under Section 3.1(a)(ii) in respect of the applicable Calendar Quarter, showing the Applicable Tiered Percentage applied thereto (if applicable) and a calculation of the Under Performance Payment and Generic Product Payment (if any) pursuant to Section 3.1(b), (iii) copies of the most recent quarterly statements for each Deposit Account, Securities Account, Commodities Account and other Deposit Account, Securities Account or Commodities Account of the Company and each other Company Party, and (iv) a Compliance Certificate relating to each of the items described in clauses (i), (ii) and (iii) of this sentence. For five years after each sale of the Included Product made by the Company or any of its Affiliates, the Company shall keep (and shall ensure that its Affiliates shall keep) complete and accurate records of such sale in sufficient detail to confirm the accuracy of the applicable Included Product Payment Amount paid pursuant to Section 3.1(a)(ii). The Company shall use commercially reasonable efforts to include, in each contract of the Company or any of its Affiliates for the distribution, marketing or selling of Included Products entered into on or after the Initial Closing Date, obligations reasonably appropriate to ensure that the counterparty to such contract shall furnish to the Company all information necessary for the Company to comply with this Section 3.4 and calculate the Included Product Payment Amounts that are payable as set forth in this Agreement. The Company shall use commercially reasonable efforts to, within ninety (90) days of the Effective Date, obtain the consent of the relevant Third Party to share the Third Party Reports and the Third Party Information with the Investor Representative and the Investor."

6. **Amendment to Section 8.1(c)**. Section 8.1(c) of the Agreement is hereby amended and restated in its entirety as follows:

"(c) for the third Closing (the "Third Closing"), subject to the satisfaction of the conditions set forth in Section 8.4 and Investor Representative's receipt of written notices from the Company and the Investor that Company has elected to receive, and Investor has elected to pay, the Third Investment Amount, on the date that is fifteen (15) Business Days following the satisfaction of the conditions set forth in Section 8.4 and Section 8.6(d) (the "Third Closing Date"); and"

7. **Amendment to Section 8.4**. Section 8.4 of the Agreement is hereby amended and restated in its entirety as follows:

"Section 8.4 Conditions to Third Closing. The obligations of the Investor relating to the Third Closing shall be subject to (a) the Company's election to receive, and the Investor's election to pay, the Third Investment Amount, and (b) no Bankruptcy Event with respect to any member of the Company Group or no Special Termination Event, Change of Control, Default or Event of Default having occurred or be continuing (and the Investor Representative's receipt of the certification from a Responsible Officer to that effect)."

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

"(d) At the Third Closing (should the Third Closing occur), the Company shall deliver or cause to be delivered to the Investor Representative the following:

(i) A certificate of a Responsible Officer of each Company Party (the statements made in which shall be true and correct on and as of the Third Closing Date): (A) attaching copies, certified by such officer as true and complete, of (x) the Organization Documents of the Company Party and (y) confirming that resolutions of the governing body of the Company Party authorizing and approving the execution, delivery and performance by the Company Party of the Transaction Documents and the transactions contemplated herein and therein remain in full force and effect; (B) attaching a copy, certified by such officer as true and complete, of a good standing certificate of the appropriate Governmental Authority of the Company Party's jurisdiction of organization, stating that the Company Party is in good standing under the Applicable Laws of such jurisdiction, and (C) certifying that no Bankruptcy Event with respect to the Company Party and no Special Termination Event, Change of Control, Default or Event of Default has occurred and is continuing; and

(ii) A certificate of a Responsible Officer of the Company Party certifying that (A) the representations and warranties set forth in ARTICLE IV (other than the Fundamental Representations) are true and correct in all material respects on and as of the Third Closing Date (or, if made as of a specific date, as of such date); provided, that to the extent that any such representation or warranty is qualified by the term "material" or "Material Adverse Effect" such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the date hereof and shall be true and correct in all respects as of the Third Closing Date or such other date, as applicable, (B) that the Fundamental Representations are true and correct in all respects on and as of the Third Closing Date (or, if made as of a specific date, as of such date), subject to any additions that the Company Party may make to the Disclosure Schedule with respect to Section 4.10 and Section 4.12 (provided that any such additions to Section 4.12 must be reasonably satisfactory to the Investor Representative (it being

acknowledged that any addition that would not be reasonably expected to have a Material Adverse Effect shall be conclusively deemed satisfactory)) as of the Third Closing Date and (C) that the Company Party has complied in all material respects with its covenants, agreements and other obligations under this Agreement and the other Transaction Documents; and

(iii) Such other documents, instruments, reports, statements and information as may be reasonably requested by the Investor Representative.

9. **Amendment to Section 8.6(e)**. Section 8.6(e)(i) and (ii) of the Agreement is hereby amended and restated as follows:

"(i) A certificate of a Responsible Officer of each Company Party (the statements made in which shall be true and correct on and as of the Fourth Closing Date): (A) attaching copies, certified by such officer as true and complete, of (x) the Organization Documents of the Company Party and (y) confirming that resolutions of the governing body of the Company Party authorizing and approving the execution, delivery and performance by the Company Party of the Transaction Documents and the transactions contemplated herein and therein remain in full force and effect; (B) attaching a copy, certified by such officer as true and complete, of a good standing certificate of the appropriate Governmental Authority of the Company Party's jurisdiction of organization, stating that the Company Party is in good standing under the Applicable Laws of such jurisdiction; and (C) certifying that no Bankruptcy Event with respect to the Company Party and no Special Termination Event, Change of Control, Default or Event of Default has occurred and is continuing.

(ii) A certificate of a Responsible Officer of the Company Party certifying that (a) the representations and warranties set forth in ARTICLE IV (other than the Fundamental Representations) are true and correct in all material respects on and as of the Fourth Closing Date (or, if made as of a specific date, as of such date); provided, that to the extent that any such representation or warranty is qualified by the term "material" or "Material Adverse Effect" such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the date hereof and shall be true and correct in all respects as of the Fourth Closing Date or such other date, as applicable, (b) that the Fundamental Representations are true and correct in all respects on and as of the Fourth Closing Date (or, if made as of a specific date, as of such date), subject to any additions that the Company Party may make to the Disclosure Schedule with respect to Section 4.10 and Section 4.12 (provided that any such additions to Section 4.12 must be reasonably satisfactory to the Investor Representative (it being acknowledged that any addition that would not be reasonably expected to have a Material Adverse Effect shall be conclusively deemed satisfactory)) as of the Fourth Closing Date and (c) that the Company Party has complied in all material respects with its covenants, agreements and other obligations under this Agreement and the other Transaction Documents."

10. **Amendment to Exhibit C**. **Exhibit C** of the Agreement is hereby amended and restated in its entirety as set forth on **Exhibit A** to this Amendment.

11. **Reimbursement of Attorneys' Fees**. The Company agrees to reimburse the Investor Representative for all reasonable and documented fees, charges and disbursements of Sidley Austin LLP, counsel to the Investor Representative, required in connection with this Amendment and incurred as of the Amendment Effective Date, provided such reimbursement shall not to exceed [***].

12. **Representations and Warranties**. To induce the Investor Representative to enter into this Amendment, each of the Company and each other member of the Company Group represents and warrants

to the Investor Representative 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 Organization 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, (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.

13. **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.

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

15. **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.

16. **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.

17. **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.

18. **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.

19. **Reaffirmation by the Company Parties**. Each Company Party that is a 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 Amendment Effective Date.

**THE COMPANY:**

LIQUIDIA TECHNOLOGIES, INC.

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

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

**INVESTOR REPRESENTATIVE:**

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

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

**EXHIBIT A**

[***]

**Exhibit 10.3**

# LICENSE AGREEMENT

DATED AS OF JUNE 28, 2023

BY AND BETWEEN

PHARMOSA BIOPHARM INC.

AND

LIQUIDIA TECHNOLOGIES, INC.

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**Schedules and Exhibit**

**LICENSE AGREEMENT**

This License Agreement (this "**Agreement**") is dated as of June 28, 2023 (the "**Effective Date**") by and between Pharmosa Biopharm Inc., a corporation incorporated under the laws of Taiwan having a place of business at 3F.-3, No. 66, Sanchong Road, Nangang District, Taipei City 11502, Taiwan ("**Licensor**"), and Liquidia Technologies, Inc., a corporation incorporated under the laws of the State of Delaware, USA having a place of business at 419 Davis Drive, Suite 100, Morrisville, NC 27560, USA ("**Company**"). Licensor and Company may be referred to herein as a "**Party**" or, collectively, as "**Parties**".

**RECITALS:**

**WHEREAS**, Licensor is a biopharmaceutical company engaged in the development of the Licensor Technology and has in development the Existing Product;

**WHEREAS**, Company is a biopharmaceutical company engaged in the development, manufacture and commercialization of pharmaceutical products and is interested in developing, manufacturing and commercializing Products, including the Existing Product; and

**WHEREAS**, Company desires to license from Licensor, and Licensor wishes to license to Company, on an exclusive basis, the right to develop, manufacture and commercialize Products (including the Existing Product) in the Field in the Territory.

**NOW, THEREFORE**, in consideration of the various promises and undertakings set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

**ARTICLE 1**
**DEFINITIONS**

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 "**Adverse Event**" means any serious untoward medical occurrence in a patient or subject who is administered Product, but only if and to the extent that such serious untoward medical occurrence is required under Laws to be reported to applicable Regulatory Authorities.

1.2 "**Affiliate**" means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.2, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person or entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

1.3 "**Bankruptcy Event**" means: (a) voluntary or involuntary proceedings by or against a Party are instituted in bankruptcy under any insolvency Law, which proceedings, if involuntary, shall not have been dismissed within [***] after the date of filing; (b) a receiver or custodian is appointed for a Party; (c) proceedings are instituted by or against a Party for corporate reorganization, dissolution, liquidation or winding-up of such Party, which proceedings, if involuntary, shall not have been dismissed within [***] after the date of filing; or (d) substantially all of the assets of a Party are seized or attached and not released within sixty (60) days thereafter.

1.4 "**Business Days**" means the days when the banks in Taiwan and the United States remain open.

1.5 "**Calendar Quarter**" means each three (3) month period commencing January 1, April 1, July 1 or October 1 of any year; provided, however, that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.

1.6 "**Calendar Year**" means the period beginning on the 1st of January and ending on the 31st of December of the same year; provided, however, that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same year and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

1.7 "**Change of Control**" means, with respect to a Person: (a) a transaction or series of related transactions that results in the sale or other disposition of all or substantially all of such Person's assets; or (b) a merger or consolidation in which such Person is not the surviving corporation or in which, if such Person is the surviving corporation, the shareholders of such Person immediately prior to the consummation of such merger or consolidation do not, immediately after consummation of such merger or consolidation, possess, directly or indirectly through one or more intermediaries, a majority of the voting power of all of the surviving entity's outstanding stock and other securities and the power to elect a majority of the members of such Person's board of directors; or (c) a transaction or series of related transactions (which may include a tender offer for such Person's stock or the issuance, sale or exchange of stock of such Person) if the shareholders of such Person immediately prior to the initial such transaction do not, immediately after consummation of such transaction or any of such related transactions, own, directly or indirectly through one or more intermediaries, stock or other securities of the entity that possess a majority of the voting power of all of such Person's outstanding stock and other securities and the power to elect a majority of the members of such Person's board of directors.

1.8 "**Clinical Trial**" means a clinical trial in human subjects that has been approved by a Regulatory Authority and Institutional Review Board or Ethics Committee, and is designed to measure the safety and/or efficacy of a Product. Clinical Trials shall include the Existing Clinical Trial and the Planned Phase III Clinical Trial.

1.9 "**Combination Product**" means a Product that: (a) includes one (1) or more active ingredients in addition to treprostinil; or (b) is combined with one (1) or more products, processes, devices, pieces of equipment or components, either co-formulated or packaged together and sold as a single unit for a single price.

1.10 "**Commercialization**" or "**Commercialize**" means any and all activities undertaken before and after Regulatory Approval of a MAA for the Product and that relate to the marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of the Product, and interacting with Regulatory Authorities regarding the foregoing.

1.11 "**Commercially Reasonable Efforts**" means: (a) with respect to the efforts to be expended by a Party with respect to any objective, such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances; and (b) with respect to any objective relating to Commercialization of the Product by a Party, the application by such Party, consistent with the exercise of its prudent scientific and business judgment, of diligent efforts and resources to fulfill the obligation in issue, consistent with the level of efforts such Party would devote to a product at a similar stage in its product life as the Product and having profit potential and strategic value comparable to that of the Product, taking into account, without limitation, commercial, legal and regulatory factors, target product profiles, product labeling, past

performance, the regulatory environment and competitive market conditions in the therapeutic area, safety and efficacy of the Product, the strength of its proprietary position and such other factors as such Party may reasonably consider, all based on conditions then prevailing. For clarity, Commercially Reasonable Efforts will not mean that a Party guarantees that it will actually accomplish the applicable task or objective.

1.12 "**Company Competitor**" means any company that (itself or through an Affiliate) is developing or commercializing in or for the Territory a product that is, or could reasonably be expected to be a Competing Product or a product that operates through the same or a similar mechanism of action to prostacyclin or through prostacyclin pathway to the Product.

1.13 "**Competing Product**" means any pharmaceutical product in any dosage form, formulation, presentation or package configuration (a) which exhibits therapeutic or prophylactic activity which is similar to that exhibited by the Product for PAH, PH-ILD or any other Indication for which Company has either (i) an open IND with at least one ongoing or completed Clinical Trial that includes such Indication, or (ii) received Regulatory Approval (PAH, PH-ILD and the Indications described in (i) and (ii) being referred to herein as "**Contemplated Indications**"), and (b) (i) for which an application seeking Regulatory Approval has been filed or Regulatory Approval has been obtained in the Territory for the Contemplated Indications or (ii) that is being Commercialized in the Territory with off-label prescription for at least [***] or use for the Contemplated Indications. For purposes of this Agreement, the [***] Product does not constitute a Competing Product unless and until it satisfies clauses (a) and (b) above.

1.14 "**Compulsory License**" means a compulsory license under Licensor Technology obtained by a Third Party through the order, decree, or grant of a competent Governmental Body or court, authorizing such Third Party to develop, make, have made, use, sell, offer to sell or import a Product in the Field in any country in the Territory. For clarity, the failure of a court to enjoin infringement as a remedy in a patent infringement proceeding shall not be deemed to be a Compulsory License. A Compulsory License shall not be deemed to be a sublicense under Section 2.2.

1.15 "**Compulsory License Compensation**" shall mean, for a given Product and a given country or region in the Territory, the compensation received from a licensee of the Compulsory License by Company or Licensor or any of their Affiliates or Sublicensees under a Compulsory License.

1.16 "**Confidential Information**" of a Party, means information relating to the business, operations or products of a Party or any of its Affiliates, including any Know-How, that such Party discloses to the other Party under this Agreement, or otherwise becomes known to the other Party by virtue of this Agreement.

1.17 "**Controlled**" means, with respect to (a) Patent Rights, (b) Know-How or (c) biological, chemical or physical material, that a Party or one of its Affiliates owns or has a license or sublicense to such Patent Rights, Know-How or material (or in the case of material, has the right to physical possession of such material) and has the ability to grant a license or sublicense to, or assign its right, title and interest in and to, such Patent Rights, Know-How or material as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

1.18 "**Cover**", "**Covering**" or "**Covered**" means, with respect to Product, that the using, selling, or offering for sale of Product would, but for a license granted in this Agreement under the Licensor Patents, infringe a Valid Claim of the Licensor Patents in the country in which the activity occurs.

1.19 "**Development**" or "**Develop**" means, with respect to the Product, the performance of all pre-clinical and clinical research and development (including toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis), Clinical Trials (excluding Clinical Trials conducted after Regulatory Approval of an NDA), manufacturing and regulatory activities that are required to obtain Regulatory Approval of Product in the Territory.

1.20 "**Device Agreement**" means an agreement between Company and a Third Party, whether entered into directly by Company or assigned by Licensor to Company, pursuant to which Company secures rights to use a device for the purpose of Developing, manufacturing or Commercializing a Combination Product consisting of the Product and such device under this Agreement.

1.21 "**Executive Officers**" means, together, the Chief Executive Officer of Company and the General Manager of Licensor or their respective designees.

1.22 "**Existing Clinical Trial**" means that certain Phase III Clinical Trial that is being actively conducted by Licensor as of the Effective Date for the Existing Product for PAH.

1.23 "**Existing Product**" means L606 Treprostinil as more fully described in Schedule 1.23.

1.24 "**Existing Third Party Agreements**" means the agreements set forth on Schedule 1.24.

1.25 "**FDA**" means the United States Food and Drug Administration or a successor federal agency thereto.

1.26 "**Field**" means all Indications and uses in humans, including, without limitation, the diagnosis, treatment, management or prevention of any and all diseases.

1.27 "**First Commercial Sale**" means, on a country-by-country basis, the first commercial transfer or disposition for value of Product in such country to a Third Party by Company, or any of its Affiliates or Sublicensees. For clarity, the sale of a Product pursuant to a Compulsory License shall not be deemed to be a First Commercial Sale.

1.28 "**GAAP**" means US generally accepted accounting principles, as such principles may be amended from time to time.

1.29 "**Governmental Body**" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.30 "**Indication**" means a generally acknowledged disease or condition, a significant manifestation of a disease or condition, or symptoms associated with a disease or condition or a risk for a disease or condition for which a MAA may be obtained. Indications include, but are not limited to, PAH and PH-ILD.

1.31 "**IND**" means an investigational new drug application submitted to applicable Regulatory Authorities for approval to commence Clinical Trials in a given jurisdiction.

1.32 "**Know-How**" means any: (a) scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, that is not in the public domain or otherwise publicly known, including discoveries, inventions, trade secrets, devices, databases, practices, protocols, regulatory filings, methods, processes (including manufacturing processes, specification and techniques), techniques, concepts, ideas, specifications, formulations, formulae, data (including pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), case reports forms, medical records, data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), summaries and information contained in submissions to and information from ethical committees, or Regulatory Authorities, and manufacturing process and development information, results and data, whether or not patentable, all to the extent not claimed or disclosed in a patent or patent application; and (b) compositions of matter, assays, animal models and physical, biological or chemical material, including drug substance samples, intermediates of drug substance samples, drug product samples and intermediates of drug product samples. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, and/or a development relating to the item, is (and remains) not known to the public. "Know-How" includes any rights including copyright, database or design rights protecting such Know-How. "Know-How" excludes Patent Rights.

1.33 "[***] **Product**" means Licensor's existing pharmaceutical product that includes [***] and is formulated with Licensor Liposomal Technology.

1.34 "**Law**" or "**Laws**" means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.

1.35 "**Licensor Know-How**" means all Know-How that is Controlled by Licensor or any of its Affiliates as of the Effective Date, including what is set forth on Schedule 1.35, or at any time thereafter during the Term that is necessary or useful in the Development, manufacture, use, or Commercialization of Products in the Field.

1.36 "**Licensor's Knowledge**" means, with respect to a matter that is the subject of a given representation or warranty of Licensor, the actual knowledge of the executive officers of Licensor, and the vice presidents and senior directors of Licensor's research and development department, including the individuals set forth in Schedule 1.36, after making reasonable inquiry into the relevant subject matter.

1.37 "**Licensor Liposomal Technology**" means Licensor's proprietary liposomal drug delivery system and all technology related thereto.

1.38 "**Licensor Patents**" means all Patent Rights that are Controlled by Licensor or any of its Affiliates as of the Effective Date or at any time thereafter during the Term that are necessary or useful for the research, Development, manufacture, use, or Commercialization of Products in the Field. Listed on Schedule 1.38 are all Licensor Patents existing as of the Effective Date; provided, that Licensor shall update Schedule 1.38 from time-to-time to include any new Patent Rights that come to be Controlled by Licensor or any of its Affiliates at any time during the Term on or following the Effective Date that are necessary or useful for the Development, manufacture, use, or Commercialization of Product.

1.39 "**Licensor Technology**" means the Licensor Patents, Licensor Liposomal Technology, and the Licensor Know-How.

1.40 "**MAA**" means a Marketing Authorization Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. C.F.R.§ 314.3 et seq, a Biologics License Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. C.F.R. § 601, and any equivalent application submitted in any country in the Territory, including all additions, deletions or supplements thereto, and as any and all such requirements may be amended, or supplanted, at any time.

1.41 "**NDA**" means a New Drug Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 314.3 et seq., a Biologics License Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 601, and any equivalent application submitted in any country in the Territory, together, in each case, with all additions, deletions or supplements thereto.

1.42 "**Net Sales**" means, without duplication, (i) the "net sales" with respect to the sales of the Products by Company or any of its Affiliates or Sublicensees as reported on the Parent Company's (or any successor's) periodic reports filed with the SEC on Form 10-Q and Form 10-K (as applicable); and (ii) for any sales of the Products that are not reported in the Parent Company's (or any successor's) periodic reports filed with the SEC on Form 10-Q and Form 10-K (as applicable), then the gross amounts recognized by Company or any of its Affiliates or Sublicensees, in accordance with GAAP for sales of Product to independent or unaffiliated Third Party purchasers of such Product, less those deductions with respect to such sales that are either included in the billing as a line item as part of the gross amount invoiced or otherwise documented as a deduction in accordance with GAAP to be attributable to actual sales of such Product.

If a Product under this Agreement is sold in the form of a Combination Product, then Net Sales for such Combination Product shall be determined on a country-by-country basis by mutual agreement of the Parties in good faith taking into account the perceived relative value contributions of the Product and the other ingredient or component in the Combination Product, as reflected in their respective market prices at arms-length transactions. In case of disagreement, an independent expert agreed upon by both Parties or, failing such agreement, designated by the International Chamber of Commerce, shall determine such relative value contributions and such determination shall be final and binding upon the Parties.

In the event Product is "bundled" for sale together with one or more other products in a country (a "**Product Bundle**"), then Net Sales for such Product sold under such arrangement shall be determined on a country-by-country basis by Company in good faith taking into account the relative value contributions of the Product and the other products in the Product Bundle, as reflected in their individual sales prices at arms-length transactions. If the Product or other product(s) are not sold separately, Licensor and Company shall negotiate in good faith a reasonable imputed price for the Product and other product(s) and the allocation of Net Sales with respect thereto shall be based on such imputed list price. In case of disagreement, an independent expert agreed upon by both Parties or, failing such agreement, designated by the International Chamber of Commerce, shall determine such allocation and such determination shall be final and binding upon the Parties.

In determining the Net Sales for the Combination Product and the Product in the Product Bundle, Company shall provide the individual market and sale prices of the products in the Combination Product and Product Bundle to Licensor and in the case of a Combination Product combined with nebulizer devices, a reasonably redacted copy of the agreement with the nebulizer device providers.

In the case of disagreement regarding the allocation of Net Sales for a Combination Product or Product Bundles as described in the preceding paragraphs, Company shall make applicable payments based on the lower of the Net Sales allocation proposed by the Parties pending the final resolution of the disagreement.

For clarification, sale of Product by Company or any of its Affiliates or Sublicensees to another of these entities for resale by such entity to a Third Party shall not be deemed a sale for purposes of this definition of "Net Sales". Further, transfers or dispositions of Product: (a) in connection with patient assistance programs; (b) for charitable or promotional purposes; (c) for preclinical, clinical, regulatory or governmental purposes; (d) for use in any tests or studies reasonably necessary to comply with any Law, regulation or request by a Regulatory Authority; or (e) for use in pre-clinical studies, Clinical Trials or other Development activities, shall not, in each case of (a) through (e), be deemed sales of such Product for purposes of this definition of "Net Sales."

Sale of Products pursuant to a Compulsory License shall not be included in any Net Sales.

1.43 "**Out-of-Pocket Expenses**" means expenses actually paid by a Party or its Affiliate to any Third Party.

1.44 "**PAH**" means pulmonary arterial hypertension.

1.45 "**Parent Company**" means Liquidia Corporation, a Delaware corporation.

1.46 "**Patent Rights**" means: (a) an issued or granted patent, including any extension, supplemental protection certificate, registration, confirmation, reissue, reexamination or renewal thereof; (b) a pending patent application, including any continuation, divisional, continuation-in-part, substitute or provisional application thereof; and (c) all counterparts or foreign equivalents of any of the foregoing issued by or filed in any country or other jurisdiction.

1.47 "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

1.48 "**PH-ILD**" means pulmonary hypertension associated with interstitial lung disease.

1.49 "**Phase II Clinical Trial**" means a human clinical trial for which the primary endpoint is an indication of efficacy of a therapeutic agent in patients being studied as described in 21 CFR § 312.2(b), or an equivalent human clinical trial in a country or territory in the Territory other than the United States, and that is prospectively designed to generate sufficient data (if successful) to commence pivotal clinical trials.

1.50 "**Phase III Clinical Trial**" means a human clinical trial that is prospectively designed to demonstrate statistically for registration in the United States whether a therapeutic agent is safe and effective for use in humans in the Indication being investigated as described in 21 CFR § 312.2(c), or an equivalent human clinical trial in a country or territory in the Territory other than the United States.

1.51 "**Planned Phase III Clinical Trial**" means that certain Phase III Clinical Trial designed and planned to be conducted by Licensor as of the Effective Date (but, for clarity, for which enrollment has not yet commenced) for the Existing Product for PH-ILD. For the avoidance of doubt, the Existing Clinical Trial is not the Planned Phase III Clinical Trial.

1.52 "**Price Approvals**" means, in those countries in the Territory where Regulatory Authorities may approve or determine pricing and/or pricing reimbursement for pharmaceutical or biotechnology products, such pricing and/or pricing reimbursement approval or determination.

1.53 "**Product**" means (a) the Existing Product, and (b) any other product that includes treprostinil and is formulated with Licensor Liposomal Technology, if any. For clarity, Product includes the Existing Product.

1.54 "**Regulatory Approval**" means any and all approvals, licenses, registrations, or authorizations of the relevant Regulatory Authority, including Price Approvals, necessary for the Development, manufacture, use, storage, import, transport or Commercialization of Product in a particular country or jurisdiction. For the avoidance of doubt, Regulatory Approval to Commercialize Product shall include Price Approval, if required in a particular country or jurisdiction.

1.55 "**Regulatory Authority**" means: (a) in the US, the FDA; or (b) in any other jurisdiction anywhere in the world, any regulatory body with similar regulatory authority over pharmaceutical or biotechnology products.

1.56 "**Royalty Term**" means, on a Product-by-Product and country-by-country basis in the Territory, the period from the First Commercial Sale of such Product in such country in the Territory until the latest of (a) [***] years from such First Commercial Sale of such Product in such country, (b) expiration of the last-to-expire Valid Claim within the Licensor Patents Covering the manufacture, use or sale of such Product in such country, or (c) expiry of any marketing exclusivity right for such Product in such country granted by a Regulatory Authority.

1.57 "**SEC**" means the U.S. Securities and Exchange Commission or any successor agent or authority thereto.

1.58 "**Sublicensee**" means a Person other than an Affiliate of Company to which Company (or its Affiliate) has, pursuant to Section 2.2, granted sublicense rights under any of the Licensed Rights; provided, that "Sublicensee" shall exclude distributors and Subcontractors. For clarity, the licensee of a Compulsory License shall not be deemed to be a Sublicensee.

1.59 "**Tax**" or "**Taxes**" means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.

1.60 "**Territory**" means all of the countries, jurisdictions and territories in North America, including Canada, the United States and Mexico.

1.61 "**Third Party**" means any Person other than Licensor, Company or any of their respective Affiliates.

1.62 "**Third Party Action**" means any Action made by a Third Party against either Party that claims that a Product, or its use, Development, manufacture or Commercialization infringes or misappropriates such Third Party's intellectual property rights.

1.63 "**Third Party License Agreement**" means any agreement entered into by a Party or its Affiliate with a Third Party, or any amendment or supplement thereto, in each case following the Effective Date, whereby royalties, fees or other payments are to be made by a Party or its Affiliate to such Third Party in connection with the grant of rights under intellectual property rights Controlled by such Third Party, which rights are necessary or useful to Develop, manufacture, have made, import, export, use or Commercialize Product under the Licensed Rights.

1.64 "**United States**" or "**US**" means the United States of America, its territories and possessions.

1.65 "**USD**" or "**$**" means the lawful currency of the United States.

1.66 "**Valid Claim**" means (a) a claim of an issued and unexpired patent which has not lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or governmental or supra-governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise, or (b) a pending claim of a patent application which patent application has not been pending for more than five (5) years from the date of filing such application and which claim has not lapsed or been cancelled, withdrawn, abandoned or rejected.

1.67 **Other Terms**. The definition of each of the following terms is set forth in the section of this Agreement indicated below:

| Defined Term | Section |
|---|---|
| "**Action**" | 7.5.2 |
| "**Agreement**" | Preamble |
| "**Asset Transfer Agreement**" | 2.7 |
| "**Company**" | Preamble |
| "**Company Indemnitees**" | 10.2 |
| "**Company Patents**" | 7.4.5 |
| "**Company Tech Transfer Materials**" | 2.6 |
| "**Competitive Action**" | 13.4 |
| "**Contemplated Indications**" | 1.13 |
| "**Cure Period**" | 11.2.2 |
| "**Development Milestones**" | 6.2 |
| "**Development Support**" | 4.1.2 |
| "**Disputes**" | 12.1 |
| "**Effective Date**" | Preamble |
| "**Ex-Territory Rights Agreement**" | 2.8 |
| **"Ex-Territory Rights Terms Sheet"** | 2.8 |
| "**Ex-Territory Sublicensees**" | 2.6 |
| "**Exclusive Option**" | 2.8 |
| "**Existing Regulatory Documentation**" | 5.4.3 |
| "**Filled Ampules**" | 4.3 |
| "**ICC**" | 12.3.1 |
| "**Joint Steering Committee**" or "**JSC**" | 3.1 |
| "**Licensed Rights**" | 2.1 |
| "**Licensor**" | Preamble |
| "**Licensor Indemnitees**" | 10.1 |
| "**Licensor Technology Transfer Plan**" | 2.3 |

| | |
|---|---|
| "**Losses**" | 10.1 |
| "**Non-Specific Licensor Patents**" | 7.4.2 |
| "**Option Exercise Notice**" | 2.8 |
| "**Party**" and "**Parties**" | Preamble |
| "**Product Bundle**" | 1.42 |
| "**Re-Examination Action**" | 7.5.2 |
| "**Regulatory Support**" | 5.3 |
| "**Regulatory Transition Plan**" | 5.4.1 |
| "**Representatives**" | 4.1.2 |
| "**Right of First Refusal**" | 11.6.2 |
| "**Right of First Refusal Notice Period**" | 11.6.2(b) |
| "**Rules**" | 12.3.1 |
| "**Sales Milestones**" | 6.3 |
| "**Specific Licensor Patents**" | 7.4.1 |
| "**Subcontractor**" | 4.4 |
| "**Supply Agreement**" | 4.3 |
| "**Supply Terms**" | 4.3 |
| "**Term**" | 11.1 |
| "**Terms Sheet Negotiation Period**" | 2.8 |
| "**Third Party Transaction**" | 2.8 |

## ARTICLE 2
## LICENSES AND OTHER RIGHTS

2.1 **Grant of License to Company**. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Company and its Affiliates (a) an exclusive (even as to Licensor), royalty-bearing right and license (with the right to sublicense, subject to the provisions of Section 2.2) under the Licensor Technology to Develop, have Developed, manufacture, have manufactured, use and Commercialize Products in the Field in the Territory, (b) a non-exclusive right and license (with the right to sublicense, subject to the provisions of Section 2.2) under the Licensor Technology to Develop and have Developed (but not seek MAA) and use (but not Commercialize) Products in the Field outside the Territory for the sole purpose of exploiting its right and license under clause (a); and (c) a non-exclusive right and license (with the right to sublicense, subject to the provisions of Section 2.2) under the Licensor Technology to manufacture or have manufactured the Products in the Field outside the Territory (other than Taiwan) (clauses (a), (b) and (c) collectively, the "**Licensed Rights**"). For the avoidance of doubt, any services or efforts requested by Company to be performed by Licensor with respect to the Development, manufacture and/or Commercialization of any Product developed individually by Licensor other than the Existing Product shall be subject to a separate collaboration agreement between the Parties, including such additional initial fees and milestone payments for each such Product as may be agreed by the Parties.

2.2 **Grant of Sublicense by Company**. Company shall have the right, in its sole discretion, to grant sublicenses, in whole or in part, through multiple tiers, under the Licensed Rights to Third Parties; provided, however, that (a) the granting by Company of a sublicense shall not relieve Company of any of its obligations hereunder; (b) Licensor' obligations to such Third Party will be no broader than Licensor' obligations were to Company under this Agreement prior to the grant of such a sublicense, (c) the rights granted to such Third Party under the Licensor Technology will be consistent with the rights granted to Company under Section 2.1 applicable to the scope of the sublicense granted to such Third Party, (d) Company shall provide a copy of each sublicense (and any sub-sublicense) agreement to Licensor within thirty (30) Business Days after execution of such

sublicense (subject to reasonable redactions), (e) the terms of each sublicense (and any sub-sublicense) agreement shall be consistent with all applicable terms of this Agreement, and (f) Company remains primarily responsible for the actions or omissions of its Sublicensees. In no event shall Company grant a sublicense in whole of the Licensed Rights (including the entire Field and entire Territory) to any single Third Party and/or its Affiliates without the prior written consent of Licensor, such consent not to be unreasonably withheld, conditioned or delayed.

2.3 **Licensor Technology Transfer**. As soon as reasonably practicable after the Effective Date and subject to Section 2.5 and the Licensor technology transfer plan ("**Licensor Technology Transfer Plan**") set forth in Schedule 2.3, Licensor will transfer to Company, at Licensor's cost and expense (except as set forth in the Supply Terms), all Licensor Know-How pursuant to Section 2.5. For the avoidance of doubt, nothing in this Agreement shall be in any way interpreted that Licensor is transferring its ownership or proprietary right to Licensor Technology.

2.4 **Regulatory Technology Transfer and Existing Third Party Agreements**. As soon as possible following the Effective Date and subject to Section 5.4 and the Regulatory Transition Plan, Licensor shall (to the extent allowed or consented to by Law and permitted, or, if not permitted, consented to by the applicable Third Party, under the Existing Third Party Agreement, as applicable), at Licensor's cost and expense, assign to Company (a) all applications and filings made by or on behalf of Licensor with any Regulatory Authority with respect to Product, including any IND, MAA or orphan drug designations or any other application for regulatory consultations or consideration, including sponsorship thereof, and (b) the Existing Third Party Agreements. With respect to each assignment of an Existing Third Party Agreement from Licensor to Company, each Party and, to the extent consent of the Third Party that is a party to such Existing Third Party Agreement is required under such Existing Third Party Agreement for the effectiveness of such assignment, such Third Party shall execute an Assignment and Assumption in the form attached hereto as Exhibit A. To the extent consent of the Third Party that is a party to an Existing Party Agreement is required under such Existing Third Party Agreement for the effectiveness of such assignment, Licensor shall use commercially reasonable efforts to cause such Third Party to provide its consent. Notwithstanding the foregoing, until any Existing Third Party Agreement assigned (including in the event that an Existing Third Party Agreement is unable to be assigned), Licensor shall (i) to the fullest extent possible under such Existing Third Party Agreement, assign and subcontract to Company all of Licensor's rights and obligations arising after the Effective Date thereunder and (ii) continue to perform its obligations and exercise its rights thereunder at Company's direction and expense to the extent of the obligations and rights that were not assigned or subcontracted to Company; provided, however, that Company may, upon written notice to Licensor, elect to cease its use of such Existing Third Party Agreement as described hereunder.

2.5 **Procedures for Licensor Technology Transfer**. The technology transfers set forth in Sections 2.3 and 2.4 shall occur in an orderly fashion and in a manner such that the value, usefulness and confidentiality of the transferred Licensor Know-How for the Existing Product and regulatory documentation are preserved in all material respects in accordance with the Licensor Technology Transfer Plan. During the Term, Licensor shall provide to Company full and prompt disclosure, but in no event less frequently than semi-annually, of any Licensor Technology for the Existing Product that becomes Controlled by Licensor or any of its Affiliates after the Effective Date and that is necessary or useful to Company to conduct its activities or exercise its rights as contemplated hereunder and shall, in the case of Licensor Know-How for the Existing Product, promptly following such disclosure, transfer to Company such Licensor Know-How. Notwithstanding the foregoing, the transfer of Licensor Know-How for the manufacture of the Product will be provided to Company Secondary Sites (as such term defined in the Supply Terms) after being identified by Company.

2.6 **Company Technology Transfer**. During the Term and upon Licensor's reasonable written request (but no more frequently than twice each Calendar Year), Company shall provide to Licensor copies of all technical information, data, reports and regulatory dossiers generated by or on behalf of Company during the Development and Commercialization of the Existing Product and that are necessary for Licensor to seek Regulatory Approvals for the Existing Product in the Field outside the Territory (the "**Company Tech Transfer Materials**") at no cost to Licensor. Licensor shall have the right to incorporate, and sublicense such right to any Third Party to which Licensor licenses the right of development, manufacture or commercialization to such Third Party in any country outside of the Territory ("**Ex-Territory Sublicensees**"), any such Company Tech Transfer Materials into its regulatory filings for Regulatory Approvals for the Existing Product in the Field outside of the Territory; provided, however, that, notwithstanding any permitted assignment or transfer pursuant to Section 13.2, in no event shall the Company Tech Transfer Materials (including any rights with respect thereto) be assignable, licensable or otherwise transferable to a Third Party, including any Third Party licensee or successor-in-interest to Licensor's business to which this Agreement relates, that is a Company Competitor in the Territory.

2.7 **Asset Transfer Agreement**. As of the Effective Date, Licensor and Company shall enter into that certain Asset Transfer Agreement, dated as of the Effective Date, pursuant to which Licensor shall transfer its inventory of physical materials (including Filled Ampules and Existing Product) as set forth therein (the "**Asset Transfer Agreement**"). The Parties acknowledge and agree that execution of the Asset Transfer Agreement by the Parties is a material condition to the Parties entering into, and the effectiveness of, this Agreement.

2.8 **Right of First Negotiation**. In the event that (a) Licensor or any Ex-Territory Sublicensee incorporates any Company Tech Transfer Materials into any regulatory filing related to a Product in the Field outside of the Territory pursuant to Section 2.6 and (b) Licensor wishes to sell or license its rights with respect to such Product in the Field in any jurisdiction outside of the Territory (provided that, for the avoidance doubt, Licensor shall not be permitted to sell, license, assign or otherwise transfer any of its rights with respect to Company Tech Transfer Materials unless otherwise permitted under this Agreement), Licensor shall, and hereby does, grant to Company and its Affiliates an exclusive and sole right of first option (the "**Exclusive Option**"), at Company's election, to acquire or license such rights in such jurisdiction upon such terms as may be mutually agreed upon by the Parties in writing (the "**Ex-Territory Rights Agreement**"). Licensor shall promptly notify Company in writing of the occurrence of the events in clauses (a) and (b) triggering the Exclusive Option and Company shall have a period of [***] following such notice to provide Licensor with written notice identifying Company's desire to exercise the Exclusive Option with a proposal of the terms to acquire or license such rights (the "**Option Exercise Notice**"). For a period of [***] thereafter (the "**Terms Sheet Negotiation Period**"), the Parties shall negotiate the terms sheet for the Ex-Territory Rights Agreement in good faith (the "**Ex-Territory Rights Terms Sheet**"). Upon execution of the Ex-Territory Rights Terms Sheet, the Parties shall negotiate in good faith the Ex-Territory Rights Agreement. In the event (i) Company fails to provide the Option Exercise Notice prior to the foregoing [***] period, (ii) the Parties are unable to execute the Ex-Territory Rights Terms Sheet within the Terms Sheet Negotiation Period, or (iii) the Parties fail to enter into and execute the Ex-Territory Rights Agreement within the later of (x) [***] following the execution of the Ex-Territory Rights Terms Sheet and (y) [***] following Company's delivery of the Option Exercise Notice, Licensor shall be free to solicit and negotiate a transaction with one (1) or more Third Parties (a "**Third Party Transaction**"); provided, however, that Licensor shall not enter into a Third Party Transaction on terms and conditions that, in the aggregate, are less favorable to Licensor than the terms last proposed by Company without first bringing such terms to Company. Company shall have a period of [***] to notify Licensor if it will match such terms and provide Licensor written notice exercising such right. Following Licensor's receipt of such

written notice, the Parties will negotiate for a period of up to [***] (or such longer period as may be mutually agreed upon by the Parties) to execute an Ex-Territory Rights Agreement containing such terms.

## ARTICLE 3
## JOINT STEERING COMMITTEE

3.1 **Formation**. Within [***] calendar days following the Effective Date, the Parties will form a Joint Steering Committee comprised of up to [***] representatives of each of the Parties (the "**Joint Steering Committee**" or "**JSC**"). Each Party shall appoint its respective representatives to the JSC from time to time and may substitute one (1) or more of its representatives, in its sole discretion, effective upon written notice to the other Party of such change. One (1) representative of Company at the JSC will be selected to act as the chairperson of the JSC.

3.2 **Meetings**. The JSC will meet in the first month of each calendar quarter or such other time as the JSC may agree. Company may also schedule a meeting of the JSC on an *ad hoc* basis at any time upon two (2) weeks' notice to the other Party. Meetings of the JSC may be conducted by videoconference, teleconference or in person, as agreed by the Parties. The JSC will agree upon the time and location of the meetings. The chairperson, or his or her designee, will circulate an agenda for each meeting approximately one (1) week before the date scheduled for the meeting, and will include all matters requested to be included on such agenda by either Party. The chairperson, or his or her designee, will take complete and accurate minutes of all discussions occurring at the JSC meetings and all matters decided upon at the meetings, except those matters reflecting legal advice of counsel will not be included in such minutes. A copy of the draft minutes of each meeting will be provided to each Party by the chairperson, or his or her designee, after each meeting, and such minutes will be reviewed by the JSC members, any needed changes discussed and final minutes agreed to and provided to each Party within thirty (30) days after each meeting unless otherwise agreed. A reasonable number of additional representatives of a Party may attend meetings of the JSC in a non-voting capacity. Each Party is responsible for their travel costs and expenses associated with attending meetings.

3.3 **JSC Functions and Powers**. The responsibilities of the JSC will be as follows:

(a) encouraging and facilitating communication between the Parties with respect to the Development and Commercialization of the Product;

(b) coordinating and reviewing regulatory activities in the Territory;

(c) monitoring the progress of the Development and Commercialization of the Product in the Territory;

(d) coordinating and reviewing Company's Commercialization activities in the Territory;

(e) coordinating and reviewing the establishment of a redundant supply chain for Products in alternative geographic locations;

(f) coordinating the transfer of vendor relationships to Company as contemplated by this Agreement;

(g) reviewing and addressing Disputes related to breach of this Agreement;

(h) establishing subcommittees on an as-needed basis, overseeing the activities of all such subcommittees and attempting to resolve disputes or disagreements arising in all such subcommittees; and

(i) carrying out the other duties and responsibilities described for it in this Agreement.

The JSC may form sub-committees for execution of its responsibilities which shall be comprised of representatives appointed by the Parties. The sub-committees shall meet at such times and on such schedule as may be established by such sub-committees.

3.4 **JSC Decision Making**. The JSC is intended to serve primarily as an advisory body and to serve as a forum for the Parties to discuss matters relating to this Agreement and to provide a convenient mechanism for implementation of any review and/or approval rights granted to a Party under this Agreement. However, to the extent that the JSC is entitled to make decisions on a matter, all such decisions of the JSC will be made by unanimous vote, with each Party having one (1) vote. In the event there is a tie that cannot be resolved through good faith negotiations between the Parties' representatives in the JSC, Company shall have the final decision-making authority except in the case of a disagreement related to Section 3.3(e) or 3.3(g) in which case the Dispute shall be handled in accordance with the terms set forth in Article 12. Notwithstanding the foregoing and for the avoidance of doubt, the JSC shall not have any authority other than that expressly set forth in Section 3.3 and notwithstanding Section 3.3, specifically, shall have no authority (a) to amend or interpret this Agreement or to waive any Party's rights or interest, (b) to determine whether or not Company or Licensor has met its diligence or other obligations under this Agreement, (c) to determine whether or not a breach of this Agreement has occurred, or (d) to increase or expand any Party's liability or responsibility beyond that is expressly set forth in this Agreement without such Party's express written consent.

## ARTICLE 4
## DEVELOPMENT, COMMERCIALIZATION AND MANUFACTURE OF PRODUCT

4.1 **Development**.

4.1.1 General. Subject to Section 4.1.3, Company shall have the exclusive right, and sole responsibility and decision-making authority, at Company's cost and expense, to Develop Products and to conduct (either itself or through its Affiliates, agents, Subcontractors and/or Sublicensees) all Clinical Trials and non-clinical studies Company believes appropriate to obtain Regulatory Approval for Product in the Field in the Territory.

4.1.2 Licensor Support. Licensor shall make its employees, consultants, contractors, advisors and agents ("**Representatives**") that are knowledgeable regarding the Licensor Technology and Product (including the properties and functions thereof), available to Company for scientific and technical explanations, advice, on-site support (limited to once a year and one (1) week for each on-site support) and meetings with Regulatory Authorities that may reasonably be required by Company (provided Company shall consider in good faith Licensor's requests regarding when such meetings are scheduled) relating to the Development of Existing Product (the "**Development Support**"). The Development Support shall be provided by Licensor free-of-charge during the Term except for reasonable Out-of-Pocket Expenses.

4.1.3 Conduct of Existing Clinical Trial. Until the date of transfer of sponsorship and control of the Existing Clinical Trial to Company pursuant to the Regulatory Transition Plan in

accordance with Section 5.4, Licensor shall have the exclusive right and obligation to conduct the Existing Clinical Trial at Company's cost. On and after the date of transfer sponsorship and control of the Existing Clinical Trial to Company pursuant to the Regulatory Transition Plan in accordance with Section 5.4, as between the Parties, Company shall have the exclusive right to conduct the Existing Clinical Trial. Notwithstanding the foregoing, following the transfer of sponsorship of the Existing Clinical Trial, the Parties may agree in writing (which may be set forth in the Regulatory Transition Plan) for Licensor to continue to conduct certain activities related to the Existing Clinical Trial on behalf of Company (as sponsor) at reasonable charges agreed by Company and Licensor in writing in advance, in which event Licensor shall conduct such activities in accordance with such agreement and direction of Company and strictly in accordance with the Regulatory Transition Plan (as may be amended in writing by the Parties). Licensor shall not, at any time on or following the Effective Date, without Company's prior written consent, (i) terminate or amend the protocol of the Existing Clinical Trial, (ii) modify or amend any agreements with any Third Parties related to the Existing Clinical Trial or (iii) add or terminate any clinical sites related to the Existing Clinical Trial.

4.2 **Commercialization**.

4.2.1 Generally. Company shall have the exclusive right, and sole responsibility and decision-making authority, to Commercialize Product in the Field in the Territory itself or through one (1) or more Affiliates or Sublicensees or other Third Parties selected by Company and shall have the sole decision-making authority and responsibility in all matters relating to the Commercialization of the Product in the Field in the Territory. The Parties shall schedule a meeting reasonably in advance of each Product launch and once each year thereafter pursuant to which Company shall provide Licensor with a high-level summary of its commercial strategy and execution related to the Commercialization of such Product in the Field in the Territory; provided, however, that for the avoidance of doubt, Company shall have the exclusive right to determine, in its sole discretion, the launch and commercial strategy for each Product in the Field in the Territory.

4.2.2 Diligence. Subject to Licensor's fulfillment of its obligations under this Agreement, including, without limitation, supply of Filled Ampules pursuant to the Supply Agreement, Company shall use Commercially Reasonable Efforts to Develop and Commercialize at least one (1) Product in the Field in the United States; provided, that such Commercialization and Development diligence obligation shall be expressly conditioned upon the continuing absence of any adverse condition or event (including an Adverse Event) relating to the safety or efficacy of Product, legal impediments, or Third Party intellectual property rights, and Company's Development and Commercialization diligence obligation shall be delayed or suspended so long as, in Company's reasonable opinion, any such condition or event exists and Company shall notify Licensor promptly in writing of such delay or suspension. Activities by Company's Affiliates and Sublicensees will be considered as Company's activities under this Agreement for purposes of determining whether Company has complied with its obligation under this Section 4.2.2 to use Commercially Reasonable Efforts. For clarity, Company shall have no obligation to Commercialize Product in any particular country or countries in addition to the United States.

4.3 **Manufacturing**. As soon as possible after the Effective Date, the Parties shall negotiate in good faith and enter into that certain supply agreement pursuant to which Licensor shall have the right to supply to Company ampules filled with drug product ("**Filled Ampules**") on the terms and

conditions set forth therein (the "**Supply Agreement**"). The Supply Agreement shall include at least the terms set forth in Schedule 4.3 (the "**Supply Terms**").

4.4 **Right to Subcontract of Company**. Company may exercise any of its rights, or perform any of its obligations, under this Agreement (including any of the Licensed Rights) by subcontracting the exercise or performance of any portion of such rights and obligations on Company's behalf to a Third Party that has entered into a subcontract agreement to provide services to Company for the purpose of fulfilling Company's obligations hereunder (a "**Subcontractor**"); provided that (i) any subcontract granted or entered into by Company as contemplated by this Section 4.4 of the exercise or performance of any portion of the rights or obligations that Company may have under this Agreement shall not relieve Company from any of its obligations under this Agreement, (ii) the terms of each subcontract agreement shall be consistent with all applicable terms of this Agreement and (iii) Company shall remain primarily responsible for the actions or omissions of its Subcontractors. In no event shall Company subcontract all of its obligations under this Agreement to a single Third Party and/or its Affiliates, other than in connection with a sublicense as permitted pursuant to Section 2.2, without the prior written consent of Licensor, such consent not to be unreasonably withheld, conditioned or delayed.

4.5 **Trademarks**. As between Licensor and Company, Company shall have the sole authority to select trademarks for the Product and shall own all such trademarks.

## ARTICLE 5
## REGULATORY MATTERS

5.1 **Regulatory Filings**. Subject to Section 5.4, as between Company and Licensor, Company shall make, own and maintain all regulatory filings and Regulatory Approvals for the Product in the Territory and the regulatory filings and Regulatory Approvals for the Clinical Trials for the Product conducted outside the Territory, including all INDs and MAAs at its cost after the Effective Date. Company shall provide a copy of (a) any substantive written communications, notices, or other materials received from any Regulatory Authorities regarding any of the foregoing regulatory filings for Regulatory Approvals and Regulatory Approvals, (b) any substantive written communications with any Regulatory Authority regarding any of the foregoing regulatory filings for Regulatory Approvals, and (c) any proposed significant written communications with any Regulatory Authority regarding any of the foregoing regulatory filings for Regulatory Approval reasonably in advance of submission and, with respect to clause (c), shall consider all of Licensor's comments thereto in good faith.

5.2 **Communications with Authorities**. Subject to Section 5.4, Company (or one of its Affiliates or Sublicensees) shall be responsible, and act as the sole point of contact, for communications with all Regulatory Authorities in the Territory in connection with the Development, Commercialization, and manufacturing of Product. Following the Effective Date but subject to Section 5.4, Licensor shall not initiate, with respect to Product, any meetings or contact with any Regulatory Authorities in the Territory without Company's prior written consent. To the extent Licensor receives any written or oral communication from any Regulatory Authority in the Territory relating to Product, Licensor shall (a) refer such Regulatory Authority to Company, and (b) as soon as reasonably practicable (but in any event within twenty-four (24) hours), notify Company and provide Company with a copy of any written communication received by Licensor or, if applicable, complete and accurate minutes of such oral communication. At the request of Company, Licensor shall make available to Company, free of charge, a qualified representative who shall, together with the representatives of Company, participate in and contribute to meetings

with the Regulatory Authorities with respect to regulatory matters relating to the Licensor Technology.

5.3 **Licensor Support in Regulatory Matters**. Licensor shall make its Representatives that are knowledgeable regarding the Licensor Technology or Product available to Company upon Company's request for regulatory explanations, advice and on-site support, that may reasonably be required by Company relating regulatory matters (including preparation and filing for any INDs and MAAs and obtaining and maintaining Marketing Authorizations) for the Existing Product (the "**Regulatory Support**"). The Regulatory Support shall be provided by Licensor free-of-charge during the Term.

5.4 **Regulatory Transition Plan**.

5.4.1 Licensor shall transfer the regulatory, clinical and operational responsibilities of the Existing Clinical Trial in accordance with the regulatory transition plan set forth in Schedule 5.4.1 with respect to the Existing Product (the "**Regulatory Transition Plan**"), which outlines the Parties' responsibilities with respect to the Existing Clinical Trial. The Regulatory Transition Plan may be amended by the mutual written agreement of the Parties. Each Party shall conduct its responsibilities in accordance with the Regulatory Transition Plan and shall use best efforts to achieve the timelines set forth therein.

5.4.2 Notwithstanding Section 5.2, until the transfer of sponsorship and control of the Existing Clinical Trial to Company pursuant to the Regulatory Transition Plan, Licensor shall be responsible for any communications and interactions with Regulatory Authorities with respect to the Existing Clinical Trial in accordance with Section 5.2. Notwithstanding the foregoing, Licensor shall provide a copy of (a) any communications, notices, or other materials received from any Regulatory Authorities with respect to the Existing Clinical Trial, (b) any interim or final data or results from the Existing Clinical Trial, and (c) any proposed communications with, or submissions to, any Regulatory Authority reasonably in advance of submission and, with respect to clause (c), shall incorporate all of Company's comments thereto in good faith (provided incorporation of such comments does not, upon the advice of Licensor's outside counsel, violate Law).

5.4.3 Prior to the transfer of all regulatory documentation for the Existing Clinical Trial held or filed by or on behalf of Licensor or its Affiliates prior to the Effective Date in accordance with the Regulatory Transition Plan (the "**Existing Regulatory Documentation**"), Licensor (or its designee) shall file, maintain, and hold title to such Existing Regulatory Documentation. Licensor shall not assign, license, or grant any right of reference or use to the Existing Regulatory Documentation except as expressly set forth in the Regulatory Transition Plan.

5.5 **Adverse Event Reporting**. The Parties agree to comply with any and all Laws that are applicable as of the Effective Date and thereafter during the Term in connection with Product safety data collection and reporting. If Licensor has or receives any information regarding any Adverse Event which may be related to the use of Product, then Licensor shall provide Company with all such information in English within such reasonable timelines which enable Company to comply with all Laws and relevant regulations and requirements. Company shall report to Licensor any Adverse Event culminating in death or permanent disability of a patient or subject who is administered Product. The information exchanged between the Parties pursuant to this Section 5.5 shall be transmitted by e-mail or overnight courier to the following address:

Transmission to Licensor:

Weishu Lu
Pharmosa Biopharm Inc.
3F.-3, No.66, Sanchong Rd., Nangang Dist., Taipei City 11502, Taiwan
Tel: + 886-2-2782-7561#121
Fax: +886-2-2782-9013
Mobile: +886-958940912
Weishu.lu@pharmosa.com.tw

Transmission to Company:

Jennifer Weidman
Liquidia Technologies, Inc.
419 Davis Drive, Suite 100
Morrisville, NC 27560
USA
Telephone: 919-704-5916
E-mail: jennifer.weidman@liquidia.com

5.6 **Safety Data Exchange Agreement**. Without limitation of Section 5.5, the Parties shall, as soon as practical following the Effective Date, negotiate in good faith and enter into a safety data exchange agreement, which shall set forth standard operating procedures governing the collection, investigation, reporting, and exchange of information concerning adverse drug reactions or other adverse events (including Adverse Events) sufficient to permit each Party to comply with its regulatory and other legal obligations within applicable timeframes.

5.7 **Recalls**. Company shall have the sole right to determine whether and how to implement a recall or other market withdrawal of any Product in the Territory. Company shall, to the extent allowed by Law and reasonably practicable, provide written notice to Licensor of any such recall or market withdrawal and consider Licensor's comments in good faith, provided, however, that in no event shall Company be obligated to delay any such recall or market withdrawal. Licensor shall take all actions requested by Company in connection with such recall or other market withdrawal.

## ARTICLE 6
## FINANCIAL PROVISIONS

6.1 **Initial Fee**. Company shall pay, or cause to be paid, to Licensor a non-refundable and non-creditable fee of [***] within [***] days following Company's receipt of an invoice from Licensor following the Effective Date.

6.2 **Development Milestones**. Company shall pay, or cause to be paid, to Licensor the following one-time (except with respect to the last event in the table below), non-refundable, non-creditable milestone payments with respect to the first achievement of the milestone events described in the table below (the "**Development Milestones**"). Company shall notify Licensor in writing of the achievement of any such Development Milestone within ten (10) Business Days and Licensor shall issue Company an invoice for the amount of the corresponding milestone payment, which invoice Company shall pay within [***] days following Company's receipt of such invoice.

| **Development Milestone** | **Milestone Payment USD** |
|---|---|
| Enrollment of [***] patients in the Planned Phase III Clinical Trial | [***] |

| | |
|---|---|
| Filing of an NDA with the FDA for the Existing Product | [***] |
| Approval by the FDA of an NDA for the Existing Product for PAH | [***] |
| Approval by the FDA of an NDA for the Existing Product for PH-ILD | [***] |
| Approval by the FDA of an NDA for the Existing Product for each additional Indication (other than PAH and PH-ILD)* | [***] |
| Approval by the FDA of an NDA for any additional Product* | [***] |

With respect to each Development Milestone, the corresponding milestone payments to be made under this Agreement shall be due and payable only once (except with respect to the Development Milestones marked with an asterisk).

For purposes of the Development Milestones, an additional Product entitled to [***] in the foregoing table shall mean a Product with new dosage form, new formulation, new combination and the next generation version of Existing Product. Notwithstanding the foregoing, such Development Milestone payment shall not apply to the Existing Product in the following instances: (a) a different dosage amount; (b) different batch size; or (c) a manufacturing change to the Existing Product in consideration of supply issues (e.g., a change in liposomes used to manufacture the Existing Product due to insufficient supply of the existing liposomes or for cost reasons).

6.3 **Sales Milestones**. Company shall pay Licensor the following one-time, non-refundable, non-creditable amounts for the first achievement of the following sales event milestone events (the "**Sales Milestones**").

| **Sales Milestones** | **Milestone Payment USD** |
|---|---|
| The first Calendar Year in which annual Net Sales of the Products in the Territory exceed [***] | [***] |
| The first Calendar Year in which annual Net Sales of the Products in the Territory exceed [***] | [***] |
| The first Calendar Year in which annual Net Sales of the Products in the Territory exceed [***] | [***] |
| The first Calendar Year in which annual Net Sales of the Products in the Territory exceed [***] | [***] |

Company shall deliver written notice to Licensor within sixty (60) days following the end of the Calendar Year in which a Sales Milestone occurs and Licensor shall issue Company an invoice for the amount of the corresponding Sales Milestone payment, which invoice Company shall pay within [***] following receipt of such invoice.

For the avoidance of doubt, each aforementioned Sales Milestone payment shall be made only once and only with respect to Net Sales of the Products.

The achievement of a higher Sales Milestone shall trigger the payment of a lower Sales Milestone in addition to the payment of the Milestone Payment for such higher Sales Milestone in the event such lower Sales Milestone had not been triggered prior to achievement of the higher Sales Milestone.

For the avoidance of doubt, the total maximum Sales Milestones payable under this Section 6.3 shall not exceed [***].

6.4 **Royalty Payments for Product**.

6.4.1 Royalty Rate. During the Royalty Term, Company shall pay to Licensor a royalty on aggregate annual Net Sales of Products in the Territory for each Calendar Year at the percentage rates set forth below (subject to Sections 6.5 and 6.6 below):

| **Annual Net Sales of Products per Calendar Year (in USD) in the Territory** | **Incremental Royalty Rate** |
|---|---|
| For Net Sales of Products from [***] up to and including [***] | [***] |
| For that portion of Net Sales of Products that is greater than [***] | [***] |

By way of illustration, assume in a Calendar Year, during the Royalty Term, that (i) aggregate annual Net Sales of Products in USD total [***] and (ii) no adjustments or deductions to payments under this Article 6 apply. The total royalties due and payable by Company to Licensor for such Net Sales would be [***], calculated as follows:

[***] x [***] = [***]

[***] x [***] = [***]

Total Royalty = [***]

6.4.2 Net Sales Subject to Royalty Payments and Sales Milestones. For purposes of determining whether a royalty threshold or a Sales Milestone has been attained, only Net Sales that are subject to a royalty payment shall be included in the total amount of Net Sales and any Net Sales that are not subject to a royalty payment shall be excluded. In addition, in no event shall the manufacture of a Product give rise to a royalty obligation. For clarity, Company's obligation to pay royalties to Licensor under this Article 6 is imposed only once with respect to the same unit of Product regardless of the number of Licensor Patents pertaining thereto.

6.5 **Compulsory License**. In the event that Licensor or Company receives a request for a Compulsory License in the Territory, it shall promptly notify the other Party. If any Third Party obtains a Compulsory License in any country in the Territory, then Licensor or Company (whoever has first notice) shall promptly notify the other Party. Thereafter, as of the date the Third Party commences the First Commercial Sale of the Product under such Compulsory License in such country, the royalty rate payable under Section 6.4.1 to Licensor for Net Sales in such country will be adjusted to equal any lower royalty rate granted to such Third Party for such country with respect to the sales of such Product therein. In addition, should Company grant a sublicense to a Third Party in any country of the Territory to avoid the imposition of such a Compulsory License in good faith after consultation with Licensor, the royalty rate payable under Section 6.4.1 to Licensor for Net Sales in such country shall also be adjusted to match any lower royalty rate payable by such Sublicensee for such country under such sublicense. Notwithstanding the foregoing, the Compulsory License Compensation shall be shared equally between the Licensor and Company.

6.6 **Third Party License Agreements and Device Agreement**. In the event that, to avoid infringement of the Third Party's intellectual property rights by either (a) use of the Licensor Technology under the Licensed Rights or (b) Developing, manufacturing or Commercializing the Existing Product, it is reasonably necessary for Company to make payments to a Third Party with respect to a license under such Third Party's intellectual property rights, to develop, manufacture, use, or sell a Product in the Field in the Territory, Company will be entitled to deduct an amount equal to [***] of any such amounts due to such Third Party for such license from any amounts payable to Licensor under Section 6.4. The Parties further agree that Company is entitled to deduct an amount equal to [***] of any amounts (other than amounts due for actual manufacture and supply of a device) due under the Device Agreement from any amounts payable to Licensor under Section 6.4. In no event shall the amount otherwise due to Licensor be less than [***] of the amount that would be payable to Licensor absent the deductions pursuant to this Section 6.6. Notwithstanding the foregoing, Company shall be entitled to carry forward to future Calendar Quarters any amounts that Company would, but for the [***] payment floor in the preceding sentence, be permitted to deduct under this Section 6.6 from amounts payable to Licensor under Section 6.4.

6.7 **Timing of Payment**. Royalties payable under Section 6.4.1 shall be payable on actual Net Sales and shall accrue when such amounts are received and recognized as revenue by Company in accordance with GAAP. Royalty obligations that have accrued during a particular Calendar Quarter shall be paid, on a Calendar Quarter basis in accordance with Section 6.9.

6.8 **Mode of Payment and Currency; Invoices**.

6.8.1 Currency. All payments to Licensor hereunder shall be made by deposit of USD in the requisite amount to such bank account as Licensor may from time to time designate by written notice to Company. With respect to sales not denominated in USD, Company shall convert applicable sales in foreign currency into USD by using the then current and reasonable standard exchange rate methodology applied to its external reporting. Based on the resulting sales in USD, the then applicable royalties shall be calculated. The Parties may vary the method of payment set forth herein at any time upon mutual written agreement, and any change shall be consistent with the local Law at the place of payment or remittance.

6.8.2 Invoices. Licensor shall address its invoices to:

Liquidia Technologies, Inc.
419 Davis Drive, Suite 100
Morrisville, North Carolina
USA
Attn: Accounts Payable
E-mail: ap_invoices@liquidia.com

With a copy to:

Liquidia Technologies, Inc.
419 Davis Drive, Suite 100
Morrisville, NC 27560
USA
Attn: Legal Department

E-mail: legal@liquidia.com

6.9 **Royalty Reports and Records Retention**. Within [***] days after the end of each Calendar Quarter during which Product has been sold, Company shall deliver to Licensor a written royalty report in the form attached hereto as Schedule 6.9. Such report shall be deemed "Confidential Information" of Company subject to the obligations of Article 8 of this Agreement. For two (2) years (unless Company's, or any of its relevant Affiliate's, internal company procedures require a shorter period) after each sale of Product occurs, Company shall, and shall ensure that its Affiliates and Sublicensees, keep complete and accurate records of such sale in sufficient detail to confirm the accuracy of the royalty calculations hereunder.

6.10 **Legal Restrictions**. If at any time legal restrictions prevent the remittance by Company of all or any part of royalties due on Net Sales in any country, Company shall have the right and option to make such payment either by depositing the amount thereof in local currency to an account in the name of Licensor in a bank or other depository selected by Licensor in such country.

6.11 **Taxes**.

6.11.1 Withholding Tax. Licensor shall be responsible for the payment of any and all Taxes levied on account of the royalties and other payments paid to Licensor by Company or its Affiliates or Sublicensees under this Agreement. If Law requires that Taxes be deducted and withheld from royalties or other payments paid under this Agreement, Company shall (a) deduct those Taxes and interests and penalties assessed thereon from the payment or from any other payment owed by Company hereunder; (b) pay the Taxes to the proper Governmental Body; (c) send evidence of the obligation together with proof of Tax payment to Licensor within thirty (30) days following such payment; (d) remit the net amount, after deductions or withholding made under this Section 6.11.1; and (e) cooperate with Licensor in any way reasonably requested by Licensor, to obtain available reductions, credits or refunds of such Taxes; provided, however, that Licensor shall reimburse Company for Company's Out-of-Pocket Expenses incurred in providing such assistance.

6.11.2 Value Added Tax. It is understood and agreed between the Parties that any payments made by Company under this Agreement are exclusive of any value added or similar Tax imposed upon such payment and that Company shall be responsible for the payment of any and all value added Taxes levied on account of any payments paid to Licensor by Company. Company is entitled to receive a proper tax invoice where any value added Tax amount is shown separately. The foregoing notwithstanding, if (a) Licensor or its Affiliates redomiciles to a new jurisdiction that is outside of its current residence and therefore becomes subject to new value added Tax obligations, or (b) Licensor assigns any rights or obligations under this Agreement to a Person that is domiciled in or redomiciles to a new jurisdiction outside its residence and therefore new value added Tax obligations apply, or (c) Licensor, its Affiliates or such assignee thereof otherwise becomes subject to value added Tax obligations in a jurisdiction outside its residence or new value added Tax obligations in its residence, whether through a change in Law or otherwise, then such Licensor (or its Affiliate or assignee) that has re-domiciled or become subject to value added Tax obligations as described in clauses (a) through (c) shall be responsible for any such new value added Tax obligations in accordance with Law and cooperate with Company, where appropriate and relevant.

6.12 **Audits**.

6.12.1 Audits Generally. During the Royalty Term and for [***] Calendar Years thereafter, and not more than once in each Calendar Year unless Licensor has reasonable grounds and evidence to suspect a material inaccuracy in the amount of royalty payments reported and paid by Company hereunder for any period subject to (but that has not already been) audit hereunder, Company shall permit, and shall cause its Affiliates or Sublicensees to permit, an independent certified public accounting firm of internationally recognized standing selected by Licensor, and reasonably acceptable to Company or such Affiliate or Sublicensee, to have access to and to review, during normal business hours upon reasonable prior written notice, the applicable records of Company and its Affiliates or Sublicensees to verify the accuracy of the royalty reports and payments under this Article 6. Such review may cover the records for sales made in any Calendar Year ending not more than two (2) years prior to the date of such request (unless Company's, or any of its relevant Affiliate's, internal company procedures require a shorter period); provided, however, that Licensor shall not be permitted to review any period (or portion thereof) more than once. The accounting firm shall disclose to Licensor and Company only whether the royalty reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Licensor.

6.12.2 Audit-Based Reconciliation. If such accounting firm concludes that additional royalties were owed during such period, and Company agrees with such calculation, Company shall pay the additional undisputed royalties within thirty (30) days after the date Licensor delivers to Company such accounting firm's written report. If such accounting firm concludes that an overpayment was made, such overpayment shall be fully creditable against amounts payable in subsequent payment periods or, at Company's request, shall be reimbursed to Company within thirty (30) days after the date of receipt of the foregoing report. If Company disagrees with such calculation, it may retain its own independent certified public accounting firm of recognized standing and reasonably acceptable to Licensor, to conduct a review, and if such firm concurs with the other accounting firm, Company shall make the required payment within thirty (30) days after the date Company receives the report of its accounting firm. If Company's accounting firm does not concur, Company and Licensor shall meet and negotiate in good faith a resolution of the discrepancies between the two firms. Licensor shall pay for the cost of any audit, unless Company has underpaid Licensor by the greater of (a) [***] or more or (b) [***], in which case Company shall pay for the costs of audit.

6.12.3 Audit Confidentiality. Each Party shall treat all information that it receives under this Section 6.12 in accordance with the confidentiality provisions of Article 8 of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the other Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, except to the extent necessary for such Party to enforce its rights under this Agreement.

## ARTICLE 7
## INTELLECTUAL PROPERTY MATTERS

7.1 **Certification Under Drug Price Competition and Patent Restoration Act**. Each Party shall immediately give written notice to the other Party of any certification of which they become aware filed pursuant to 21 U.S.C. Section 355(b)(2)(A) or 21 U.S.C. Section 355(j)(2)(A) (or any amendments or successor statutes thereto) claiming that any Licensor Patents Covering Product, or the manufacture or use of each of the foregoing, are invalid or unenforceable, or that infringement will not arise from the manufacture, use or sale of a product by a Third Party.

7.2 **Listing of Patents**. Notwithstanding any Licensor Patent prosecution rights of Licensor under this Agreement, Company shall have the sole right to determine which of the Licensor Patents, if any, shall be listed for inclusion in the Approved Drug Products with Therapeutic Equivalence Evaluations pursuant to 21 U.S.C. Section 355, or any successor Law in the United States, together with any comparable Laws in any other country in the Territory.

7.3 **Further Assurances**. Licensor shall require all of its employees, and use its commercially reasonable efforts to require its contractors and agents, and any Affiliates and Third Parties working on its behalf under this Agreement (and their respective employees, contractors and agents), to assign to Licensor any Licensor Technology.

7.4 **Patent Prosecution and Maintenance**.

7.4.1 Specific Licensor Patents. With respect to Licensor Patents that recite at least one claim that (a) encompasses any Product or (b) encompasses any composition of matter covering a Product and explicitly recites treprostinil as the explicit and sole active pharmaceutical ingredient, in the Territory ("**Specific Licensor Patents**"), including the Licensor Patents identified as such in Schedule 1.38 (as may be updated by Company from time to time), Company shall have the first right, and the obligation, to file, prosecute (including initiating or defending any reexamination and reissue proceedings) and maintain, using counsel of Company's choosing, such Specific Licensor Patents in Licensor's name in the Territory. Company shall bear all costs and expenses of filing, prosecuting and maintaining Specific Licensor Patents in the Territory. Company shall keep Licensor informed of the status of the filing and prosecution of Specific Licensor Patents by promptly forwarding to Licensor copies of all official correspondence (including, but not limited to, applications, office actions, and responses) relating thereto. Licensor shall have the right, and Company shall provide Licensor a reasonable opportunity, to comment on and advise Company as to the conduct of such filing, prosecution and maintenance of Specific Licensor Patents, provided, however, that Company shall have the final decision-making right for all matters associated with such filing, prosecution and maintenance. At Company's request, Licensor will provide Company with reasonable free-of-charge assistance in prosecuting Specific Licensor Patents to the extent possible, including providing such data in Licensor's Control that is, in Company's reasonable judgment, needed to support the prosecution of a Specific Licensor Patent.

7.4.2 Non-Specific Licensor Patents. Subject to Section 7.4.1, with respect to all Licensor Patents in the Territory other than Specific Licensor Patents ("**Non-Specific Licensor Patents**") as listed in Schedule 1.38 (as may be updated from time to time by Company), Licensor shall have the first right, and the obligation, to file, prosecute (including initiating or defending any reexamination and reissue proceedings) and maintain, using counsel of Licensor's choosing, such Non-Specific Licensor Patents in Licensor's name. Licensor shall bear all costs and expenses of filing, prosecuting and maintaining Non-Specific Licensor Patents. Licensor shall keep Company informed of the status of the filing and prosecution of Non-Specific Licensor Patents by promptly forwarding to Company copies of all official material correspondence (including, but not limited to, applications, office actions, and responses) relating thereto. Company shall have the right, and Licensor shall provide Company a reasonable opportunity, to comment on and advise Licensor as to the conduct of such filing, prosecution and maintenance of Non-Specific Licensor Patents, provided, however, that Licensor shall have the final decision-making right for all matters associated with such filing, prosecution and maintenance. Notwithstanding the foregoing of this Section 7.4.2, in the event that Licensor or Company wishes to file any continuation

or divisional with respect to any Non-Specific Licensor Patent that claims treprostinil as the explicit and sole active pharmaceutical ingredient, then the prosecution and maintenance of any such continuation or divisional shall be governed by Section 7.4.1.

7.4.3 Election Not to File and Prosecute Licensor Patents. If either Party elects not to file or to continue to prosecute or maintain a Licensor Patent in the Territory where it is permitted to do so pursuant to Sections 7.4.1 and 7.4.2 above, as applicable, or fails to do so after receipt of notice from the other Party, then it shall notify the other Party in writing at least ninety (90) days before any deadline applicable to the filing, prosecution or maintenance of such Licensor Patent, as the case may be, or any other date by which an action must be taken to establish or preserve such Licensor Patent in such country or possession. In such case, the other Party shall have the right to pursue the filing or support the continued prosecution or maintenance of such Licensor Patent. If Licensor fails to continue prosecution or maintenance of any of the Non-Specific Licensor Patents in the Territory, then such abandoned Licensor Patents shall not extend the Royalty Term (i.e., no royalty payments shall be due under this Agreement on account of such abandoned Licensor Patents). If Company fails to continue prosecution or maintenance of any of the Specific Licensor Patents in the Territory, then the Product shall be deemed to be Covered under a Valid Claim for the purposes of the Royalty Term, unless and until Licensor fails to continue such prosecution or maintenance.

7.4.4 Patent Term Extension. Notwithstanding any Licensor Patent prosecution rights of Licensor under this Agreement, Company shall be responsible, in Licensor's name, for obtaining patent term extensions or supplemental protection certificates or comparable extensions in any other country in the Territory, wherever available for Specific Licensor Patents in the Territory. Licensor shall provide Company with all relevant information, documentation and assistance in this respect as may reasonably be requested by Company. Any such assistance, supply of information and consultation shall be provided promptly and in a manner that will ensure that all patent term extensions for Specific Licensor Patents are obtained wherever legally permissible, and to the maximum extent available. In the event that any election with respect to obtaining patent term extensions is to be made, Company shall have the right to make such elections, and Licensor shall abide by all such elections.

7.4.5 Company Patents. Company shall own any Know-How and Patent Rights developed by Company or any of its Affiliates or a Third Party on behalf of Company and shall have the right, but not the obligation, to file, prosecute and maintain any such Patent Rights (collectively, "**Company Patents**"). Company shall bear all costs and expenses of filing, prosecuting and maintaining Company Patents and Licensor shall have no right, title or interest in or to Company Patents.

7.5 **Enforcement**.

7.5.1 Notice.

(a) If either Party believes that an infringement, unauthorized use, misappropriation or ownership claim or threatened infringement or other such activity by a Third Party with respect to any Licensor Technology, or if a Third Party claims that any Licensor Patent is invalid or unenforceable, in each case in the Territory, the Party possessing such knowledge or belief shall notify the other Party and provide it with details of such infringement or claim that are known by such Party.

(b) In the event that Licensor believes that a Company Patent, if any, is being infringed by a Third Party or if a Third Party claims that any Company Patent is invalid or unenforceable, Licensor shall notify Company and provide it with details of such infringement or claim.

7.5.2 Actions. Company shall have the exclusive right, at its own cost (subject to the indemnity obligations set forth in Section 10.2), to attempt to resolve any infringement or claim, including by filing an infringement suit, defending against such claim or taking other similar action, with respect to a Licensor Patent in the Territory (each, an "**Action**") and to compromise or settle any such infringement or claim; provided that the compromise or settlement shall require Licensor's prior written consent if the compromise or settlement will have an adverse impact on Licensor's business outside the Territory or ownership of the Licensor Technology, such consent not to be unreasonably withheld, conditioned or delayed. At Company's request, Licensor shall immediately provide Company with all relevant documentation (as may be requested by Company) evidencing that Company is validly empowered by Licensor to take such an Action. Licensor shall join Company in such Action upon Company's written request. Licensor shall provide reasonable assistance to Company, at the Company's cost, including providing access to relevant documents and other evidence and making its employees available. All amounts recovered by Company shall be allocated, first, to the costs and expenses of the Parties incurred to enforce the Licensor Patents and, second, to Company (provided that such remaining amounts after deduction of the costs and expenses of the Action shall be deemed Net Sales for royalty and Sales Milestone calculation purposes). In the event that Company does not bring such Action against the Third Party infringer within ninety (90) days of the notice delivered under Section 7.5.1, Licensor may request in writing that Company bring an Action, and Company shall consider such request in good faith. Notwithstanding the foregoing, in the event that a Third Party institutes a re-examination action or *inter partes* review proceeding or brings an action where the sole relief sought is declaratory judgment, in each case seeking to have a Licensor Patent declared invalid or unenforceable (a "**Re-Examination Action**"), and Company does not elect to defend such Re-Examination Action within thirty (30) days following Licensor's request pursuant to the preceding sentence, Licensor shall be free to defend the Re-Examination Action, at its own expense, and retain any award or settlement in its entirety. If necessary, Company shall join or be joined as a party to the Re-Examination Action, but shall be under no obligation to participate, except to the extent that such participation is required as a result of being named a party to the Re-Examination Action. Company shall offer reasonable assistance in connection therewith, at no charge to Licensor, except for reimbursement of reasonable Out-of-Pocket Expenses.

7.5.3 Company Patents. Company shall have the sole right and authority, but not the obligation, to enforce Company Patents against any Third Party infringer; provided, however, that Licensor shall provide reasonable assistance to Company with respect thereto, including providing access to relevant documents and other evidence and making its employees available, subject to Company's reimbursement of any Out-of-Pocket Expenses incurred on an on-going basis in providing such assistance.

7.6 **Third Party Actions Claiming Infringement**.

7.6.1 Notice. If Company becomes aware of any Third Party Action against Company, Company shall promptly notify Licensor thereof in writing, setting for the facts of such claim in reasonable detail.

7.6.2 Right to Defend. As between the Parties, Company shall have the exclusive right, at its sole expense and with counsel of its sole choice, but not the obligation, to defend a Third Party Action described in Section 7.6.1 and to compromise or settle such Third Party Action; provided, however, that Company shall not enter into a settlement, consent judgment or other voluntary disposition of any such Third Party Action without consent by Licensor if the settlement, consent judgment or voluntary disposition will have an adverse impact on Licensor's business outside of the Territory or Licensor Technology or involve the admission of liability on the part of Licensor. Licensor shall provide reasonable assistance to Company, at the Company's cost (subject to the indemnity obligations set forth in Section 10.2), including providing access to relevant documents and other evidence and making its employees available.

## ARTICLE 8
## CONFIDENTIALITY

8.1 **Confidentiality Obligations**. Each Party agrees that, for the Term and for five (5) years thereafter, such Party shall, and shall ensure that its Representatives hold in confidence all Confidential Information disclosed to it by the other Party pursuant to this Agreement, unless such information:

(a) is or becomes generally available to the public other than as a result of disclosure by the recipient;

(b) is already known by or in the possession of the recipient at the time of disclosure by the disclosing Party;

(c) is independently developed by recipient without use of or reference to the disclosing Party's Confidential Information; or

(d) is obtained by recipient from a Third Party that has not breached any obligations of confidentiality.

The recipient shall not disclose any of the Confidential Information, except to Representatives of the recipient who need to know the Confidential Information for the purpose of performing the recipient's obligations, or exercising its rights, under this Agreement and who are bound by obligations of non-use and non-disclosure substantially similar to those set forth herein. The recipient shall be responsible for any disclosure or use of the Confidential Information by such Representatives. The recipient shall protect Confidential Information using not less than the same care with which it treats its own confidential information, but at all times shall use at least reasonable care. Each Party shall: (i) implement and maintain appropriate security measures to prevent unauthorized access to, or disclosure of, the other Party's Confidential Information; (ii) promptly notify the other Party of any unauthorized access or disclosure of such other Party's Confidential Information; and (iii) cooperate with such other Party in the investigation and remediation of any such unauthorized access or disclosure.

8.2 **Use**. Notwithstanding Section 8.1, a Party may use the Confidential Information of the other Party for the purpose of performing its obligations, or exercising its rights, under this Agreement, including for purposes of:

(a) filing or prosecuting patent applications, subject to the terms of Section 7.4;

(b) prosecuting or defending litigation;

(c) conducting pre-clinical studies or Clinical Trials pursuant to this Agreement;

(d) seeking or maintaining Regulatory Approval of the Product; or

(e) complying with Law, including securities Law and the rules of any securities exchange or market on which a Party's securities are listed or traded.

In addition to the foregoing, Company may, in furtherance of its rights under this Agreement, disclose Confidential Information of Licensor to any Third Party, provided that such Third Party is bound by obligations of confidentiality at least as stringent as the ones herein.

In making any disclosures pursuant to this Section 8.2, the disclosing Party shall, where reasonably practicable, give such advance notice to the other Party of such disclosure requirement as is reasonable under the circumstances and will use its commercially reasonable efforts to cooperate with the other Party in order to secure confidential treatment of such Confidential Information required to be disclosed. In addition, in connection with any permitted filing by either Party of this Agreement with any Governmental Body the filing Party shall endeavor to obtain confidential treatment of economic, trade secret information and such other information as may be requested by the other Party, and shall provide the other Party with the proposed confidential treatment request with reasonable time for such other Party to provide comments, and shall include in such confidential treatment request all reasonable comments of the other Party.

For the avoidance of doubt and notwithstanding anything in this Agreement to the contrary, in no event may Licensor use or reference any Confidential Information of Company, including any information reported by Company to Licensor in connection with this Agreement, to engage in any Competitive Action.

8.3 **Required Disclosure**. The recipient may disclose the Confidential Information to the extent required by Law or court order; provided, however, that the recipient promptly provides to the disclosing party prior written notice of such disclosure and provides reasonable assistance in obtaining an order or other remedy protecting the Confidential Information from public disclosure. If the recipient is required to make a disclosure as described in this Section 8.3, the recipient will furnish only that portion of the Confidential Information that is legally required.

8.4 **Publications**. Licensor shall not publish any information relating to Product without the prior written consent of Company (which consent may be withheld or given in Company's sole discretion), unless such information has already been publicly disclosed either prior to the Effective Date or after the Effective Date through no fault of Licensor or otherwise not in violation of this Agreement. Company shall have the right to make such publications as it chooses, in its sole discretion, without the approval of Licensor. Licensor shall submit to Company for Company's written approval (which approval be granted or denied in Company's sole discretion) any publication or presentation (including in any seminars, symposia or otherwise) of information related directly or indirectly to the Product for review and approval at least ninety (90) days prior to submission for the proposed date of publication or presentation.

8.5 **Press Releases and Disclosure**.

8.5.1 Initial Press Release. The proposed joint public announcement by Licensor and Company of the execution of this Agreement is set forth on Schedule 8.5.1 hereto.

8.5.2 Public Disclosures by Licensor. Except as provided in Section 8.5.4, Licensor may not make any subsequent press release or public announcement regarding the terms of this Agreement or any matter covered by this Agreement, including the Development or Commercialization of Licensed Products, without the prior written consent of Company.

8.5.3 Public Disclosures by Company. Except as provided in Section 8.5.4, Company may not make any subsequent press release or public announcement regarding the terms of this Agreement; provided, however, that Company shall have the right to make such press releases as it chooses, in its sole discretion, regarding the status of its Development or Commercialization of Licensed Products without the approval of Licensor, provided further, that, to the extent practicable, Company shall use commercially reasonable efforts to notify Licensor in advance of any such press release that would reasonably be expected to trigger any securities filing obligations for Licensor.

8.5.4 Exceptions. Notwithstanding the foregoing, either Party shall have the right, without the approval of the other Party, (a) to make securities filings that such Party determines are required under applicable securities laws and regulations (provided, that to the extent practicable, it provides the text of such planned disclosure to the non-disclosing Party no less than two (2) days prior to disclosure, and has used commercially reasonable efforts to incorporate all reasonable comments of the non-disclosing Party regarding such disclosure); and (b) to make disclosures of information that has been previously published or released in accordance with the terms and conditions of this Agreement.

## ARTICLE 9
## REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 **Representations and Warranties**. Each Party represents and warrants to the other Party that, as of the Effective Date:

(a) such Party is duly organized and validly existing under the Laws of the jurisdiction of its incorporation;

(b) such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;

(c) this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement by such Party does not conflict with, breach or create in any Third Party the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound, and does not violate any Law of any Governmental Body having authority over such Party; and

(d) such Party has all right, power and authority to enter into this Agreement, to perform its obligations under this Agreement.

9.2 **Additional Representations and Warranties of Licensor**. Licensor represents and warrants to Company that, as of the Effective Date:

(a) no consent by any Third Party or Governmental Body is required with respect to the execution and delivery of this Agreement by Licensor or the consummation by Licensor of the transactions contemplated hereby;

(b) no claims have been asserted or threatened by any Person, nor to Licensor's Knowledge, are there any valid grounds for any claim of any such kind, (i) challenging the validity, effectiveness, or ownership of Licensor Technology, and/or (ii) to the effect that the use, reproduction, modification, manufacturing, distribution, licensing, sublicensing, sale or any other exercise of rights in any of Licensor Technology infringes or will infringe on any intellectual property right of any Person;

(c) to Licensor's Knowledge, there is no unauthorized use, infringement or misappropriation of any of Licensor Technology by any employee or former employee of Licensor, or any other Third Party in the Territory;

(d) the Licensor Patents are subsisting and all registration, renewal, maintenance and other official fees with respect to the Licensor Patents due on or before the date of this Agreement have been paid in full. Licensor is the sole assignee and owner of each item listed on Schedule 1.38. To Licensor's Knowledge, the Licensor Patents are not the subject of any litigation procedure, discovery process, interference, reissue, reexamination, opposition, appeal proceedings or any other legal dispute;

(e) the Licensor Patents (i) constitute all Patent Rights owned or Controlled by Licensor as of the Effective Date that are directly related to, necessary or useful for, or used in, the Development, regulatory approval, manufacture, use, marketing, sale, offer for sale, import, export or Commercialization of the Existing Product in the Territory and (ii) listed on Schedule 1.38 hereto constitute all Patent Rights that are directly related to, necessary or useful for, or used in, the Development, regulatory approval, manufacture, use, marketing sale, offer for sale, import, export or Commercialization of the Existing Product in the Territory;

(f) the Licensor Know-How (i) constitutes all Know-How owned or Controlled by Licensor as of the Effective Date that is directly related to, or are necessary or useful for, the Development, manufacture, use or Commercialization of the Existing Product under the Licensed Rights and (ii) to Licensor's Knowledge, constitutes all Know-How that is directly related to, or are necessary or useful for, the Development, manufacture, use or Commercialization of the Existing Product under the Licensed Rights;

(g) all of the Licensor Technology is owned by Licensor or its Affiliates and Licensor has not in-licensed, or otherwise obtained any rights, from a Third Party with respect to the Existing Product or the Licensor Technology;

(h) Licensor has not licensed to a Third Party the right to develop a Product;

(i) no Third Party has filed, pursued or maintained or threatened in writing to file, pursue or maintain any claim, lawsuit, charge, complaint or other action alleging that any Licensor Patent is invalid or unenforceable;

(j) to Licensor's Knowledge, Company's and its Affiliates' and Sublicensees' practice and use of the inventions claimed in the Licensor Patents under the Licensed Rights as

permitted herein (including the sale, offer for sale, Commercialization or regulatory approval of Product) will not infringe any intellectual property rights of any Third Party;

(k) all Representatives of Licensor who have performed any activities on its behalf in connection with Development regarding Product have assigned to Licensor the whole of their rights in any intellectual property made, discovered or developed by them as a result of such Development, and no Third Party has any rights to any such intellectual property;

(l) Licensor has all right, title and interest in and to the Licensor Technology and Licensor Technology is free and clear of any liens, charges, encumbrances or rights of others to possession or use;

(m) Licensor has not previously licensed, assigned, transferred, or otherwise conveyed any right, title or interest in and to the Licensor Technology to any Third Party in the Territory, including any rights with respect to Product;

(n) to Licensor's Knowledge, the Licensor Technology constitutes all of the intellectual property which could reasonably be expected to be necessary or useful for, or used in, the Development, manufacture, regulatory approval, import, export, use, marketing, sale, offer for sale or Commercialization of the Existing Product;

(o) the Existing Product falls within the scope of at least one valid claim of at least one of the Licensor Patents listed on Schedule 1.38;

(p) to Licensor's Knowledge, there is no additional Third Party licenses that have to be taken now or in the future to guarantee freedom-to-operate to Develop, manufacture and Commercialize the Existing Product without any limitation;

(q) except as set forth in Schedule 9.2(q), Licensor has the right, power and authority to assign the Existing Third Party Agreements to Company. In particular, except as set forth in Schedule 9.2(q), no such assignment requires consent, waiver or other action by any party to the applicable Existing Third Party Agreement;

(r) the Existing Third Party Agreements constitute all agreements that were entered into by Licensor or its Affiliates with Third Parties for the conduct of Clinical Trials for the Existing Product. Licensor has provided to Company an accurate, true and complete copy of each of the Existing Third Party Agreements, as amended to date and each of the Existing Third Party Agreements is in full force and effect. Licensor is not, and to Licensor's Knowledge no other party to any Existing Third Party Agreement is, in breach or default in the performance of its obligations under any of the Existing Third Party Agreements. Licensor has not received any notice from any Third Party of any breach, default or non-compliance of Licensor under the terms of any of the Existing Third Party Agreements. There have been no amendments or other modification to any Existing Third Party Agreements, except as have been disclosed to Company in writing;

(s) all tangible information and data provided by or on behalf of Licensor to Company on or before the Effective Date in contemplation of this Agreement was and is true, accurate and complete in all material respects, and Licensor has not failed to disclose, or cause to be disclosed, any information or data that would cause the information and data that has been disclosed to be misleading in any material respect;

(t) Licensor (and its Affiliates) has not employed or otherwise used in any capacity, and will not employ or otherwise use in any capacity, the services of any Person debarred under any Law, including under Section 21 USC 335a or any foreign equivalent thereof, with respect to the Licensor Technology or Product;

(u) all Development related to Existing Product prior to the Effective Date has been conducted in accordance with all Laws; and

(v) Licensor has on hand as of the Effective Date the inventory of materials set forth in Exhibit A to the Asset Transfer Agreement (including in the quantities set forth therein). Such materials to be provided to Company pursuant to the Asset Transfer Agreement were (and at all times up until delivery of such materials hereunder shall remain) manufactured, packaged, labeled, tested, stored and handled in accordance with all Laws and specifications (including, to the extent applicable, release specifications as provided by Licensor to Company in writing prior to the Effective Date). Such materials are not adulterated or misbranded within the meaning of any Law. All such materials are free and clear of all encumbrances (including through lien, charge, security interest, mortgage, encumbrance or otherwise) and are suitable for use in Clinical Trials.

9.3 **Licensor Covenants**. Licensor covenants to Company that:

(a) Licensor shall fulfill all of its obligations, including but not limited to its payment obligations, under each Existing Third Party Agreement that related to periods prior to the assignment of such Existing Third Party Agreement to Company;

(b) Licensor shall fulfill all of its obligations, including but not limited to its payment obligations, under any Third Party License Agreement;

(c) Licensor shall not amend or waive, or take any action or omit to taking any action that would alter, any of Licensor's rights under any Third Party License Agreement in any manner that adversely affects, or would reasonably be expected to adversely affect, Company's rights and benefits under this Agreement. Licensor shall promptly notify Company of any default under, termination or amendment of, any Third Party License Agreement; and

(d) without limiting Section 2.4, with respect to each Existing Third Party Agreement, until such time as such Existing Third Party Agreement has been assigned to, and assumed by, Company, (i) Licensor shall not amend or terminate such Existing Third Party Agreement, or waive, or take any action or omit to take any action that would alter, any of Licensor's rights under any Existing Third Party Agreement, and (ii) Licensor shall promptly notify Company of any default under, or termination or amendment of, any Existing Third Party Agreement. In the case of any default by Licensor under an Existing Third Party Agreement, Licensor shall provide Company a reasonable opportunity to cure such default.

## ARTICLE 10
## INDEMNIFICATION AND INSURANCE

10.1 **Indemnification by Company**. Company shall indemnify, defend and hold Licensor and its Affiliates and each of their respective employees, officers, directors and agents (the "**Licensor Indemnitees**") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees) (collectively, the "**Losses**") to the extent arising out of Third

Party claims or suits to the extent arising out of: (a) the Development, sale, offer for sale, import, export and other Commercialization of the Product by or on behalf of Company, its Affiliates or Sublicensees after the Effective Date; (b) Company's gross negligence or willful misconduct; (c) Company's breach of its obligations under this Agreement; or (d) breach by Company of its representations or warranties set forth in Article 9; except, in each case (a)-(d), to the extent such Losses arise out of (i) any activities set forth in Sections 10.2(a)-(d) for which Licensor is obligated to indemnify any Company Indemnitee under Section 10.2 or (ii) any liability for which Licensor is responsible under the Supply Agreement or any other agreement between Licensor and Company.

10.2 **Indemnification by Licensor**. Licensor shall indemnify, defend and hold Company and its Affiliates and each of their respective agents, employees, officers and directors ("**Company Indemnitees**") harmless from and against any and all Losses to the extent arising out of Third Party claims or suits to the extent arising out of: (a) Licensor's Development, manufacture, use or Commercialization of the Licensor Technology and Product (including Existing Product) prior to the Effective Date; (b) Licensor's gross negligence or willful misconduct; (c) Licensor's breach of its obligations under this Agreement; or (d) breach by Licensor of its representations, warranties or covenants set forth in Article 9; except, in each case (a)-(d), to the extent such Losses arise out of any activities set forth in Sections 10.1(a)-(d) for which Company is obligated to indemnify any Licensor Indemnitee under Section 10.1.

10.3 **No Consequential Damages**. EXCEPT WITH RESPECT TO EACH PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 10.1 OR SECTION 10.2, AS APPLICABLE, IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOSS OF PROFITS, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT SHALL LIMIT EITHER PARTY FROM SEEKING OR OBTAINING ANY REMEDY AVAILABLE UNDER LAW FOR ANY BREACH OF BY THE OTHER PARTY OF ITS CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 8.

10.4 **Notification of Claims; Conditions to Indemnification Obligations**. As a condition to a Party's right to receive indemnification under this Article 10, it shall: (a) promptly notify the other Party as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto; (b) cooperate, and cause the individual indemnitees to cooperate, with the indemnifying Party in the defense, settlement or compromise of such claim or suit; and (c) permit indemnifying Party to control the defense, settlement or compromise of such claim or suit, including the right to select defense counsel. In no event, however, may the indemnifying Party compromise or settle any claim or suit in a manner which admits fault or negligence on the part of the indemnified Party or any indemnitee without the prior written consent of the indemnified Party. Each Party shall reasonably cooperate with the other Party and its counsel in the course of the defense of any such suit, claim or demand, such cooperation to include without limitation using commercially reasonable efforts to provide or make available documents, information and witnesses. The indemnifying Party shall have no liability under this Article 10 with respect to claims or suits settled or compromised without its prior written consent.

10.5 **Insurance**. During the Term, each Party shall obtain and maintain, at its sole cost and expense, insurance (including any self-insured arrangements) in types and amounts, that are reasonable and

customary in the United States and Taiwan, as applicable, pharmaceutical and biotechnology industry for companies engaged in comparable activities. It is understood and agreed that this insurance shall not be construed to limit either Party's liability with respect to its indemnification obligations hereunder. Each Party will, except to the extent self-insured, provide to the other Party upon request a certificate evidencing the insurance such Party is required to obtain and keep in force under this Section 10.5.

## ARTICLE 11
## TERM AND TERMINATION

11.1 **Term and Expiration**. The term of this Agreement (the "**Term**") shall commence on the Effective Date and, unless earlier terminated as provided in this Article 11, shall continue in full force and effect, on a country-by-country and Product-by-Product basis until the date on which the Royalty Term in such country with respect to such Product expires, at which time this Agreement shall expire in its entirety with respect to such Product in such country and the terms of Section 11.5.2(a) shall apply.

11.2 **Termination upon Material Breach**.

11.2.1 Material Breach. If a Party breaches any of its material obligations under this Agreement, the Party not in default may give to the breaching Party a written notice specifying the nature of the default, requiring it to cure such breach, and stating its intention to terminate this Agreement if such breach is not cured within [***] days. If such breach is not cured within [***] days after the receipt of such notice, the Party not in default shall be entitled to terminate this Agreement immediately by written notice to the other Party. For clarity, such material obligations may apply to the performance of either: (a) this Agreement in its entirety, in which case this provision shall apply to the entire Agreement; (b) a specific Product or Product(s), in which case this provision shall apply only to such affected Product or Product(s); or (c) a specific country or countries within the Territory, in which case this provision shall apply only to such affected country or countries.

11.2.2 Licensor Cure Period. If Licensor is the defaulting party and a material breach by Licensor is not cured within [***] days of receipt following a notice from Company under Section 11.2.1 (the "**Cure Period**"), Company may elect not to terminate this Agreement and, instead, during the period commencing at the end of the Cure Period and continuing until the end of the last Royalty Term in all countries, reduce the Development Milestone payments under Section 6.2, the Sales Milestone payments under Section 6.3 and the then applicable royalty rates under Section 6.4.1 by [***]; provided, that such reduction shall not be Company's sole remedy with respect to the breach by Licensor.

11.2.3 Material Breach Dispute. Any Dispute regarding an alleged material breach of this Agreement shall be resolved in accordance with Article 3 and Article 12. In such event, termination will be tolled and the termination will become effective only if such material breach remains uncured for the applicable cure period after the final resolution of the Dispute through such dispute resolution procedures.

11.3 **Bankruptcy Event Termination**. This Agreement may be terminated by written notice by a Party at any time during the Term in the event of a Bankruptcy Event of the other Party.

11.4 **Mutual Termination**. The Parties may terminate this Agreement in its entirety or on a country-by-country or Product-by-Product basis upon mutual written agreement.

11.5 **Effects of Termination**.

11.5.1 Survival.

(a) Notwithstanding the expiration or termination of this Agreement, the following provisions shall survive: Articles 1, 8 (solely with respect to the time period set forth in Section 8.1) and 12; and Sections 4.5 (with respect to trademark ownership), 5.1 (with respect to ownership of regulatory filings and Regulatory Approvals), 5.7, 6.9, 6.11, 6.12.1-6.12.2 (solely with respect to audits conducted within the period set forth in Section 6.12.1), 6.12.3, 7.4.5, 10.1-10.4, 11.5-11.7, 13.1, 13.2.1-13.2.4, 13.2.5 (for so long as Company has a continuing license hereunder), 13.3, and 13.5-13.18.

(b) Expiration or termination of this Agreement shall not relieve the Parties of any liability that accrued hereunder prior to the effective date of such termination. In addition, termination of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

**11.5.2** Licenses.

(a) As of the effective date of expiration of the Royalty Term with respect to a given Product and country, the Licensed Rights shall convert to a fully paid, royalty free, irrevocable, perpetual, exclusive, and sublicensable license under the Licensor Technology to Develop, manufacture, have manufactured, use and Commercialize such Product in the Field in such country.

(b) Upon termination of this Agreement by Licensor pursuant to Section 11.2.1 or 11.3, the following terms and conditions shall apply with respect to such Product(s) and country(ies) as are the subject of such termination:

(i) all licenses granted to Company under Section 2.1 shall terminate;

(ii) Company shall, upon written request by Licensor and within three (3) months therefrom, and subject to Licensor assuming legal responsibility for any Clinical Trials of the Existing Product then ongoing, transfer to Licensor or its Third Party designee at no cost to Licensor (except in any such case where Licensor is seeking a claim for damages from Company with respect to any such breach or termination of this Agreement, in which case Company shall be entitled to offset any costs against any such damages in an amount equal to the sum of the Development Milestone payments made by Company to Licensor prior to the commercial launch of the Existing Product) ownership and control of all regulatory filings, Regulatory Approvals and product data prepared or obtained by or on behalf of Company prior to the date of such termination, to the extent solely related to the Existing Product and country(ies) and transferable, and Company shall take any actions reasonably necessary to effect such transfer, provided Company shall have the right to retain one copy of such transferred regulatory filings, Regulatory Approvals and product data for record-keeping purposes;

(iii) Company shall, upon written request of Licensor, return to Licensor or, at Company's option, destroy, at Company's cost and expense, all relevant records and materials in its possession or control containing or comprising the Licensor Know-How, or such other Confidential Information of Licensor, to the extent solely related to such Product(s) and country(ies); provided, however, that Company shall have the right to retain one copy of such Licensor Know-How and such other Confidential Information of Licensor for archival purpose;

(iv) Company shall, at Licensor's election within thirty (30) days following termination, sell such materials (in whole or in part) to Licensor at a price equal to Company's costs of goods. Any clinical supplies of such Product(s) or other materials purchased by Licensor from Company shall be purchased on an "as is" basis with no representations or warranties. In the event that Licensor does not make an election within such thirty (30) day period or elects not to purchase such materials, Company shall have the right to (A) destroy or retain any and all chemical, biological or physical materials relating to or comprising such Product(s), including clinical supplies of such Product(s), that are Controlled by Company to the extent solely related to such country(ies) or (B) sell such materials to a Third Party;

(v) To the extent not prohibited by Law, Company shall wind down any ongoing Clinical Trials to the extent solely related to such Product(s) and country(ies);

(vi) Company and its Affiliates and Sublicensees shall be entitled, during the [***] month period following such termination, to sell any commercial inventory of such Product(s) which remains on hand as of the date of the termination, so long as Company pays to Licensor the royalties applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement. Any commercial inventory remaining following [***] month period shall be offered for sale to Licensor at a price equal to Company's costs of goods; and

(vii) Upon any termination of this Agreement, each of Company's Sublicensees shall continue to have the rights and license set forth in its sublicense agreements, which agreements shall be automatically assigned to Licensor, to the extent solely related to such Product(s) and country(ies); provided, however, that such Sublicensee is not then in breach of any of its material obligations under its sublicense agreement.

11.6 **Additional Effects of Termination for a Licensor Bankruptcy Event**.

11.6.1 Continuing Rights. The Parties agree that Company, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of a Licensor Bankruptcy Event, Company shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in Company's possession, shall be promptly delivered to it (a) following any such commencement of a bankruptcy proceeding upon Company's written request therefor, unless Licensor elects to continue to perform all of its obligations

under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by Licensor upon written request therefor by Company.

11.6.2 Right of First Refusal. In addition to the foregoing, in the event of a Licensor Bankruptcy Event, Company shall, to the extent allowed by Law (including to the extent enforceable under the Laws of Taiwan), have a right of first refusal to purchase all of Licensor's interest in the Product and the Licensor Technology (the "**Right of First Refusal**"). The Right of First Refusal shall operate as follows:

(a) Licensor (or other authorized representative of Licensor, including a bankruptcy trustee) shall promptly send to Company a reasonably detailed written notification of any Licensor Bankruptcy Event.

(b) Licensor (or other authorized representative of Licensor, including a bankruptcy trustee) shall promptly send to Company a written notification of any Third Party offer made on Product or Licensor Technology. For a period of up to [***] after Company receives such notice (such period, the "**Right of First Refusal Notice Period**"), it shall notify Licensor of its intention to exercise its Rights of First Refusal. In the event Company exercises its Right of First Refusal, the terms of the Third Party offer shall become binding upon Company and Licensor. For the avoidance of doubt, Licensor shall not enter into any agreement with a Third Party relating to Licensor's interest in the Products or Licensor Technology during the Right of First Refusal Notice Period.

11.7 **Other Remedies**. Termination of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to such termination. Termination of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect or limit, any rights or remedies that otherwise may be available at Law or in equity.

## ARTICLE 12
## DISPUTE RESOLUTION

12.1 **General**. The Parties recognize that disputes ("**Disputes**") as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish under this Article 12 procedures to facilitate the resolution of Disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation.

12.2 **Escalation to Executive Officers**. Either Party may, by written notice to the other Party, request that a Dispute that remains unresolved by the Parties or the JSC for a period of thirty (30) days be submitted to the Executive Officers for resolution. If the Executive Officers cannot resolve such Dispute within thirty (30) days after referral of such Dispute to them, then, at any time after such thirty (30) day period, either Party may refer such Dispute to arbitration by submitting a written notice of such request to the other Party.

12.3 **Arbitration**.

12.3.1 Disputes. The Parties hereby agree that, except as otherwise expressly set forth herein, in the event the Parties are unable to resolve any Dispute after referring such Dispute to the Executive Officers, the Dispute shall be settled by binding arbitration administered by the

International Chamber of Commerce ("**ICC**") in accordance with its Rules of Arbitration (the "**Rules**"). Either Party may refer any Dispute to arbitration by submitting a written notice of such request to the other Party.

12.3.2 Arbitrators. Any arbitration shall be presided over by three (3) arbitrators. Each Party shall select one (1) arbitrator, and such selected arbitrators shall mutually agree upon the third arbitrator who shall act as the chairman of the arbitration panel. If either Party fails or both Parties fail to choose an arbitrator or arbitrators within thirty (30) days after receiving notice of commencement of arbitration or if the two (2) arbitrators fail to choose a third arbitrator within thirty (30) days after their appointment, then either or both Parties shall immediately request that the ICC select the remaining number of arbitrators to be selected. The arbitrators shall be neutral and independent of the Parties and their respective Affiliates, and may not be current or former directors, officers or employees of the Parties or their respective Affiliates. No Party may have any *ex parte* discussion with any potential arbitrator, except for confirming if such arbitrator is willing and able to serve on the arbitration panel. All arbitrators shall have ten (10) or more years of experience in the pharmaceutical and biotechnology industries, shall have appropriate experience with respect to the matter(s) to be arbitrated, and shall have some experience in mediating or arbitrating issues relating to such agreements.

12.3.3 Arbitration Process. The seat of the arbitration shall be New York, New York, USA. The arbitrators shall set a date for a hearing that shall be held no later than sixty (60) days following the appointment of the last of such three (3) arbitrators. The Parties shall have the right to be represented by counsel. No less than thirty (30) days prior to the hearing, each Party shall submit the following to the other Party and the arbitration panel: (a) a copy of all exhibits on which such Party intends to rely in any oral or written presentation to the panel; (b) a list of any witnesses such Party intends to call at the hearing, and a short summary of the anticipated testimony of each witness; and (c) a brief in support of such Party's proposed rulings and remedies; provided that the brief shall not exceed twenty-five (25) pages. This page limitation shall apply regardless of the number of issues raised in the arbitration proceeding. The arbitrators shall determine what discovery will be permitted in accordance with the Rules, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery; provided, however, that the arbitrators shall permit discovery as they deem proportionate to the issues in dispute. The arbitration panel shall have sole discretion regarding the admissibility of any evidence, except statements made during settlement negotiations and affidavits prepared for the purposes of the hearing shall not be admissible. Within ten (10) days following completion of the hearing, each Party may submit to the other Party and the panel a post-hearing brief in support of its proposed rulings and remedies; provided that such brief shall not contain or discuss any new evidence and shall not exceed ten (10) pages. This page limitation shall apply regardless of the number of issues raised in the proceeding.

12.3.4 Decision of Arbitrators. The arbitrators shall use their best efforts to rule on each disputed issue within thirty (30) days after completion of the hearing described in Section 12.3.3. The determination of the arbitrators as to the resolution of any Dispute shall be binding and conclusive upon the Parties, absent manifest error. All rulings of the arbitrators shall be in writing and shall be delivered to the Parties as soon as is reasonably possible.

12.3.5 Awards. Any award to be paid by one Party to the other Party as determined by the arbitrators as set forth above under this Section 12.3 be promptly paid in USD free of any Tax, deduction or offset, and any costs, fees or Taxes incident to enforcing the award shall,

to the maximum extent permitted by Law, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Section 12.3, and agrees that, subject to the Federal Arbitration Act, judgment may be entered upon the final award in a court of competent jurisdiction and that other courts may award full faith and credit to such judgment in order to enforce such award.

12.3.6 Costs and Expenses. The Parties agree that they shall share equally in the joint costs associated with the arbitration hearing(s) and any procedural conferences (location, stenographer and similar), the fees and expenses of any independent expert retained by the arbitrators, if any, and the fees and expenses of the arbitrators (as set forth above) and administrative fees and expenses of ICC. Each Party shall bear its own costs and attorneys' and witnesses' fees and associated costs and expenses. The existence and substance of the arbitration proceedings and the decision of the arbitrators shall be kept confidential by the Parties and the arbitrators except to the extent disclosure may be necessary to conduct the arbitration, or in connection with a court application for a preliminary remedy, a judicial challenge to an award or its enforcement, or unless otherwise required by law or judicial decision.

12.4 **Injunctive Relief**. Notwithstanding anything to the contrary in this Agreement, either Party will have the right to seek temporary injunctive or preliminary equitable relief pending final resolution of any Dispute under Section 12.3, in any court of competent jurisdiction as may be available to such Party under Law in such jurisdiction with respect to any matters arising out of the other Party's performance or breach of its obligations under this Agreement.

## ARTICLE 13
## MISCELLANEOUS PROVISIONS

13.1 **Relationship of the Parties**. Nothing in this Agreement is intended or shall be deemed, for financial, Tax, legal or other purposes, to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties.

13.2 **Assignment**.

13.2.1 Assignment Generally. Except as expressly provided herein, neither this Agreement nor any interest hereunder shall be assignable, nor any other obligation delegable, by Licensor without the prior written consent of Company (not to be unreasonably withheld or delayed).

13.2.2 Assignment by Company. Except as expressly provided herein, neither this Agreement nor any interest hereunder shall be assignable, nor any other obligation delegable, by Company without the prior written consent of Licensor (not to be unreasonably withheld, conditioned or delayed); provided, however, that Company may, without the prior written consent of Licensor, assign this Agreement to an Affiliate or to any Third Party in connection with a Change of Control or sale of all or substantially all of its assets to which this Agreement relates.

13.2.3 Continuing Obligations. No assignment under this Section 13.2 shall relieve the assigning Party of any of its responsibilities or obligations hereunder and, as a condition of such assignment, the assignee shall agree in writing to be bound by all obligations of the assigning Party hereunder. This Agreement shall be binding upon the successors and permitted assigns of the Parties.

13.2.4 Void Assignments. Any assignment not in accordance with this Section 13.2 shall be void.

13.2.5 Assignment of Licensor Technology. Licensor shall not assign or transfer any Licensor Technology to any of its Affiliates without the prior written consent of Company unless such Affiliate agrees in writing to be bound by all obligations of Licensor.

13.3 **Performance and Exercise by Affiliates**. Company shall have the right to have any of its obligations hereunder performed, or its rights hereunder exercised, by, any of its Affiliates and the performance of such obligations by any such Affiliate shall be deemed to be performance by Company; provided, however, that Company shall be responsible for ensuring the performance of its obligations under this Agreement and that any failure of any Affiliate performing obligations of Company hereunder shall be deemed to be a failure by Company to perform such obligations. For clarity, the foregoing means that Company may designate an Affiliate to perform its obligations hereunder or to be the recipient of Licensor's performance obligations hereunder.

13.4 **Competition**. In the event (a) of a Change of Control of Licensor in which a Company Competitor acquires control (as defined in Section 1.2) of Licensor or (b) Licensor or its Affiliates (i) file for or receive Regulatory Approval for a Competing Product for the Contemplated Indications in the Territory or (ii) are Commercializing a Competing Product in the Territory with off-label prescription for at least [***] or use in the Territory for the Contemplated Indications ("**Competitive Action**"), then as from the date of such Change of Control or the date on which Licensor or its Affiliates begin such Competitive Action, Company shall cease to have obligations to provide royalty reports to Licensor or its successor entity or share any market information pursuant to Section 4.2.1 and the JSC shall be immediately disbanded. In the event that such reporting obligations cease and the JSC is disbanded as a result of Competitive Action, such reporting obligations and the JSC will be resumed at the time when (x) Licensor or its Affiliates grants an exclusive (even as to Licensor and its Affiliates) license to a Third Party to research, develop, manufacture and commercialize the Competing Product for the entire Territory or (y) all Competitive Action ceases.

13.5 **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.

13.6 **Accounting Procedures**. Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with GAAP.

13.7 **Force Majeure**. Neither Party shall be liable to the other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a governmental authority, acts of a government or an agency thereof or judicial orders or decrees or restrictions or any other reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities) and will use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable.

13.8 **No Trademark Rights**. No right, express or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name or trademark of the other Party in connection with the performance of this Agreement or otherwise.

13.9 **Entire Agreement of the Parties; Amendments**. This Agreement and the Schedules and Exhibits hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

13.10 **Captions**. The captions to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement.

13.11 **Governing Law**. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, USA, excluding application of any conflict of laws principles that would require application of the Law of a jurisdiction outside of State of New York, USA.

13.12 **Notices and Deliveries**. Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person or transmitted by express courier service (signature required) to the Party to which it is directed at its address shown below or such other address as such Party shall have last given by notice to the other Party.

If to Company, addressed to:

Liquidia Technologies, Inc.
419 Davis Drive, Suite 100
Morrisville, North Carolina 27560
USA
Attention: General Counsel
Email: legal@liquidia.com

With a copy, which shall not constitute notice, to:

DLA Piper LLP (US)
51 John F. Kennedy Parkway, Suite 120
Short Hills, New Jersey 07078
USA
Attention: Andrew P. Gilbert
Email: andrew.gilbert@us.dlapiper.com

If to Licensor, addressed to:

Pharmosa Biopharm Inc.
3F.-3, No. 66, Sanchong Road
Nangang District, Taipei City 11502
Taiwan
Attention: Pei Kan/ Weishu Lu
Email: peikan@pharmosa.com.tw/ Weishu.lu@pharmosa.com.tw

With a copy, which shall not constitute notice, to:

K&L Gates
30F, No. 95. Dun Hua S. Road, Section 2
Ta-an District, Taipei City 106
Taiwan
Attention: Jacqueline Fu
Email: jacqueline.fu@klgates.com

13.13 **Language.** The official language of this Agreement and between the Parties for all correspondence shall be the English language.

13.14 **Waiver**. A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

13.15 **Severability**. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under Law, but if any provision of this Agreement is held to be prohibited by or invalid under Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

13.16 **No Implied License**. No right or license is granted to Licensor hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by Company or its Affiliates.

13.17 **Interpretation**. The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “without limitation.” All references herein to Articles, Sections, Schedules and Exhibits shall be deemed references to Articles and Sections of, and Schedules and Exhibits to, this Agreement unless the context shall otherwise require. Except as otherwise expressly provided herein, all terms of an accounting or financial nature shall be construed in accordance with GAAP. Unless the context otherwise requires, countries shall include territories.

13.18 **Counterparts**. This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.

**[SIGNATURE PAGE FOLLOWS]**

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

| **PHARMOSA BIOPHARM INC.** | **LIQUIDIA TECHNOLOGIES, INC.** |
|---|---|
| Signature: /s/ Pei Kan | Signature: /s/ Roger Jeffs |
| Printed Name: Pei Kan | Printed Name: Roger Jeffs |
| Title: President | Title: CEO |

**[Signature Page to License Agreement]**

Schedule 1.23

Existing Product

[***]

Schedule 1.24

Existing Third Party Agreements

[***]

Schedule 1.35

Licensor Know-How

[***]

Schedule 1.36

Licensor's Knowledge Individuals

[***]

Schedule 1.38

Licensor Patents

[***]

Schedule 2.3

Licensor Technology Transfer Plan

[***]

Schedule 4.3

Supply Agreement Key Terms

The terms outlined below, together with any terms contained or described in the Agreement, will serve as the basis for the definitive Supply Agreement between the Parties. Unless otherwise set forth herein, capitalized terms shall have the meanings ascribed to them in the Agreement.

| **CLINICAL SUPPLY TERMS** | |
|---|---|
| **Clinical Supply Obligation** | During the term of the Supply Agreement, Company may deliver purchase orders to Licensor for the manufacture and supply of Filled Ampules for the development of Product in the Territory (including use of Filled Ampules in clinical trials). Within [***] following Company's issuance of each purchase order, Licensor shall acknowledge receipt and acceptance of such purchase order; provided, that Company provides at least [***] of lead time for such purchase order. In the event that Company does not provide such minimum lead time for such purchase order, Licensor shall be permitted to reject any amounts ordered without such minimum lead time; provided, however, that Licensor shall use commercially reasonable efforts to manufacture and supply all such Filled Ampules to Company in such requested delivery date set forth in such purchase order. In the event that Licensor fails to reject in writing to Company any purchase order hereunder within [***] following issuance from Company, such purchase order shall be deemed accepted by Licensor and Licensor shall be responsible for manufacturing and supplying all quantities of Filled Ampules thereunder in accordance with the terms of such purchase order. The purchase order shall be placed in a number of Filled Ampules equal to a multiple of Licensor's standard batch size (the "**Order Size Requirement**"). Company will use reasonable efforts to satisfy its clinical supply requirements through the submission of no more than [***] orders per year. |
| **Clinical Supply Price** | [***] of the Manufacturing Cost. "**Manufacturing Cost**" means the actual and verifiable costs and expenses paid by Licensor to one (1) or more Third Parties for the manufacture and supply of the Filled Ampules, including but not limited to, Licensor's external, out-of-pocket costs of materials, production, factory overhead, quality control, quality assurance, bulk and finished packaging, transportation and insurance.<br><br>Licensor will invoice Company for (i) [***] of the estimated price at the time of Licensor's acceptance or deemed acceptance of the purchase order, and (ii) the balance upon delivery of the Filled Ampules. Company will pay within thirty (30) days upon receipt of each invoice. |
| **Remaining Shelf Life at Time of Delivery for Clinical Supply** | At a minimum, each Filled Ampule shall, at the time of delivery, have at least a number of months of shelf life remaining equal to the greater of (i) the number of months equal to the approved shelf life for the Filled Ampules minus [***] and (ii) [***]. |
| **COMMERCIAL SUPPLY TERMS** | |
| **Commercial Supply Obligation** | Forecast. Commencing [***] prior to anticipated launch of the first Product in the Territory and on or before the last day of the first month of each calendar quarter thereafter, Company will provide Licensor with a |

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| | written rolling forecast (each, a "**Forecast**") of Company's quarterly anticipated orders of Filled Ampules for commercialization in the Territory for the following [***] (commencing with the calendar quarter immediately following the calendar quarter in which such Forecast is delivered), which forecast shall be broken down on a quarterly basis. The first [***] of each Forecast shall be binding and Company shall be required to deliver to Licensor with its Forecast a purchase order for the [***] of the binding Forecast (for clarity, the [***] of each Forecast will be covered by earlier submitted purchase orders). The Forecast and the purchase orders shall be provided in compliance with the Order Size Requirement.<br><br>Acceptance and Delivery. Licensor shall, within [***] of receipt of a purchase order, confirm in writing that a purchase order has been accepted. Subject to the Company's compliance with the Order Size Requirement, Licensor shall be required to accept and fulfill the purchase orders (or portions thereof, as applicable) which are provided to Licensor in accordance with the terms and conditions of the Supply Agreement; provided, however, that the quantity of Filled Ampules in a given purchase order is no more than [***] or less than [***] of the quantity forecasted for such quarter when such quarter was in the binding portion of the Forecast. Should Company request Filled Ampules in excess of [***] of the quantity forecasted for such quarter when such quarter was in the binding portion of the latest Forecast, then Licensor shall use commercially reasonable efforts to meet such request. Licensor shall deliver Filled Ampules to satisfy each purchase order (including with respect to the delivery dates, delivery locations, quantities and other terms set forth therein).<br><br>In the event that Company orders less than [***] of Filled Ampules in the aggregate in any [***], Licensor shall not be liable for failure to deliver the Filled Ampules in quantities up to [***] quantity due to batch failure either in the event of shortage in quantity or total batch failure. For the avoidance of doubt, in the case of shortage in quantity in a particular batch instead of a total batch failure, Company will still pay for the remaining Filled Ampules in that batch duly delivered in accordance with the terms of the Supply Agreement. |
| **Commercial Supply Price** | [***] of the Manufacturing Cost.<br><br>Licensor will invoice Company for (i) [***] of the estimated price at the time of Licensor's acceptance or deemed acceptance of the purchase order, and (ii) the balance upon delivery of the Filled Ampules. Company will pay within thirty (30) days upon receipt of each invoice. |
| **Remaining Shelf Life at Time of Delivery for Commercial Supply** | At a minimum, each Filled Ampule shall, at the time of delivery, have at least a number of months of shelf life remaining equal to the greater of (i) the number of months equal to the approved shelf life for the Filled Ampules minus [***] and (ii) [***]. |
| **Cooperation to Improve Terms of Commercial Supply** | Licensor and Company shall reasonably cooperate to improve the efficiency of Licensor's commercial supply chain, including Licensor's costs, payment terms to vendors, lead times and approved shelf life. In the event any such improvements are achieved, Licensor and Company shall amend the commercial supply terms to pass through the benefit of such improvements to Company. |

| TERMS COMMON TO CLINICAL AND COMMERCIAL SUPPLY | |
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| **Specifications and Product Warranties** | The Supply Agreement shall set forth the release specifications for Filled Ampules (the "**Specifications**"). The Filled Ampules will be packaged in pouches for delivery and Company shall be responsible for the secondary outer packaging and labeling.<br><br>In addition to other representations and warranties to be set forth in the Supply Agreement, Licensor will represent and warrant that the Filled Ampules shall be manufactured (a) to meet the Specifications, (b) in compliance with cGMP (to be defined in the Supply Agreement), (c) in compliance with applicable law and (d) in compliance with the Regulatory Approvals. Without limiting the foregoing, Licensor shall further represent and warrant that (i) the Filled Ampules will not be adulterated or mislabeled within the meaning of the U.S. Federal Food, Drug and Cosmetic Act or any similar law of any other jurisdiction, (ii) the Filled Ampules will not be an article which may not, under the provisions of the U.S. Federal Food, Drug and Cosmetic Act or any similar law of any other jurisdiction, be introduced into interstate commerce in the Territory, (iii) the Filled Ampules and its method of manufacture do not and will not infringe any letters patent or any extension thereof, copyrights, trade secrets, know-how, trademarks or any other intellectual property rights of a Third Party, or breach any confidentiality or non-use obligation owed to a Third Party, (iv) the Filled Ampules are in a form suitable for packaging and labeling by or on behalf of Company (or its Affiliate or designee) and ultimate distribution, sale and/or other exploitation in the Territory and (v) all Filled Ampules will be free and clear of all liens and encumbrances other than statutory lien on the payment not yet due (the "**Product Warranties**"). |
| **Delivery Terms** | Licensor shall deliver or arrange for delivery of Filled Ampules to a carrier designated by Company in the applicable purchase order, EXW (Incoterms 2020), Licensor's (or, as the case may be, its Affiliate's or designee's) facility as indicated in the applicable purchase order. |
| **Defective Product** | If Company claims that any Filled Ampules did not meet any Product Warranty, Company shall notify Licensor thereof in writing within thirty (30) days after Company's discovery and confirmation of such defect.<br><br>At Licensor's request, Company shall forward for inspection a representative sampling of the Filled Ampules that is the subject of Company's claim. Licensor shall, as soon as is reasonably practicable, inspect such samples. If Licensor concurs with Company's claim, Licensor shall (at Company's option) either replace (as soon as reasonably practicable) the defective Filled Ampules without any cost to Company or credit or refund Company for the amount of the Supply Price for such quantities of Filled Ampules. If Licensor disagrees with Company's claim and the Parties are unable to resolve their differences, then either Party may refer the matter to an independent specialized firm of international reputation agreeable to both Parties for final analysis, which shall be a final resolution of such issue, binding on both Parties. If the Filled Ampules are determined to have met the warranty any Product Warranty, then Company shall bear the cost of the foregoing independent specialized firm and the independent laboratory testing. If the Filled Ampules are determined not to |

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| | have met the Product Warranties, then Licensor shall bear the costs of such independent specialized firm and laboratory testing and Licensor shall (at Company's option) either replace (as soon as reasonably practicable) the defective Filled Ampules without any cost to Company or credit Company for the amount of the Supply Price of such quantities of Filled Ampules. |
| **OTHER TERMS** | |
| **Supply Redundancy** | Company shall have the right, at its own cost and expense, to qualify and maintain a secondary site outside Taiwan for each stage of the manufacture of Filled Ampules and each supplier of materials, components and processes necessary for the manufacture of Filled Ampules if the primary site (a "**Primary Site**") under Licensor's existing supply chain as of the Effective Date is in Taiwan ("**Company Secondary Sites**"), and Licensor shall provide reasonable assistance necessary or desirable for the qualification and maintenance of the secondary site at reasonable, mutually agreed upon charges to Company. With respect to any materials, components and processes sourced from Primary Sites outside of Taiwan, Company shall have the right to source, directly from such Primary Site or any applicable Licensor Secondary Site (or their respective affiliates) or indirectly through Licensor, any and all materials, components and processes necessary for Company Secondary Sites to perform their respective manufacturing activities for their respective stages.<br><br>Licensor may, at its sole discretion, at its own cost and expense, qualify and maintain a secondary site for each stage of the manufacture of Filled Ampules and each supplier of materials, components and processes necessary for the manufacture of Filled Ampules ("**Licensor Secondary Sites**", together with Licensor's current sites, "**Licensor Sites**")).<br><br>Licensor shall ensure that all of Licensor Sites, and Company shall ensure that all of Company Secondary Sites, for the manufacture of Filled Ampules and all of their respective suppliers of materials, components and processes necessary for the manufacture of Filled Ampules are in a qualified and validated state appropriate for inclusion as a manufacturing site for Filled Ampules (or any portion thereof) as required by the applicable Governmental Body and in the Regulatory Approvals. After a Company Secondary Site for a stage has been fully qualified and all applicable regulatory approvals obtained, the manufacture of Filled Ampules (or portion thereof) and the supply of materials, components and processes necessary for the manufacture of Filled Ampules may be allocated between the Company Secondary Site and the Licensor Site for such stage in a manner to ensure that each site is able to supply Company's and/or its Affiliates (and other designees) requirements expeditiously if the need arises; provided that Company and Licensor shall reasonably cooperate and use good faith efforts to work together to set and meet any reasonable minimum purchase requirements of Primary Sites for supply of Filled Ampules, if any. If Company is using a Licensor Site outside Taiwan for the Company Secondary Site, the Parties shall use reasonable efforts to align and coordinate the manufacture schedules of such site, and such site shall fulfil the Parties' orders through an allocation reasonably determined by Company taking into consideration demand and upstream supply requirements. Further, Licensor Technology and the equipment |

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| | supplied by Licensor shall not be used to manufacture any products for Company or its Affiliates other than the Products.<br><br>As between the Parties, Company shall be responsible for obtaining the Regulatory Approvals for qualifying and maintaining Licensor Sites for the manufacture of Filled Ampules for the Field in the Territory. |
| **Tech Transfer** | Once a Company Secondary Site is identified, upon Company's request, Licensor shall provide reasonable technical assistance to Company and its Affiliates (and the Third Party contract manufacturer for such Company Secondary Site "**CMO**") at reasonable, mutually agreed upon charges with respect to Company's and its Affiliate's (and any CMO's) receipt, adoption and establishment of the manufacturing process, including: (a) making available a reasonable number of appropriately trained personnel to provide, on a mutually convenient timetable, technical assistance with respect to such transfer, (b) using commercially reasonable efforts to promptly assist Company and its Affiliates (and any CMO) in obtaining all necessary regulatory approvals and/or modifying existing health authorizations for the manufacture of Filled Ampules by Company, its Affiliate and/or a CMO at such Company Secondary Site, (c) allowing Company and its Affiliates (and any CMO) to cross reference Licensor's (and its Affiliate's) regulatory filings (such as a drug master file) and such other regulatory submissions controlled by Licensor (or its Affiliates) applicable to the Filled Ampules, as the case may be, (d) supplying analytical test methods and other testing know-how including method validation required to perform release testing or other testing as may be required by the applicable Regulatory Authority, and (e) upon request by Company, providing Company and its Affiliates (and any CMO) with appropriate quantities of reference standards related to Product in order to facilitate its testing. |
| **Audit Rights** | Licensor shall permit (and shall ensure that its Affiliates and any Third Parties involved in the manufacture of Filled Ampules permit) one or more qualified technical specialists from Company (or its Affiliate or its designees, as applicable), at Company's cost, upon reasonable prior notice and during normal business hours, to conduct one (1) annual audit of each manufacturing facility (and any other facility that is involved in the manufacture of Filled Ampules); provided, however, that in the case of a "for cause" audit, Company (or its Affiliate or its designees, as applicable) shall have the right to perform additional audits at any time (regardless of any other audits Company may have conducted during a given year) upon reasonable prior notice. Licensor shall use commercially reasonable efforts to provide a written response to any audit findings within one (1) month of receipt of such observations and conclusions. The Parties will discuss such response and Licensor shall promptly implement (and cause to be implemented) corrective actions. |
| **Ongoing Stability Studies** | For purposes of extending the permitted dating of the Filled Ampules, Licensor shall, at its own expense, (a) continue performing all stability studies ongoing at the Effective Date with an objective to achieve [***] stability dating for the Filled Ampules, and (b) conduct, in addition to those studies set forth in subsection (a), an on-going program of annual stability testing, in each case of subsection (a) and (b), in accordance with Licensor's current protocol and otherwise meeting all requirements of |

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| | cGMP, applicable laws, the Specifications and Regulatory Approvals, on samples from all batches of Filled Ampules. Such stability testing shall be stability indicating.<br><br>In the event that Licensor detects any out of Specification results, or any negative trends and/or degradant in excess of approved limits in connection with such testing, Licensor shall notify Company in the manner set forth in the Quality Agreement. Licensor shall specifically incorporate such additional testing and controls *(e.g.,* storage condition changes) as Company may reasonably specify with respect to such instability and/or degradant. In addition, Licensor shall place a number of batches, as reasonably instructed by Company, of Filled Ampules on stability following the implementation of any change request. Furthermore, any batch of Filled Ampules manufactured with one or more significant deviations should be assessed for possible inclusion in stability studies. Licensor is responsible to perform stability testing on Filled Ampules to support shipping conditions and/or temperature excursions that may occur during shipping and make available to Company such data. |
| **Quality Agreement** | The Parties shall negotiate in good faith and use commercially reasonable efforts to enter into the Quality Agreement within ninety (90) days after the effective date of the Supply Agreement, which Quality Agreement will set out the policies, procedures and standards by which the Parties and any Affiliates will coordinate and implement (or cause its Third Party contract manufacturers to coordinate and implement, as applicable) the operation and quality assurance activities and regulatory compliance objectives contemplated under the Supply Agreement. |
| **Term and Termination** | The Supply Agreement shall commence on the effective date (as set forth therein) and, unless earlier terminated, continue in effect until expiration of the last Royalty Term under the Agreement.<br><br>Either Party shall be permitted to terminate the Supply Agreement (a) for an uncured material breach of the other Party, (b) in the event of the bankruptcy of the other Party or (c) in the event that the other Party is unable to perform due to force majeure, in each case as shall be more fully set forth in the Supply Agreement.<br><br>Company shall also be permitted to terminate the Supply Agreement immediately in the event of a Change of Control of Licensor (to be defined in the Supply Agreement) in which a Company Competitor acquires control of Licensor. |
| **Additional Terms** | Other terms, conditions and provisions as are usual and customary for an agreement of this type, including, without limitation, representations, warranties, insurance, indemnification, dispute resolution and confidentiality will be negotiated and agreed upon between the Parties in the Supply Agreement. |

Schedule 5.4.1

Regulatory Transition Plan

[***]

Schedule 6.9

Form of Royalty Report

[***]

Schedule 8.5.1

Initial Press Release

**Liquidia Corporation and Pharmosa Biopharm Announce Collaboration for Sustained-Release Inhaled Treprostinil Product in North America**

- Liquidia exclusively licenses North American rights to L606, an inhaled formulation of treprostinil administered twice-daily with a short duration, next-generation nebulizer
- Liquidia funds $10 million upfront payment from finance agreement with HealthCare Royalty
- Pharmosa to receive up to $215 million in development and sales milestones for PAH and PH-ILD indications, $10 million for each additional approved indication and additional product, and royalties on net sales of L606
- Creates industry leading portfolio in rapidly expanding market for inhaled treprostinil
- Liquidia to host webcast today at 8:30 a.m. Eastern Time

**MORRISVILLE, N.C., [June X], 2023** – Liquidia Corporation (NASDAQ: LQDA) (Liquidia or the Company) and Pharmosa Biopharm (Pharmosa) today announced that they have entered into an exclusive licensing agreement for the development and commercialization in North America of L606, an inhaled, sustained-release formulation of treprostinil currently being evaluated in a clinical trial for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD).

Roger Jeffs, Chief Executive Officer of Liquidia, stated: “L606 is the perfect life-cycle complement to our pipeline and furthers our mission to provide innovative treatment options that improve the lives of patients suffering from PAH or PH-ILD. As already observed in the ongoing Phase 3 open-label study of PAH patients, Pharmosa’s novel liposomal formulation offers potential to improve patient convenience and compliance with twice-daily dosing using a short-duration, next-generation nebulizer. More importantly, we believe that the inhaled drug-device combination may provide best-in-class treprostinil exposure over a 24-hour period, including during sleeping hours, which could translate to improved efficacy, tolerability, and patient outcomes. Our investment in this collaboration, alongside our continued preparation for a potential launch of YUTREPIA™ (treprostinil) inhalation powder, are clear examples of Liquidia’s long-term commitment to addressing unmet needs in treating pulmonary hypertension and enabling choice based on patients’ preferences and circumstances.”

Pei Kan, Ph.D., President of Pharmosa, added: “Liquidia is the ideal partner to bring L606 to the North American market. Liquidia has shown an unflinching determination to bring novel products to patients, and provides clear synergies with their commercial effort, clinical expertise and deep relationships with key opinion leaders. Pharmosa will focus on advancing its sustained-release liposomal technology which has demonstrated in L606 the ability to dramatically reduce maximum systemic drug concentrations while significantly increasing local concentrations deep in the lung.”

Under the agreement, Liquidia will be responsible for development, regulatory and commercial activities of L606 in North America. Pharmosa will manufacture clinical and commercial supplies of L606 and support Liquidia in establishing a redundant global supply chain. In consideration for these exclusive rights, Liquidia will pay Pharmosa an upfront payment of $10 million, potential development and sales milestone payments of up to $215 million tied to PAH and PH-ILD indications, and two tiers of low, double-digit royalties on net sales of L606. Pharmosa will also receive a $10 million milestone payment for each additional indication and additional product approved. Liquidia retains the first right to negotiate for development and commercialization of L606 in Europe and other territories should Pharmosa seek a partner, subject to satisfaction of certain conditions as set forth in the license agreement.

Liquidia intends to seek first regulatory approval of L606 in the United States under the 505(b)(2) regulatory pathway. The planned New Drug Application (NDA) is expected to include: (i) the completed Phase 1 trial demonstrating tolerability and comparable pharmacokinetics to nebulized Tyvaso (treprostinil) inhalation solution; (ii) clinical data from the on-going, open-label Phase 3 study in the United States in PAH and PH-ILD patients; and (iii) clinical data from a double-blind, randomized, placebo-controlled study to evaluate treatment of PH-LD patients with L606. Liquidia intends to initiate the PH-ILD trial in first half of 2024.

In support of today's announcement, HealthCare Royalty (HCRx) will fund Liquidia $10.0 million from the Revenue Interest Financing Agreement (RIFA) announced in January 2023. The RIFA included a $7.5 million financing tranche at Liquidia's discretion to support any acquisition of rights to a clinical stage or commercial stage biopharmaceutical product to diagnose, prevent, or treat pulmonary hypertension. In connection with the transaction with Pharmosa, HCRx has agreed to advance an additional $2.5 million from the $25 million fourth tranche under the RIFA, which was to be funded upon the mutual election of both Liquidia and HCRx. Today's announcement does not impact the $35 million tranche that will be available to Liquidia upon favorable resolution of the ongoing patent litigation with United Therapeutics Corporation. Total proceeds funded to Liquidia by HCRx are now $42.5 million of the up to $100 million contemplated by the RIFA. As previously announced, HCRx will receive a tiered royalty on net revenue generated by YUTREPIA and other products marketed by Liquidia. The aggregate payments to HCRx are capped at 175% of the total amounts advanced by HCRx, with the potential for a true-up payment to be made by Liquidia if HCRx's internal rate of return is less than 18% on the date the cap is reached.

**Conference Call**

Liquidia will host a webcast call today at 8:30 a.m. Eastern Time. To listen to the webcast, please visit https://liquidia.com/investors/events-and-presentations.

**About L606 (liposomal treprostinil) inhalation suspension**

L606 is an investigational, liposomal formulation of treprostinil administered twice-daily with a short-duration next-generation nebulizer. The L606 suspension uses Pharmosa's proprietary liposomal formulation to encapsulate treprostinil which can be released slowly at a controlled rate into the lung, enhancing drug exposure over an extended period of time and reducing local irritation of the upper respiratory tract. L606 is currently being evaluated in an open-label study in the United States for treatment of pulmonary arterial hypertension (PAH) with a planned pivotal study for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD).

**About YUTREPIA™(treprostinil) inhalation powder**

YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a convenient, low-resistance, palm-sized device. On November 5, 2021, the FDA issued a tentative approval for YUTREPIA, which is indicated for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability in adult patients with New York Heart Association (NYHA) Functional Class II-III symptoms. The FDA has confirmed that YUTREPIA may add the indication to treat pulmonary hypertension with interstitial lung disease (PH-ILD) without additional clinical studies. YUTREPIA was designed using Liquidia's PRINT® technology, which enables the development of drug particles that are precise and uniform in size, shape, and composition, and that are engineered for enhanced deposition in the lung following oral inhalation. Liquidia has completed INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, an open-label, multi-center phase 3 clinical study of YUTREPIA in patients diagnosed with PAH who are naïve to inhaled treprostinil or who are transitioning from Tyvaso® (nebulized treprostinil). YUTREPIA was previously referred to as LIQ861 in investigational studies.

**About pulmonary arterial hypertension (PAH)**

Pulmonary arterial hypertension (PAH) is a rare, chronic, progressive disease caused by hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death. Currently, an estimated 45,000 patients are diagnosed and treated in the United States. There is currently no cure for PAH, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression, and improve quality of life.

**About pulmonary hypertension associated with interstitial lung disease (PH-ILD)**

Pulmonary hypertension (PH) associated with interstitial lung disease (ILD) includes a diverse collection of up to 150 different pulmonary diseases, including interstitial pulmonary fibrosis, chronic hypersensitivity pneumonitis, connective tissue disease related ILD, and sarcoidosis among others. Any level of PH in ILD patients is associated with poor 3-year survival between 30 to 35%. A current estimate of PH-ILD prevalence in the United States is greater than 60,000 patients, though population growth in many of these underlying ILD diseases is not yet known due to factors including underdiagnosis and lack of approved treatments until March 2021 with inhaled treprostinil.

**About Liquidia Corporation**

Liquidia Corporation is a biopharmaceutical company focused on the development and commercialization of products in pulmonary hypertension and other applications of its PRINT® Technology. The company operates through its two wholly owned subsidiaries, Liquidia Technologies, Inc. and Liquidia PAH, LLC. Liquidia Technologies has developed YUTREPIA™ (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension (PAH). Liquidia PAH provides the commercialization for pharmaceutical products to treat pulmonary disease, such as generic Treprostinil Injection. For more information, please visit www.liquidia.com.

**About Pharmosa Biopharm**

Pharmosa Biopharm Inc. (PBI) is a Taiwan-based biotechnology company focused on developing new drugs by exploiting its proprietary liposomal formulations and manufacturing technology. With regional

and global strategic partnerships, PBI develops products through 505(b)2 or hybrid applications to regulatory authorities with the intent to expand the clinical potential of existing drugs by exploiting innovative delivery formulations and medical devices. For more information, please visit https://www.pharmosa.com.tw

**About HealthCare Royalty**

HCRx is a leading royalty acquisition company focused on commercial or near-commercial stage biopharmaceutical products. HCRx has $6.3 billion in cumulative capital commitments with offices in Stamford (CT), San Francisco, Boston and London. For more information, visit www.hcrx.com. HEALTHCARE ROYALTY® and HCRx® are registered trademarks of HealthCare Royalty Management, LLC.

**Contact Information for Media & Investors**

Jason Adair
Senior Vice President, Corporate Development and Strategy
919.328.4400
jason.adair@liquidia.com

Schedule 9.2(q)

Existing Third Party Agreements Requiring Consent

[***]

Exhibit A

Form of Assignment and Assumption

**ASSIGNMENT AND ASSUMPTION AGREEMENT**[1]

THIS ASSIGNMENT AND ASSUMPTION AGREEMENT (this "**Assignment Agreement**") is made as of the _____ day of _____, 202__ (the "**Effective Date**"), by [between/among] Pharmosa Biopharm Inc., a corporation incorporated under the laws of Taiwan having a place of business at 3F.-3, No. 66, Sanchong Road, Nangang District, Taipei City 11502, Taiwan ("**Assignor**"), [and] Liquidia Technologies, Inc., a corporation incorporated under the laws of the State of Delaware, USA having a place of business at 419 Davis Drive, Suite 100, Morrisville, NC 27560, USA ("**Assignee**")[, and _____, a _____ under the laws of _____ having a place of business at _____ ("**Counterparty**"). Assignor[,/and] Assignee [and Counterparty] may be referred to herein individually as a "**Party**" and collectively as the "**Parties**".

**WITNESSETH:**

WHEREAS, [Counterparty/_____, a _____ under the laws of _____ having a place of business at _____ ("**Counterparty**")] and Assignor entered into that certain _____ dated as of _____ ___, 20___ attached hereto as Exhibit 1 (as amended, the "**Agreement**");

WHEREAS, Assignor and Assignee have entered into that certain License Agreement dated as of _____ ___, 2023 (the "**License Agreement**"), pursuant to which Assignor agreed to assign the Agreement to Assignee upon Assignee's request;

WHEREAS, pursuant to the License Agreement, Assignee has requested that Assignor assign the Agreement to Assignor; [and]

WHEREAS, Assignor desires to assign, transfer and convey unto Assignee, and Assignee desires to assume, all of Assignor's right, title and interest in and to the Agreement and its delegation to Assignee of all of Assignor's obligations, duties and responsibilities under the Agreement; [and

WHEREAS, Counterparty desires to consent to such assignment, transfer, conveyance, assumption and delegation;]

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignor[,/and] Assignee [and Counterparty], each intending to be legally bound, hereby agree as follows:

1. Assignment. Effective as of the Effective Date, Assignor hereby assigns, transfers and conveys

[1] This form of Assignment and Assumption Agreement has been drafted to contemplate the situations in which either (a) no consent to the assignment is required by the counterparty to the Existing Third Party Agreement or (b) consent is required from such counterparty. The form should be customized by removing the inapplicable bracketed language (depending on whether counterparty consent is required) and filling in the blanks, as applicable.

unto Assignee all of Assignor's right, title and interest in and to the Agreement, and delegates all of Assignor's obligations, duties and responsibilities arising after the Effective Date under the Agreement.

2. Assumption. Effective as of the Effective Date, Assignee hereby assumes all of Assignor's right, title and interest in and to the Agreement, and assumes responsibility for the performance of all of Assignor's obligations, duties and responsibilities arising after the Effective Date under the Agreement [(paragraphs 1 and 2, collectively, the "**Assignment**")].

3. [Consent to Assignment. Licensor hereby consents to the Assignment.]

4. Representations and Warranties. Each Party represents and warrants that (a) it has the full power and authority to execute, deliver and perform this Assignment Agreement, and each person whose signature appears on this Assignment Agreement on behalf of such Party has been duly authorized and has full power and authority to execute and deliver this Assignment Agreement on behalf of such Party; (b) upon its execution and delivery, this Assignment Agreement will constitute the valid and legally binding obligation of each of the Parties, enforceable against it in accordance with its terms; and (c) the Assignment Agreement attached hereto as Exhibit 1 is a complete and correct copy of the Agreement.

5. Counterparts. This Assignment Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.

[Signature Page Follows]

IN WITNESS WHEREOF, duly authorized representatives of the Parties have executed this Assignment Agreement as of the Effective Date.

**ASSIGNOR:**

PHARMOSA BIOPHARM INC.

Signature:_____
Printed Name:_____
Title: _____

**ASSIGNEE:**

LIQUDIA TECHNOLOGIES, INC.

Signature:_____
Printed Name:_____
Title: _____

**[COUNTERPARTY:**

_____

Signature:_____
Printed Name:_____
Title: _____]

Exhibit 1 to Assignment Agreement

*See attached.*[2]

[2] Agreements set forth on Schedule 1.24 to be assigned (including all amendments) to be attached.

**Exhibit 10.4**

# ASSET TRANSFER AGREEMENT

This ASSET TRANSFER AGREEMENT (this "**Agreement**") is made and entered as of June 28, 2023 ("**Effective Date**") by and between Pharmosa Biopharm Inc., a corporation incorporated under the laws of Taiwan having a place of business at 3F.-3, No. 66, Sanchong Road, Nangang District, Taipei City 11502, Taiwan ("**Seller**"), and Liquidia Technologies, Inc., a corporation incorporated under the laws of the State of Delaware, USA having a place of business at 419 Davis Drive, Suite 100, Morrisville, NC 27560, USA ("**Buyer**"). Seller and Buyer may be referred to herein as a "**Party**" or, collectively, as "**Parties**", and certain other capitalized terms not otherwise defined herein shall have the definitions set forth in Article V hereof.

W I T N E S S E T H:

WHEREAS, concurrently with and contingent on the execution of this Agreement, the Parties are entering into that certain License Agreement by and between the Buyer and Seller dated on or around the date hereof (the "**License Agreement**") pursuant to which the Buyer is obtaining an exclusive license to certain intellectual property rights owned, licensed to or otherwise controlled by the Seller; and

WHEREAS, in connection with the License Agreement, Seller desires to transfer ownership of the Inventory to Buyer, and Buyer desires to obtain ownership of the Inventory from Seller, upon the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual representations, promises and covenants set forth herein and in the License Agreement, and for other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, intending to be legally bound, the Parties hereby agree as follows:

## ARTICLE I
## TRANSFER OF INVENTORY

**Section 1.01. Transfer of Inventory**. On the terms and subject to the conditions of this Agreement and for the consideration set forth herein and in the License Agreement, Seller hereby conveys, assigns, transfers and delivers to Buyer, and Buyer hereby acquires from Seller, the Inventory. Such rights, title and interests in and to the Inventory shall be free and clear of any and all claims, Liabilities, liens and encumbrances, except as expressly provided herein.

**Section 1.02. Inventory**. Seller shall Deliver to Buyer the Inventory in accordance with Section 1.06 on the respective delivery dates set forth in Exhibit A (or such other date as may be agreed by the Parties in writing). As of each date of Delivery of Inventory, Seller shall transfer all rights, title and interests in and to the respective Inventory to Buyer. Prior to the date of each Delivery, Seller shall provide an invoice to Buyer for the applicable amount(s) set forth on Exhibit A for the respective Inventory. Buyer shall pay the applicable amount(s) set forth in Exhibit A for such Inventory at the time of Delivery.

**Section 1.03. Excluded Liabilities**. In connection with the transfer of the Inventory pursuant to this Agreement, Buyer shall assume no Liabilities or obligations of any nature, whether known or unknown, whether fixed or contingent, including any warranties of previously sold products or inventory, accrued or not accrued, which arise out of any events occurring or actions taken or omitted to be taken by or on behalf of Seller, or otherwise arising out of or incurred in connection with the conduct of the manufacture, purchase

and sale, use and possession of Inventory on or prior to the applicable date of Delivery of such Inventory (the "**Excluded Liabilities**"), and Seller shall remain solely liable therefore for the Excluded Liabilities.

**Section 1.04. Closing**. Subject to the terms and conditions set forth herein, the closing with respect to the transfers contemplated herein (the "**Closing**") shall take place with respect to each item of Inventory upon its applicable date of Delivery (the "**Closing Date**").

**Section 1.05. Bill of Sale**. Seller shall, simultaneously with the Effective Date, execute and deliver to Buyer a Bill of Sale with respect to the Inventory (the "**Bill of Sale**"), substantially in the form of Exhibit B hereto, effective as of the Effective Date.

**Section 1.06. Delivery.** The Inventory shall be delivered Ex Works (Incoterms 2020) the location and on the delivery date of the respective Inventory identified in Exhibit A ("**Delivery**") whereupon the risk of loss for the Inventory shall pass to Buyer. Seller will assist Buyer in shipping the Inventory to the destinations designated by Buyer at Buyer's cost. Notwithstanding the foregoing, with respect to any Inventory currently stored at the Philadelphia GMP Depot Facility and which Buyer elects to continue to store at such location, Delivery (and risk of loss) shall be deemed to occur at the time (a) Buyer has entered into an agreement with Marken Limited or the applicable third party responsible for such storage at the Philadelphia GMP Depot Facility and (b) such Inventory has been transferred to Buyer's account at the Philadelphia GMP Depot Facility. If Buyer fails to take Delivery of the Inventory in other locations on the applicable delivery date set forth in Exhibit A by more than seven (7) days, the Delivery shall be deemed to occur on the eighth ($8^{th}$) day following the applicable delivery date, and Buyer shall be responsible for all costs arising therefrom including the storage costs after the date of the deemed Delivery.

**Section 1.07. Further Action**. In the event that at any time after any Closing any further action is necessary or desirable to carry out the purposes of this Agreement, each Party agrees that it will take such further action (including the execution and delivery of such further instruments and documents) as the other Party may reasonably request, and all at the sole cost and expense of the requesting Party (unless the requesting Party is entitled to indemnification therefor under Article IV).

## ARTICLE II
## REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Buyer that the statements contained in this Article II are true and correct as of the Effective Date and shall be true and correct as of the date of each Delivery with the same force and effect as though such representations and warranties had been made on and as of the Effective Date.

**Section 2.01. Organization**. Seller is a corporation duly incorporated, validly existing and in good standing in Taiwan. Seller has all corporate power required to carry on its business as now conducted and to transfer and assign the Inventory to Buyer.

**Section 2.02. Authorization**. The execution, delivery and performance of this Agreement by Seller is within Seller's corporate power, has been duly authorized by all necessary action on the part of Seller and constitutes a valid and legally binding obligation of Seller enforceable in accordance with its terms.

**Section 2.03. Title**. Seller is the owner of good and valid title to Inventory, and on the applicable Closing Date, the respective Inventory shall not be subject to any Liabilities, liens, leases, charges, claims, licenses, rights, encumbrances or restrictions on transfers other than the Permitted Liens, and no financing statement for security interest covering all or any portion of the Inventory and naming

Seller as debtor will be in effect. As of the date of each Delivery of Inventory, Buyer will acquire such Inventory for its exclusive use free and clear of all Liabilities owed by Seller to third parties, liens, leases, charges, claims, licenses, rights, encumbrances and restrictions on transfers. As of the date of Delivery of Inventory, Seller shall have no right, title or interest in such Inventory.

**Section 2.04. Agreements**. Each agreement relating to the Inventory was duly executed and delivered by, and constitutes a valid and binding obligation of, Seller, enforceable against Seller in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar Laws of general applicability relating to or affecting creditors' rights and to general equity principles. There has been no breach of the terms of any agreement related to the Inventory by Seller or, to the Knowledge of Seller, by any other party to such agreement.

**Section 2.05. Inventory**. Exhibit A sets forth a report by units, expiration date, lot number (as applicable) and location of the Inventory as of the Effective Date in each case owned or controlled by Seller or its Affiliates as of the Effective Date. To the Knowledge of Seller, the Inventory has been manufactured in accordance with the applicable specification therefor and good manufacturing practices in all material respects. The Inventory, while in possession of Seller or its Affiliates, has been stored and handled in conformity with the applicable specifications for such Inventory in all material respects. To Seller's Knowledge, all Inventory (a) has been manufactured, handled, and stored in accordance with cGMP, and applicable Law in all material respects, and (b) are free of defects and useable in the ordinary course of business.

**Section 2.06. Tax Matters**. There are no liens with respect to Taxes upon Delivery of any of the Inventory (except for Taxes not yet due).

**Section 2.07. Licenses and Permits**. Seller has all governmental licenses, authorizations and permits required to sell, transfer, assign and deliver the Inventory to Buyer pursuant to Section 1.06, and all such licenses, authorizations and permits are in full force and effect.

## ARTICLE III
## REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller that the statements contained in this Article III are true and correct as of the Effective Date and shall be true and correct as of the date of each Delivery with the same force and effect as though such representations and warranties had been made on and as of the Effective Date.

**Section 3.01. Organization**. Buyer is a corporation duly incorporated, validly existing and in good standing in the State of Delaware. Buyer has all corporate power required to carry on its business as now conducted and to purchase, acquire and assume the Inventory from Seller.

**Section 3.02. Authorization**. The execution, delivery and performance of this Agreement by Buyer is within Buyer's corporate power, has been duly authorized by all necessary action on the part of Buyer and, when executed and delivered in accordance with the terms hereof, will constitute a valid and legally binding obligation of Buyer enforceable in accordance with its terms.

## ARTICLE IV
## INDEMNIFICATION

**Section 4.01. Seller's Indemnity.** Subject to the limitations set forth herein, Seller hereby agrees to indemnify Buyer and its Affiliates, and their respective stockholders, officers, directors, employees,

representatives, counsel, agents, successors and assigns (collectively, the "**Buyer Indemnified Parties**"), against, and agrees to hold the Buyer Indemnified Parties harmless from, any Loss incurred or suffered by such Buyer Indemnified Parties (individually, "**Claim**" or collectively, "**Claims**"), directly or indirectly (whether based on contract, tort, product liability, strict liability or otherwise), incurred in litigation or otherwise, and any investigation relating thereto, by any of the Buyer Indemnified Parties, to the extent resulting from or arising out of: (a) any breach of any of the representations or warranties of Seller or any of its Affiliates contained in this Agreement, (b) nonfulfillment of or any failure by Seller to perform any covenant or agreement made or undertaken by Seller or its Affiliates in this Agreement, (c) all Excluded Liabilities, or (d) any Liability of Seller that becomes a Liability of any Buyer Indemnified Parties under bulk sales, bulk transfers or similar applicable Laws of any jurisdiction, under any common law doctrine or de facto merger or successor liability, or otherwise by operation of applicable Law.

**Section 4.02. Buyer's Indemnity.** Subject to the limitations set forth herein, Buyer hereby agrees to indemnify Seller and its Affiliates, and their respective stockholders, officers, directors, employees, representatives, counsel, agents, successors and assigns (collectively, the "**Seller Indemnified Parties**"; Seller Indemnified Parties and Buyer Indemnified Parties each constitute, as applicable, "**Indemnified Parties**"), against, and agrees to hold the Seller Indemnified Parties harmless from all Claims, directly or indirectly (whether based on contract, tort, product liability, strict liability or otherwise), incurred in litigation or otherwise, and any investigation relating thereto, by any of the Seller Indemnified Parties, to the extent resulting from or arising out of: (a) any breach of any of the representations or warranties of Buyer or any of its Affiliates contained in this Agreement or (b) nonfulfillment of or any failure by Buyer to perform any covenant or agreement made or undertaken by Buyer or its Affiliates in this Agreement.

**Section 4.03. General**. Indemnification under this Article IV shall extend to, and shall include, reasonable attorneys' fees, reasonable accountants' fess, costs of litigation and other expenses reasonably incurred by the Indemnified Parties in the investigation or defense of any Claim asserted against such Indemnified Party and any amounts paid in settlement or compromise of any Claim asserted against it, but only to the extent that the Claim asserted is or would have been subject to this Article IV.

**Section 4.04.** EXCEPT WITH RESPECT TO EACH PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 4.01 OR 4.02, AS APPLICABLE, IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOSS OF PROFITS, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF.

## ARTICLE V
## MISCELLANEOUS

**Section 5.01. Notices**. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt, or (a) personal delivery to the party to be notified, (b) when sent, if sent by electronic mail during normal business hours of the recipient, and if not sent during normal business hours, then on the recipient's next Business Day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) Business Day after deposit with a nationally recognized overnight courier, freight prepaid, specifying next Business Day delivery, with written verification of receipt. All communications shall be sent to the respective Parties at the following addresses:

If to Seller:

Pharmosa Biopharm Inc.
3F.-3, No. 66, Sanchong Road
Nangang District, Taipei City 11502
Taiwan
Attention: Pei Kan/ Weishu Lu
Email: peikan@pharmosa.com.tw / Weishu.lu@pharmosa.com.tw

With a copy (which shall not constitute notice) to:

K&L Gates
30F, No. 95. Dun Hua S. Road, Section 2
Ta-an District, Taipei City 106
Taiwan
Attention: Jacqueline Fu
Email: jacqueline.fu@klgates.com

If to Buyer:

Liquidia Technologies, Inc.
419 Davis Drive, Suite 100
Morrisville, North Carolina 27560
USA
Attention: General Counsel
Email: legal@liquidia.com

With a copy (which shall not constitute notice) to:

DLA Piper LLP (US)
51 John F. Kennedy Parkway, Suite 120
Short Hills, New Jersey 07078
USA
Attention: Andrew P. Gilbert
Email: andrew.gilbert@us.dlapiper.com

**Section 5.02. Bulk Sales Laws**. Buyer and Seller hereby waive compliance with the provisions of the bulk sales Law of any state relating to bulk transfers in connection with the sale of the Inventory hereunder. Notwithstanding the foregoing, nothing herein shall estop or prevent Seller or Buyer from asserting, as a bar or defense to any Proceeding brought under any such Law, that such Law is not applicable to the transactions contemplated by this Agreement.

**Section 5.03. Amendment**. This Agreement may not be amended or supplemented except by a written instrument duly executed by the authorized representative of each Party.

**Section 5.04. Expenses**. All costs and expenses of whatsoever nature incurred in connection with this Agreement shall be paid by the Party incurring such cost or expense.

**Section 5.05. Successors and Assigns**. The provisions of this Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and assigns, provided that no Party may assign, delegate or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the other Parties hereto, except that Buyer may assign its rights or

obligations hereunder to its parent, or any of its Affiliates, without the consent of Seller. Any other purported assignment or delegation in contravention of the foregoing shall be null and void.

**Section 5.06. Governing Law**. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, USA, excluding application of any conflict of laws principles that would require application of the Law of a jurisdiction outside of State of New York, USA. Any disputes arising from this Agreement shall be resolved by the Parties pursuant to Article 12 of the License Agreement, which is hereby incorporated herein by reference.

**Section 5.07. Counterparts; Effectiveness**. This Agreement may be executed in any number of counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Agreement.

**Section 5.08. Entire Agreement**. This Agreement (including its Exhibits and any amendments) contains the entire agreement of the Parties with respect to the subject matter of this Agreement except to the extent other agreements are referenced in this Agreement, and supersedes all previous communications, representations, understandings and agreements, either oral or written, between the Parties with respect to the subject matter hereof.

**Section 5.09. Severability**. If any provision of this Agreement or the application of any such provision to any Person or circumstance shall be held invalid, illegal or unenforceable in any respect by a court of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision hereof.

## ARTICLE VI
## DEFINITIONS

"**Affiliate**" means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person or entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

"**Agreement**" has the meaning set forth in the preamble of this Agreement.

"**Bill of Sale**" has the meaning set forth in Section 1.05 hereof.

"**Business Day**" means any day, other than a Saturday or Sunday or any other day on which banks are required or authorized to close in New York, New York or Taiwan.

"**Buyer**" has the meaning set forth in the preamble of this Agreement.

"**Buyer Indemnified Parties**" has the meaning set forth in Section 4.01 hereof.

"**Claim(s)**" has the meaning set forth in Section 4.01 hereof.

"**Closing**" has the meaning set forth in Section 1.04 hereof.

"**Closing Date**" has the meaning set forth in Section 1.04 hereof.

"**Delivery**" has the meaning set forth in Section 1.06 hereof.

"**Effective Date**" has the meaning set forth in the preamble of this Agreement.

"**Excluded Liabilities**" has the meaning set forth in Section 1.03 hereof.

"**Governmental Body**" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

"**Indemnified Parties**" has the meaning set forth in Section 4.02 hereof.

"**Inventory**" means the quantities of materials set forth in Exhibit A.

"**Knowledge**" shall have the meaning set forth in the License Agreement.

"**Law**" or "**Laws**" means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.

"**Liability**" means any liability (whether known or unknown, whether asserted or unasserted, whether absolute or contingent, whether accrued or unaccrued, whether liquidated or unliquidated, and whether due or to become due), including, but not limited to, any liability for Taxes.

"**License Agreement**" has the meaning set forth in the recitals of this Agreement.

"**Loss**" means any claim, demand, Proceeding, loss, damage, penalty, Liability, obligation, settlement payment, cost and expense of every kind whatsoever (including, without limitation, costs of investigation, preparing or defending any such claim, demand or Proceeding and reasonable legal fees and disbursements).

"**Party**" or "**Parties**" has the meaning set forth in the preamble of this Agreement.

"**Permitted Liens**" means (a) any mechanic's, materialmen's or similar statutory lien incurred in the ordinary course of business for monies not yet due and (b) any lien for Taxes not yet due.

"**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

"**Philadelphia GMP Depot Facility**" means that certain storage facility located at 215 Bridgewater Rd., Bridgewater Business Park, Aston, PA 19014, USA.

"**Proceeding**" means any action, arbitration, audit, hearing, investigation, litigation or suit (whether civil, criminal, administrative, investigative, or informal) commenced, brought, conducted, or heard by or before, or otherwise involving, any court or other Governmental Body or referee, trustee, arbitrator or mediator.

"**Seller**" has the meaning set forth in the preamble of this Agreement.

"**Seller Indemnified Parties**" has the meaning set forth in Section 4.02 hereof.

"**Tax**" or "**Taxes**" means, without limitation, any federal, state, local, foreign or other net income, gross income, gross receipts, license, lease, payroll, employment, excise, severance, stamp, occupation, premium, ad valorem, windfall profits, environmental (including taxes under Section 59A of the Internal Revenue Code), customs duties, capital stock, franchise, service, service use, profits, withholding, social security (or similar), unemployment, disability, real property, customs duties, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated or other tax of any kind whatsoever, including any interest, penalty or addition thereto, whether disputed or not, and any obligations under any agreements or arrangements with respect to any taxes described herein.

*[signature page follows]*

IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed as of the Effective Date.

**BUYER:**

LIQUIDIA TECHNOLOGIES, INC.

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

**SELLER:**

PHARMOSA BIOPHARM INC.

By /s/ Pei Kan
Name: Pei Kan
Title: President

**[Signature Page to Asset Transfer Agreement]**

EXHIBIT A

Inventory

**Clinical Drug Supply**[1]

[***]

**Devices**

[***]

[1] To the extent any inventory on this Exhibit A is stated as of a specific date, any changes in inventory since that date have been in the normal course of business in the conduct of the Existing Clinical Trial (as defined in the License Agreement) consistent with past practice.

EXHIBIT B

Bill of Sale

**_____ __, 2023**

For good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Pharmosa Biopharm Inc., a Taiwan corporation ("**Seller**"), does hereby grant, bargain, transfer, sell, assign, convey and deliver to Liquidia Technologies, Inc., a Delaware corporation ("**Buyer**"), all of its rights, title and interests in and to the Inventory (as such term is defined in the Asset Transfer Agreement dated as of even date herewith, by and between Buyer and Seller ("**Asset Transfer Agreement**")) in accordance with Asset Transfer Agreement to have and to hold the same unto Buyer, its successors and assigns forever.

Seller, for itself, its successors and its assigns, hereby covenants and agrees that, at any time and from time to time upon the written request of Buyer, Seller will do, execute, acknowledge and deliver or cause to be done, executed, acknowledged and delivered, all such further acts, deeds, assignments, transfers, conveyances, powers of attorney and assurances as may be reasonably required by Buyer in order to assign, transfer, set over, convey, assure and confirm unto and vest in Buyer, its successors and its assigns, title to the assets sold, conveyed and transferred by this Bill of Sale.

IN WITNESS WHEREOF, Seller has duly executed this Bill of Sale as of the date first written above.

PHARMOSA BIOPHARM INC.

By: _____
Name:
Title:

**Exhibit 10.5**

# Supply Agreement ("Agreement")

Parties.

1. **Liquidia Technologies, Inc.**, 419 Davis Dr., Suite 100, Morrisville, NC 27560 United States email supplychain@liquidia.com ( "Liquidia").
2. **Plastiape SpA** of 23875 Osnago (Lecco) - Via 1 Maggio, 8, Italy facsimile +39 039 587805 email info.plastiape@plastiape.it ("Plastiape" and, collectively with Liquidia, the "Parties" and each a "Party").

Introduction.

A. Plastiape is in the business of manufacturing the Products (as defined below).
B. Liquidia is a pharmaceutical company.
C. Liquidia wishes to acquire the Products from Plastiape and Plastiape agrees to supply the Products to Liquidia on the terms and conditions set out in this agreement.

**Operative Clauses.**

1. Definitions and Interpretation.

1.1 Definitions. In this Agreement:

"**Affiliate**" means: (i) a holding company of the Party; (ii) a subsidiary of the Party or a subsidiary of the holding company of the Party; (iii) any entity controlled by the Party; or (iv) persons or entities who directly or indirectly have the capacity to control the Party (including persons or entities who individually or collectively have the capacity to control more than 50% of the membership of the board of directors of the Party or who control more than 50% of the equity securities of the Party or a related party).

**"Background IP"** means all Intellectual Property Rights (a) acquired, conceived or developed by a Party independently before the execution of this Agreement, or (b) independently acquired, conceived or developed by a Party outside the scope of this Agreement.

"**Arising IP**" means all Intellectual Property Rights discovered, invented, conceived or developed by a Party in connection with the activities described in this Agreement.

**"Business Day"** means any day of the week which is not a Saturday, Sunday or legal holiday observed by the federal government of the United States or Italy.

**"cGMP"** means the current and any future good manufacturing practices and quality system regulations promulgated by the FDA under the authority of the Federal Food, Drug and Cosmetic Act, as amended, as set forth in 21 C.F.R. Parts 210, 211, and 820 or the counterpart current and any future good manufacturing practices and quality system regulations in the country in which the Products are manufactured.

**"Change of Control"** occurs, in relation to a Party, if any person or group of persons acting together, other than the persons entitled on the date of this Agreement, becomes entitled to the power, whether held directly or indirectly (such as through interposed entities) and by whatever means (whether or not enforceable at law or in equity) to:

(a) exercise, or control the exercise of, more than 50% of the voting power of that Party;
(b) dispose of, or control the disposal of, more than 50% (by value) of the equity securities of that Party;
(c) appoint, or control the appointment of, directors of that Party having more than 50% of the votes at board meetings; or

(d) determine, or control the determination of, the substantial conduct of that Party's affairs, business activities or decisions.

**"Confidential Information"** means the confidential, proprietary, or other similar information of a Party which includes without limitation:

(a) information relating to scientific and technical matters, research and development activities, inventions, data and know-how, regulatory practices, personnel, policies, clientele, suppliers or business strategies, product information, financial information, prices and/or costs or information observed during facilities tours;

(b) information relating to the terms upon which the Products are to be manufactured and sold pursuant to this Agreement.

The foregoing notwithstanding, the term "Confidential Information" does not include information:

i. which the Party receiving such information (the "Receiving Party") was aware of prior to its receipt from the other party (the "Disclosing Party") and without an obligation of confidentiality to Disclosing Party;

ii. which otherwise becomes known to the Receiving Party other than through the disclosure by or on behalf of the Disclosing Party or any other source known by the Receiving Party to be under an obligation of confidentiality to Disclosing Party with respect to such information;

iii. which is in the public domain (other than through a breach of this Agreement or a breach of confidence by any person); or

iv. which is discovered or developed by the Receiving Party without use of or reference to the Disclosing Party's Confidential Information.

**"Debarred Entity"** means (i) a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or (ii) any entity that is an Affiliate of any entity described in clause (i).

**"Debarred Individual"** means an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application.

**"Effective Date"** means May 22nd, 2023.

**"FDA"** means the United States Food and Drug Administration or any successor entity thereto.

**"Force Majeure"** means, solely to the extent beyond the reasonable control of the Party whose performance is adversely affected by the event:

(a) any act of God, fires, unusually severe weather conditions, earthquakes, floods, epidemics, war, revolution or any other unlawful act against public order or authority by any third parties;

(b) governmental restrictions or sanctions embargo or other governmental action;

(c) industrial dispute or disturbance, energy shortages, raw material shortages or delays, power outages; or

(d) other event which is not within the reasonable control of a Party.

**"Insolvency Event"** in relation to a Party, means any of the following events:

(a) the Party ceases to (or is unable to) pay its creditors (or any class of them) in the ordinary course of business, or announces its intention to do so;

(b) a receiver, manager, receiver and manager, administrative receiver or similar officer is appointed to that Party or any of its assets;

(c) such Party enters into, or resolves to enter into, a scheme or arrangement, compromise or composition with any class of creditors;

(d) a resolution is passed or an application to a court is taken for the winding up, dissolution, official management or administration of that Party; or

(e) anything having a substantially similar effect to any of the events specified above happens under the law of any applicable jurisdiction.

**"Intellectual Property Rights"** means any patent, patent application, trademark, service mark, copyright, domain name, trade dress, inventions, trade secrets and know-how or any similar or equivalent rights in any part of the world whether or not patentable or copyrightable or otherwise registerable.

**"Product(s)"** means (i) dry powder inhaler known as RS00 Dry Powder Inhaler Model 8 as described on Plastiape's Type III Drug Master File, filed at the FDA with # 18418 (the "DMF"), along with any improvements which might be agreed in writing between the Parties and (ii) any other products that may be added to this Agreement by mutual agreement of the Parties.

**"Quality Agreement"** means that certain Quality Agreement, executed on July 9, 2020, by and between Liquidia and Plastiape, as it may be amended from time to time.

**"Specifications"** means the mutually agreed specifications for the design, composition, product safety assurance, manufacture, packaging, and/or quality control of the Product, as described in the DMF referenced above, as the same may be modified or supplemented by mutual agreement of the Parties in writing.

**"Term"** has a meaning described to it in clause 16.

1.2 Interpretation. In this Agreement, unless the context otherwise requires:

(a) singular includes plural and plural includes singular;

(b) reference to a person includes a corporation, firm and any other entity;

(c) reference to a Party includes that Party's successors and permitted assigns;

(d) headings do not affect interpretation of this Agreement;

(e) if any part of this Agreement is for any reason declared invalid, such decision will not affect the validity of any remaining portion, which will remain in full force and effect;

(f) no rule of construction applies to the disadvantage of a Party because that Party put forward this document or any portion of it;

(g) the schedules and annexures to this Agreement form part of this Agreement; and

(h) terms defined in Incoterms 2020 have the meaning set forth in Incoterms 2020 when used in this Agreement unless otherwise defined herein.

2. <u>Supply of Product.</u>

During the Term, Plastiape must manufacture, sell, and deliver to Liquidia and its Affiliates such quantities of Product as ordered by Liquidia and its Affiliates pursuant to this Agreement. Each Product sold under this Agreement must conform to the Specifications for such Product and otherwise be supplied in accordance with this Agreement. All Products shipped to Liquidia shall have, at the time of delivery to Liquidia, at least [***] of remaining approved Product shelf life. Plastiape acknowledges and agrees that Liquidia may, from time to time, designate in writing certain third parties who shall be authorized to purchase Products on behalf of Liquidia pursuant to this Agreement (such third parties being referred to herein as "Designees"). In the event any such Designee places any order for any Product pursuant to this Agreement, such Designee shall have all of the same rights and obligations as Liquidia under this Agreement with respect to such order. Liquidia shall have the right to withdraw the designation of any Designee pursuant to this Section 2 at any time in its sole discretion upon written notice to Plastiape. Liquidia shall notify Plastiape of its decision of withdrawal of the Designee as soon as possible.

3. <u>Prices for Supply of Product.</u>

The prices for the Products will be as set out in Schedule 1 to this Agreement and are based on FCA terms (Incoterms 2020). If customer elects the Products to be delivered on DAP terms (Incoterms 2020), Plastiape will provide the calculation of such cost (and as specified in clause 6.4.).

The prices may be increased or decreased from time to time in accordance with the pricing adjustment program set forth in Schedule 1.

4. Forecasts and Ordering.

4.1 Forecasts.

(a) At least [***] prior to the beginning of each calendar year during the term of this Agreement, Liquidia will provide Plastiape with a non-binding written forecast of Liquidia's expected requirements for Product during the following [***].

4.2 Orders.

(a) Liquidia is not required to buy any specific amount of Product under this Agreement, except for the quantities which Liquidia actually orders through binding purchase orders.

(b) Liquidia may place binding orders for Product by written or electronic purchase order to Plastiape, which shall be placed at least [***] prior to the desired date of delivery.

(c) Plastiape must provide Liquidia with written confirmation of receipt of the purchase order within five (5) business days of receipt (hereinafter "Purchase Order").

(d) Liquidia may cancel or vary a Purchase Order at any time prior to dispatch of the Product. Liquidia will be responsible for all reasonable raw material costs, molded components costs, and finished product costs incurred and subsequent destruction cost of the Products (if any), as a consequence of the cancellation or variation of such order; provided, however, that Plastiape must reasonably mitigate Liquidia' loss with respect to such costs, including by utilizing the raw materials to manufacture Product for other customers or by retaining the raw materials for use with respect to any future order made by Liquidia. Other than as set out in this sub-clause (d), Liquidia will have no other liability with respect to the cancellation or variation of a purchase order.

4.3 If Plastiape fails to deliver or anticipates that it will be unable to deliver any quantity of Products ordered pursuant to Liquidia's Purchase Orders, Plastiape will promptly notify Liquidia and consult with Liquidia to develop an interim contingency plan for meeting as much of Liquidia's then-current market needs as possible, including, by way of example, and without limitation, granting Liquidia priority treatment with respect quantities of Products that Plastiape has in its finished products inventory or stock-in-progress, to be labeled or re-labeled as Liquidia Products. In any event, in the event of a shortage of Products, Plastiape shall allocate Products to Liquidia not less than in the same proportion as Liquidia's most recent [***] average of unit purchases of Products.

4.4 To the extent of any conflict or inconsistency between this Agreement and any purchase order documentation, the terms of this Agreement prevail.

5. Payment and Invoicing.

5.1 Payment terms on the undisputed portion of all invoices are the later of (i) sixty (60) days from the receipt of invoice by Liquidia (which invoice shall not be issued until shipment of the applicable Products) or (ii) thirty (30) calendar days from the receipt of the Product by Liquidia. Undisputed invoices will comply with the invoicing instructions that will be provided in the purchase order that will be supplied to or on behalf of Liquidia via e-mail or by any different invoicing processing system agreed in writing between the Parties following the execution of this Agreement. Payment shall be made to the bank account nominated in writing

by Plastiape and time of payment is of the essence. Liquidia shall pay all amounts due in full and cleared funds without any deduction or withholding.

5.2 If any portion of an invoice is disputed by Liquidia, Liquidia will use commercially reasonable efforts to notify Plastiape within sixty (60) days of receipt of the invoice and shall pay all the undisputed amounts when due and the Parties shall use good faith efforts to reconcile the disputed amount as soon as possible; provided, however, that failure by Liquidia to dispute an invoice within the time period specified in this Section 5.2 shall not constitute a waiver by Liquidia of any claim against Plastiape, including any claim related to any error with respect to such invoice.

6. Delivery, Title and Risk of Loss, Price Revision and Adjustment.

6.1 Plastiape will deliver the Product, at the direction of Liquidia, either:

(a) Free-Carrier at the point of manufacture in Italy (FCA); or

(b) Delivered At Place (DAP) to the location specified in Liquidia's purchase order, in this latter case on or before the date specified in the purchase order.

6.2 Plastiape must pack all Product ordered in accordance with the agreed Specifications included into the Drug Master File or as otherwise agreed in writing between Liquidia and Plastiape.

6.3 The following will apply if Liquidia elects for the Product to be delivered on a Free Carrier basis (FCA):

(a) Plastiape must make all the Product set forth in the purchase order available for collection not more than [***] from the date of the order;

(b) Liquidia will select the carrier and organize for collection of the Product;

(c) Liquidia will bear all applicable taxes, duties, export or import charges and similar charges and similar imposts associated with the collection and shipping of the Products;

(d) Liquidia is responsible for all export and importation processes and costs;

(e) Liquidia will be responsible for obtaining applicable transport insurance;
and

(f) all risk of loss or damage in transportation passes ex works (Incoterms 2020) to Liquidia at the time of delivery which is taken to be when the Product is collected from Plastiape's facilities.

6.4 The following will apply if Liquidia elects for the Product to be delivered on a Delivered At Place (DAP) basis:

(a) Plastiape will engage the carrier and organize the delivery of the Product to the facilities nominated by Liquidia in the purchase order. Liquidia accepts no liability for either the choice of the carrier or the carrier's conduct or any loss or damage that may occur while the Products are being transported;

(b) Plastiape must deliver the Product set forth in the purchase order to the location nominated by Liquidia not more than [***] from the date of the order;

(c) Plastiape will bear all applicable delivery charges

(d) Plastiape must obtain applicable transport insurance;

(e) Plastiape is responsible for all export processes and costs; and

(f) all risk of loss or damage to the Products passes to Liquidia upon delivery of the Product to Liquidia at the location specified by Liquidia.

6.5 The prices quoted in Schedule 1 are for Incoterms FCA. Additional costs for DAP Incoterms will be quoted by Plastiape upon request from Liquidia in connection with a defined quantity of Product and with a defined destination address based on incremental out-of-pocket costs actually incurred by Plastiape in connection with DAP Incoterms. DAP Incoterms will be applied only if Liquidia will agree to such extra cost and places a binding Purchase Order specifying DAP Incoterms.

6.6. Price revision criteria are detailed at Schedule 1.

6.7. Title to the Products shall pass to Liquidia at such time as the risk of loss with respect to the Products passes to Liquidia pursuant to Section 6.3(f).

7. Additional Obligations of Plastiape.

Plastiape must:

(a) manufacture and supply the Products in accordance with all applicable laws, regulations and standards, including without limitation cGMP, and the Specifications for the Products. Plastiape shall bear responsibility for all product liability and quality assurance issues arising from any failure to comply with cGMP or Specifications for the Products. Plastiape shall comply in all respects with all applicable governmental laws, rules and regulations regarding the manufacture, labeling, and packaging of the Products;

(b) ensure the Products conform with the Specifications and all applicable laws, regulations and standards, including without limitation cGMP;

(c) inform Liquidia promptly of any adverse events (including without limitation fires, explosions, accidental discharges) occurring in the manufacture of the Product;

(d) inform Liquidia promptly of any allegations or findings of violations of applicable laws, regulations or standards, including without limitation cGMP, which relate to the Products or may impact on the supply of the Products;

(e) allow Liquidia to inspect Plastiape's facilities, such inspections upon written and advance request of 10 (ten) business days;

(f) implement promptly any corrective action, as a result of non-compliance to this Agreement or Product's Specifications;

(g) maintain Conformité Européene (CE) marking for the Products and any improvements;

(h) maintain the Drug Master File as required by the FDA or such other requirements under the FDA;

(i) engage in good faith discussion to review and, if warranted, amend the Quality Agreement from time to time to ensure compliance with applicable regulations relating to the production, storage, transportation and release of Products, including, but not limited to, cGMP; and

(j) provide to Liquidia upon Liquidia's request copies of Material Safety Data Sheets ("MSDSs") and any other information and documentation related to Product safety, including but not limited to physical, chemical, and biological characteristics of the Products.

8. Defective Product.

8.1 Plastiape represents and warrants that any Product sold and delivered to Liquidia complies in all respects with the Specifications and with this Agreement and is free from defects in design, material and workmanship.

8.2 The Products shall be subject to inspection, evaluation and testing by Liquidia at any reasonable time and from time to time before or during manufacture, or delivery and in any event within thirty (30) calendar days after delivery of the Products at Liquidia's warehouse or other designated delivery location. Liquidia shall be entitled to reject any Products that do not meet Specifications or are otherwise defective, whether such defects are patent within the period specified above; provided, however, that if the defect or the non-conformity of the Product(s) are not apparent on Liquidia's reasonable inspection of the Products (latent defects), then Liquidia shall notify Plastiape within five (5) Business Days after discovery thereof. Liquidia shall notify Plastiape of the existence and nature of any non-compliance or defect within the period specified above and Plastiape shall have a reasonable opportunity, not to exceed twenty (20) calendar days from receipt of notification and of defective samples or photos or other visual or written information as needed by Plastiape to assess if the Products do not meet the Specifications, to provide Liquidia with detailed written instructions to return or dispose of such defective Product unless the parties confirm that there was not, in

fact, any non-compliance or defect. Thereafter, Plastiape shall, within a reasonable time, identify the root cause of the defect and implement corrective actions to prevent the recurrence of any such non-compliance(s) or defect(s).

8.3 Without prejudice to any other remedy which Liquidia may have, Plastiape shall at Liquidia's option:

(a) replace at Plastiape's own cost and expense, including reimbursement of freight and costs incurred by Liquidia, Product that is not as warranted or otherwise fails to comply with the Specifications or other requirements of this Agreement; or

(b) repay Liquidia any amounts paid with respect to the relevant Product and for the disposal or return of defective Product.

8.4 Liquidia has no obligation to pay for any Product that is subject to such a claim of non-compliance or defect. If Plastiape fails to so inspect and instruct Liquidia as to the return of disposal of such defective Product, Liquidia may dispose of such defective Product. Plastiape must promptly reimburse Liquidia for all direct and commercially reasonable out-of-pocket costs incurred by Liquidia in such disposition, and replace such defective Product at its own cost and expense.

8.5 If, after Plastiape's inspections of such Product, the Parties disagree as to the Product's conformance to the Specifications or whether the Product has such a defect, either Party may deliver the Product to an independent third-party laboratory, reasonably acceptable to both Parties, for testing to confirm the Product's conformance to the Specifications or the presence or absence of defects. All costs associated with such third-party testing shall be at Liquidia' expense unless the tested Product is deemed by such third-party to be defective or not in compliance with the Specifications or this Agreement, in which case all such costs must be promptly paid by Plastiape. This clause in no way reduces Plastiape's own obligations for testing, inspection and quality control as provided in the Specifications or under applicable laws, regulations, standards or codes, including, but not limited to, cGMP.

8.6 Liquidia will notify Plastiape reasonably promptly after receipt of any non-medical customer complaints that implicate the Products. Plastiape, as requested by Liquidia, will conduct internal investigations to determine the validity of such complaints. Plastiape will report the findings of the investigation to Liquidia promptly following the completion of the investigation, but in no event later than thirty (30) calendar days after notification. Liquidia will be responsible for customer response communications with respect to such complaints. Plastiape, upon Liquidia's reasonable request and at Plastiape's expense, shall provide all reasonable assistance and material needed for such response communications. Plastiape shall reimburse Liquidia for all reasonable out of pocket expenses incurred by Liquidia with respect to activities under this Section 8.6 if the complaint is due to the failure of the Products to conform to the Specifications.

8.7 Plastiape shall provide Liquidia with a copy of any MedWatch report relating to any serious medical adverse events related to the Products at the same time Plastiape provides the report to the FDA. Plastiape shall be responsible for the medical investigation of, evaluation of, and reporting of all adverse events related to the Products as required by any regulatory authorities. Plastiape shall be responsible for reporting any such adverse event reports to regulatory authorities and shall provide Liquidia with a copy of any such reports. Plastiape shall be responsible for submission of all reports related to medical adverse events required by the regulatory authorities, including without limitation, global literature surveillance and periodic reporting, and shall provide Liquidia with a copy of any such reports.

8.8 Liquidia shall, with the assistance of Plastiape as needed, handle all medical and technical inquiries regarding the Products. Plastiape shall review and approve (subject to any suggested changes by Plastiape), as soon as possible but in no event later than ten (10) calendar days after receipt, the response letters prepared by Liquidia to use to respond to routine inquiries.

8.9 Any material complaint, including, but not limited to, any complaint relating to safety and/or efficacy of the Products, received by Plastiape for the Products or similar products manufactured by Plastiape will be

forwarded to Liquidia as soon as possible but in no event later than five (5) Business Days after receipt thereof via written communication. Any material complaint, including, but not limited to, any complaint relating to safety and/or efficacy of the Products, received by Liquidia for the Products will be forwarded to Plastiape as soon as possible but in no event later than five (5) Business Days after receipt thereof via written communication.

8.10 Liquidia and Plastiape must notify each other as soon as possible but in no event later than five (5) Business Days after confirmation of the event, by telephone or other rapid communication means, when there is information concerning any Products issues that may impact the quality, purity, safety and effectiveness of Products in the field. Examples of such information include any contamination, stability failure, certain confirmed Product complaints or any significant chemical, physical or other change or deterioration in the distributed Products.

8.11 In the case where a field alert or recall is deemed necessary by a regulatory authority or by Plastiape or by Liquidia, the Parties will jointly develop a strategy to handle such field alert or recall. Liquidia will be responsible for communication to its customers regarding such recall and for retrieving any Products that have been sold to its customers. Plastiape shall be responsible for reporting to the regulatory authorities all recalls and field alert notifications and for associated follow-up reports.

8.12 In the event any governmental agency having jurisdiction shall request or order, or if Liquidia shall determine to undertake, any corrective action with respect to any Product (or any finished product containing or contained in any Product), including any recall, corrective action or market action, and the cause or basis of such recall or action is attributable to a breach by Plastiape of any of its warranties, guarantees, representations, obligations or covenants contained in this Agreement or the Specifications, then Plastiape shall be liable, and shall reimburse Liquidia for the reasonable costs of such action, including the cost of any Product (or any finished product containing, contained in or included in a kit with any Product) which is affected.

9. Supply and Use of the Products.

9.1 During the Term, Plastiape will supply the Product (or any improvement or product line extensions or successors) to Liquidia. Plastiape represents and warrants to Liquidia that as of the date of this Agreement it has not entered into any agreement, understanding or arrangement with any third party that prevents Plastiape from supplying the Product to Liquidia hereunder.

9.2 Liquidia may use the Products for any lawful purpose except Liquidia agrees not to use Product in combination with: Platelet-derived growth factor receptor kinase inhibitors.

10. Improvements and Changes to the Product.

10.1 Plastiape will notify Liquidia of any Product improvement or Product line extensions, or successors, any new products, product ideas or inventions made by Plastiape which may have applicability to the Product or to Liquidia' products.

10.2 From time to time, either Party may submit to the other written proposals for the adoption, implementation or development of changes, improvements or modifications to the Product or the Specifications. Any such changes may not be implemented without the prior written agreement of the Parties.

10.3 Plastiape agrees that:

(a) no changes or modifications to the method or process of manufacture or production of the Product or the raw materials or Specifications; and

(b) no change in location of the facility used to supply Product to Liquidia under this Agreement, can be made without prior written notification to and approval of Liquidia. Any such change or modification approved by Liquidia shall be made at Plastiape's sole cost and expense.

11. Labelling, Brand Name and Trademark Matters.

11.1 (a) Subject to Clause 22, Plastiape acknowledges that Liquidia is the exclusive owner of and has all rights to the Liquidia trademarks, copyrights, and brand names of Liquidia, artwork and all other that appear on or are otherwise used in connection with the marketing, sale and or use of Liquidia's end product or finished product containing or contained in any Product.

(b) Subject to Clause 22, Liquidia acknowledges that Plastiape is the exclusive owner of and has all rights to the Plastiape trademarks, copyrights and brand names that are contained in or associated with the standard Products (excluding customized versions), including inhaler RS00.

11.2 Neither Party will register or use any names or marks that are similar to the other Party's brand name or might be confused with them. The obligations in this sub-clause survive termination or expiration of this Agreement.

11.3 Each Party shall as soon as possible advise the other Party of any suspected or actual infringement of any of the Intellectual Property Rights of such other Party in or relating to the Product.

11.4 Subject to the terms and conditions of this Agreement, (a) Plastiape hereby grants to Liquidia a limited, revocable, non-exclusive, non-transferable, fully paid license (without the right to sublicense) to use Plastiape's trademarks during the Term solely for the purposes of marketing and promoting the Product(s), and (b) to the extent Liquidia requires Plastiape to affix Liquidia's trademark(s) on the Products, Liquidia hereby grants to Plastiape a limited, revocable, non-exclusive, non-transferable, royalty free license (without the right to sublicense) to use Liquidia's trademark(s) during the Term solely for the purposes of supplying Products to Liquidia.

12. Records and Access.

12.1 Plastiape shall maintain and preserve full and accurate books and records of all matters relating to the Product (excluding any financial documentation), including, but not limited to those records required to be maintained under cGMP (ISO13485 and 21 CFR Part 820), and any other records or documentation required to be maintained pursuant to the Quality Agreement.

12.2 Liquidia and its authorized representatives have the right to inspect and examine all such books and records (excluding any financial documentation) and to access any facilities at which the Product is manufactured, tested or stored, with prior written notification of twenty (20) Business Days, during normal business hours. During any such inspection, Plastiape shall permit Liquidia upon at least twenty (20) Business Days' prior written notice and during normal business hours during Business Days and without interruption of manufacturing process of Plastiape (other than making personnel available as necessary for the conduct of the audit), access to those areas of Plastiape's manufacturing facilities where any of the Products are manufactured, tested, packaged, stored, handled and shipped and access to the regulatory, manufacturing, testing and quality assurance records for the Products. On any inspection or audit by Liquidia or by any governmental agency which results in required corrective actions, Plastiape shall have such time as is provided by such agency or as is commercially reasonable, as the case may be, to take all needed steps to implement the corrective actions identified in the aforementioned audits or inspections. Nothing in this provision is to be construed so as to place a duty on Liquidia to make any such inspection or audit or to determine whether or not Plastiape is in compliance with its obligations hereunder or with applicable laws and regulations. No determination by Liquidia that Plastiape is or is not in compliance shall be construed as relieving Plastiape from its duty to determine if it is in such compliance with such laws and regulations. The foregoing notwithstanding, in the event any such inspection or examination is "for cause" as a result of any Product defects, nonconformance, material breach of this Agreement, failure to comply with regulatory requirements

or adverse finding of any regulatory authority, then the references to “twenty (20) Business Days” in this Section 12.2 shall be deemed to be amended to “ten (10) Business Days.”

12.3 Plastiape shall maintain and preserve full and accurate records and files which Plastiape is required to maintain in connection with the Product by law, including cGMP, or any regulatory authority. Plastiape must retain all such records for the longer of the period required by law or regulations or seven (7) years. In case of longer periods required by regulatory authorities Liquidia will advise Plastiape in writing of the time required.

13. Communication.

13.1 Plastiape and Liquidia will each appoint an individual who will act as the primary liaison point between the Parties. The Parties agree to discuss regularly any issues arising in relation to the Products. If requested by Liquidia, Plastiape must advise Liquidia of the stock of Product or raw materials held by Plastiape at any particular time.

13.2 Each Party agrees to provide the other Party with prompt written notice if:

(a) there is a Change of Control of the Party;

(b) the Party is in breach of this Agreement; or

(c) Plastiape becomes aware of any issues or nonconformances with respect of any Product, any failure of any Products to meet the Specifications or any other matter which may adversely affect the supply or use of the Products.

13.3 At Liquidia’s cost and expense, Plastiape agrees to cooperate with Liquidia in doing any reasonable act or thing which is necessary or desirable to facilitate Liquidia’s compliance with any regulatory requirements.

13.4 Plastiape agrees that, unless specifically authorized in writing by Liquidia, Liquidia will be responsible for all communications with regulatory authorities with respect to Liquidia’s products (which contains or is contained in any Product).

13.5 To the extent legally permissible by law, Plastiape agrees to forward any such communications (whether oral or written) received by Plastiape from a regulatory authority in relation to the Product to Liquidia within three (3) Business Days of receipt.

14. Audit.

14.1 In addition to Liquidia’s rights pursuant to Section 12, Liquidia (or any third-party approved by Liquidia, such case, subject to a confidentiality agreement and acceptance of safety and health rules at Plastiape’s site) shall have the right, upon prior written notification of twenty (20) Business Days to Plastiape and during regular business hours and without interruption of manufacturing process (other than making personnel available as necessary for the conduct of the audit), to inspect and audit the facilities being used by Plastiape for production and storage of the Product to assure compliance by Plastiape with current cGMP and other applicable laws, rules and regulations and with other provisions of this Agreement. The foregoing notwithstanding, in the event any such audit is “for cause” as a result of any Product defects, nonconformance, material breach of this Agreement, failure to comply with regulatory requirements or adverse finding of any regulatory authority, then the references to “twenty (20) Business Days” in this Section 14.1 shall be deemed to be amended to “ten (10) Business Days.”

14.2 Plastiape will within thirty days remedy or cause the remedy of any deficiencies which may be noted in any such audit or, if any such deficiencies cannot reasonably be remedied within such thirty day period, present to Liquidia a written plan to remedy such deficiencies as soon as possible. The failure by Plastiape to remedy or cause the remedy of any such deficiencies within such thirty day period or to present such a plan within such thirty day period and then use its reasonable commercial efforts to remedy or cause the remedy of such deficiencies in accordance with such written plan, constitutes a material breach of this Agreement.

14.3 The granting to Liquidia of certain audit rights shall in no way relieve Plastiape of any of its obligations under this Agreement or other legal obligations, nor does such provision require Liquidia to conduct any such audits.

15. Insurance.

15.1 Plastiape must maintain or cause to be maintained, at its own expense, adequate insurance as is usual for a prudent manufacturer in respect of the manufacture and sale of the Product, including the following types of insurance with carriers rated A- or better with A.M. Best: (i) public liability insurance and products liability insurance, and property damage in an amount not less than one million six hundred thousand US dollars ($1,600,000) per occurrence and aggregate; and (ii) products liability insurance, with a combined single limit in an amount of not less than one million six hundred thousand (1 600,000 $) per occurrence and in the aggregate.

15.2 Plastiape shall furnish Liquidia with a letter from the insurance broker evidencing the insurance coverages stated above in place.

16. Term.

This Agreement shall commence on the effective date hereof and shall continue for a period of five (5) years, unless terminated earlier in accordance with Section 17 (such period, the "Initial Term"). Following the Initial Term, this Agreement shall automatically renew for successive five-year periods (each, a "Renewal Term") unless terminated by either Party upon notice to the other Party at least thirty-six (36) months prior to the conclusion of the Initial Term or then-current Renewal Term. The Initial Term and any Renewal Term shall be, collectively, the "Term."

17. Termination.

17.1 This Agreement may be terminated:

(a) by one Party upon one hundred and eighty (180) days written notice to the other Party if the other Party is in default in performing or observing any material terms or representation, warranty, guarantee, covenant or obligation of this Agreement or any Quality Agreement entered into in connection herewith, and that default is not remedied within a period of one hundred and eighty (180) days after written notice has been given to the Party in default;

(b) by one Party if the other Party has suffered an Insolvency Event, in which case, the Party not suffering the Insolvency Event may immediately by written notice terminate this Agreement;

(c) by Liquidia upon thirty (30) days written notice to Plastiape if there is a Change of Control of Plastiape (except change of control within Berry Global, Inc.); or

(d) by a Party if the Parties cannot agree on a proposed price modification pursuant to Schedule 1 within ninety (90) days after notice of the proposed price change and evidence supporting the proposed price change have been given by one Party to the other Party.

17.2 Liquidia may also immediately terminate this Agreement upon written notice to Plastiape

(a) if complete orders of Product are not received within the time period required by this Agreement in fulfilment of three (3) purchase orders in any twelve (12) month period; or

(b) if Liquidia receives Product that does not meet Plastiape's warranty contained in this Agreement in connection with three (3) deliveries of Product in any twelve (12)-month period.

17.3 Upon termination or expiration of this Agreement for any reason the accrued rights and obligations of each Party as at the date of termination shall not be affected. In the event of termination, then:

(a) Each Party promptly (i) shall return to the other Party all relevant materials belonging to the other Party which are in the Party's possession, or, if instructed by the other Party, the Party shall destroy such

materials and provide written confirmation to other Party of their destruction, and (ii) Plastiape shall deliver to Liquidia all Product and all associated items, including without limitation related ingredients, inventories, materials, and supplies;

(b) If the Agreement is terminated by Plastiape for any reason or by Liquidia pursuant to Section 17.1 or 17.2, and subject to Plastiape's manufacturing capacity, Liquidia shall have the right to issue a final Purchase Order for Products in such quantities as Liquidia may determine in its sole discretion.

17.4 Termination of this Agreement for any reason shall not affect either Party´s accrued right, remedies or liabilities including any payment of any sum due by Liquidia for Products, Product molds, forms, and the like, and all associated items, including without limitation related at the effective date of termination and/or Liquidia´ obligation to take delivery of and pay the price of the Products ordered before the effective date of termination and pay for any unmortised investments (if any), stock of Products (if any), unused components including raw materials, colours, additives ordered by the Supplier, in each case pursuant to a forecast or binding Purchase Order received from Liquidia and that are not able to be used by Supplier for purposes other than supplying Products to Liquidia hereunder. Liquidia shall pay within 30 (thirty) calendar days of the invoice of Plastiape.

17.5 Clauses 8, 11, 12, 13.3, 13.4, 13.5, 14, 15, 17.3, 17.4, 17.5, 18, 19, 20, 21, 22, 23, 25, 26, 27, 28, 30, 32, 33 and 34, together with other terms and conditions that by their intent or meaning have continuing validity, survive termination or expiration of this agreement.

18. Confidentiality.

18.1 The Receiving Party must not, without the prior written approval of the Disclosing Party, disclose the Disclosing Party's Confidential Information except as expressly permitted by the terms of this Agreement. Confidential Information of the Disclosing Party may only be used in a manner contemplated by this Agreement solely for the express purposes of this Agreement and not for any other purpose.

18.2 The Receiving Party will not be in breach of clause 18.1 in circumstances where it is legally compelled to disclose the Disclosing Party's Confidential Information or is required to disclose the information by as a result of the listing rules of any stock exchange on which the Party is listed or any other regulatory request. If Receiving Party becomes legally compelled (whether in judicial or administrative proceedings or to comply with requirements otherwise imposed by any governmental or regulatory agency with authority over Receiving Party) to disclose any Confidential Information, to the extent legally permissible, prompt notice of such fact shall be given to Disclosing Party so that appropriate action (including, without limitation, the seeking of a protective order) may be taken and to the extent legally permissible, Receiving Party will reasonably cooperate with Disclosing Party, at Disclosing Party's sole cost and expense, in contesting such disclosure or in obtaining a protective order. If Receiving Party is required to make a disclosure under this paragraph, Receiving Party will furnish only that portion of the Confidential Information that is legally required.

18.3 Confidential Information shall be maintained in strict confidence and otherwise may only be disclosed to Affiliates, employees, or subcontractors, legal and tax advisors of the Receiving Party (i) who have a need to know such Confidential Information and are engaged in the performance of this Agreement and (ii) who are bound by the terms of their employment agreements (or other legal obligations) to keep all Confidential Information of the Disclosing Party confidential and not to use such Confidential Information except as expressly permitted by this Agreement.

18.4 The Receiving Party will on demand return to the Disclosing Party all Confidential Information supplied by the Disclosing Party to the Receiving Party in connection with this Agreement, except that (i) the Receiving Party may retain one copy of such Confidential Information in its legal files solely for verifying compliance with its obligations under this Agreement or enforcing its rights hereunder and (ii) the Receiving Party shall not be

required to expunge Confidential Information from any computer, word processor or other similar device storing Confidential Information in electronic format that are made in the ordinary course of business or during backups; provided that the confidentiality of such electronically stored Confidential Information continues to be maintained by the receiving party in accordance with the terms of this Agreement and is not at any time copied, reproduced or summarized.

18.5 This clause 18 survives termination or expiration of this Agreement for the period of 10 years from the date of termination or expiration of this Agreement, provided, however, that any Confidential Information contained in any copy retained pursuant to sub-clause 18.4 above shall continue to be protected by the confidentiality and non-use provisions of this Agreement for as long as such copy (whether physical or electronic) is in the possession of the Receiving Party, its Affiliates or their respective employees, agents or subcontractors.

19. Representations and Warranties and Compliance With Laws.

19.1 Liquidia and Plastiape each respectively represents and warrants to the other Party that:

(a) it is duly incorporated in the jurisdiction in which it is incorporated;

(b) it has the power to enter into and perform this Agreement and has obtained all necessary consents and authorizations to enable it to do so;

(c) the entry into and the performance of this Agreement does not constitute a breach of any obligation (including without limitation, any statutory, contractual or fiduciary obligation) or default under any agreement or undertaking by which it is bound;

(d) this Agreement constitutes the valid and binding obligations of such Party, enforceable against it in accordance with its terms; and

(e) at all times, it will comply with all applicable laws, regulations, codes, rules, ordinances, judgments, orders and decrees.

19.2 Plastiape represents and warrants to Liquidia that:

(a) all Product supplied in connection with this Agreement shall be:

(1) of merchantable quality, fit for the purpose intended by this Agreement (that is disclosed in writing) and free from defects in design, material and workmanship; and

(2) manufactured and supplied in conformity with the Specifications and this Agreement.

(b) it shall comply with all applicable present and future statutes, laws, ordinances and regulations relating to the manufacture and supply of the Product, including, without limitation, cGMP, including, as applicable, (a) the principles detailed in U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) other applicable regulatory requirements and international standards specified in the Specifications;

(c) it has right and title to sell the Products to Liquidia in accordance with the terms of this Agreement and the Products will be free from all encumbrances;

(d) the Products will correspond with all mutually agreed samples used by Plastiape and conform to the Specifications;

(e) the Products will conform to any Quality Agreement signed by the Parties in connection with this Agreement;

(f) the Product(s) and Plastiape's trademarks used in connection with the Product(s) do not infringe any patent, copyright, trademark or other proprietary right of any third parties and Plastiape has title or interest in all Intellectual Property Rights in the Products sufficient to authorize use of it by Liquidia and its direct and indirect customers and the grant of rights, in the manner contemplated by this agreement;

(g) technical information, product data sheets and material safety data sheets are complete, current and accurate and suitable and sufficient for use by Liquidia to use, process, sell or otherwise make use of the Products; and

(h) neither Plastiape, nor any of its employees, has ever been, is currently, or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred Entity or Debarred Individual. Plastiape further covenants, represents and warrants that if, during the Term of this Agreement, it, or any of its employees or agents, becomes or is the subject of any FDA investigation or debarment proceeding that could lead to that party becoming, as applicable, a Debarred Entity or Debarred Individual, Plastiape shall promptly notify Liquidia and to the extent legally permissible Plastiape shall immediately terminate the employment of any Debarred Individual or remove the Debarred Individual from any activities related to the Products hereunder and shall promptly notify Liquidia and any regulatory authority of the details of the same in compliance with applicable laws.

19.2.1. The foregoing warranties will not apply in any of the following events: if (a) Liquidia makes any further use of any Products after Liquidia has given notice in accordance with this clause that such Products fail to conform to the representations set forth in Section 19.2; or (b) the defect arises because of any act or omission by Liquidia (including any unauthorized alteration or repair of the Products, a failure to follow oral or written instructions as to storage, installation, use and maintenance of the Products (or good trade practice), willful damage, negligence or storage or usage conditions that are outside of any specifications provided or notified by Plastiape to Liquidia); or (c) the defect arises as a result of the Supplier following any drawing, design or specification supplied by Liquidia.

19.3 Each Party represents and warrants that it shall comply fully with:

a) All applicable Laws relating to anti-bribery and anti-corruption and, more specifically, abide by the standards of conduct set forth in the United States Foreign Corrupt Practices Act of 1977, the United Kingdom Bribery Act of 2010 and any other applicable anti-corruption and/or anti-money laundering Laws (all together the “Anti-Corruption Laws”); and
b) All relevant export Laws, trade restriction Laws of the United States, European Union and any other applicable national Laws (“Export Laws”) in force at the relevant time. Liquidia shall not, in respect of the Products: (i) export, re-export, trans-ship, or otherwise transfer, directly or indirectly, in violation of Export Laws; or (ii) use the same for any purposes prohibited by the Export Laws (including, without limitation, nuclear, chemical, or biological weapons proliferation).

20. Indemnification.

20.1 Plastiape shall indemnify Liquidia, its Affiliates and each of their officers, directors, employees (each a ”Liquidia Indemnitee”) from and against any and all of the Liquidia Indemnitees’ direct damages, liabilities, claims, costs, charges, judgments and expenses (including reasonable attorneys’ fees) (collectively “Damages”) arising out of a claim by a third party and that is sustained, suffered or incurred by a Liquidia Indemnitee, in connection with:

(a) personal injury, death, loss or damage to any property to the extent caused by the negligent, reckless or intentional act or omission of Plastiape, provided that Plastiape shall not be liable for any product liability or personal injury claims by third parties arising from the sale, distribution or use of any Product which meets the Specifications and other requirements of this Agreement and is not otherwise defective;

(b) a breach by Plastiape of any warranty, representation, covenant or agreement made by Plastiape in this Agreement; and

(c) any claim that any Product purchased from Plastiape or the use or sale of such Product infringes any Intellectual Property Rights of any third party (excluding any claims relating solely to Liquidia’s

materials, including Liquidia's Intellectual Property Rights, brand names and copyrights contained in or used with the Product).

20.2 Liquidia shall indemnify Plastiape, its Affiliates and each of their officers, directors, employees and agents (each a "Plastiape Indemnitee") from and against any and all Damages arising out of a claim by a third party and sustained, suffered or incurred by a Plastiape Indemnitee in connection with (i) the breach by Liquidia of any warranty, representation, covenant or agreement made by Liquidia in this Agreement, (ii) any Product sold by Liquidia under the Agreement or that are in the possession or under the control of Liquidia, its employees, agents, except any claim with respect to which Plastiape is obligated to indemnify Liquidia pursuant to Section 20.1, and (iii) any infringement or alleged infringement by Liquidia of any Intellectual Property Rights of third parties relating solely to Liquidia's materials, including Liquidia's Intellectual Property Rights, Liquidia's brand names, specifications provided by Liquidia to Plastiape for changes to the Products and Liquidia's copyrights contained in or used with the Product.

20.3 Upon assertion of any third party claim against a Party that might give rise to indemnification under this Agreement, the Party claiming the right of indemnification ("Indemnified Party") must give prompt written notice to the Party alleged to have the duty to indemnify ("Indemnifying Party") of the existence of such a claim and will give the Indemnifying Party a reasonable opportunity to control, defend and/or settle such claim at its own expense and with counsel of its own selection. The Indemnified Party has the right to participate in such defense at its own expense and with separate counsel. Provided that the Parties are not contractually or legally excluded, or are not otherwise prejudiced in their legal position by doing so, the Parties will co-operate with each other and their respective insurers in relation to the defense of such third party claim. In the event that the Indemnifying Party elects to defend such a claim, neither Party may settle the claim without the prior written consent of the other Party (which consent shall not be unreasonably delayed or withheld). Notwithstanding the foregoing, in the event of a dispute with respect to the indemnity, each Party is entitled to participate in the defense of such claim and to join the other in any such action.

21. Failure to Supply; Advance Notice by Plastiape.

21.1 If during the Term, Plastiape ceases to manufacture the Product or is unable or unwilling or fails to supply any Product in such quantities as Liquidia shall order and in compliance with the required delivery periods (whether due to the occurrence of a Force Majeure or otherwise), then, without limiting Liquidia's right of termination or other rights hereunder, Liquidia shall be entitled (with no obligation or liability to Plastiape) to obtain such Product from another supplier.

21.2 If Plastiape determines to cease manufacturing the Product for any reason, it will provide Liquidia with at least three (3) years' advance notice prior to taking such action to permit Liquidia to locate and qualify a substitute supplier, and during such three (3) year period Plastiape will continue to provide Product to Liquidia under the terms of this Agreement.

22. License and Intellectual Property Rights.

22.1 As between the Parties, (i) Liquidia shall own all right, title and interest in and to Liquidia's Background IP and (ii) Plastiape shall own all right, title and interest in and to the Plastiape Background IP.

22.2 Plastiape's Background IP if any, and IP Rights created by or on behalf of Plastiape as a direct result of the Plastiape's Background IP under this Agreement ("Plastiape Arising IP") is retained by Plastiape (collectively with Plastiape Background IP, "Plastiape IP Rights"). During the term of this Agreement, Plastiape grants to Liquidia, and Liquidia hereby accepts, a , worldwide, royalty-free, non-exclusive license under Plastiape IP Rights, including the right to practice such Plastiape IP Rights in any way for Liquidia to receive the full benefit of the Products under this Agreement (license to use, market, sell or resell), which license shall be perpetual as to Products received by Liquidia pursuant to this Agreement. To the extent legally permissible,

Liquidia waives any moral rights in Plastiape IP Rights, including, without limitation, the right to be named as author, the right to modify, the right to prevent mutilation and the right to prevent commercial exploitation. To the extent such waiver is not legally permissible, Plastiape will have the irrevocable right to exercise any moral rights in Plastiape IP Rights on Liquidia's behalf to the fullest extent permitted by law.

22.3 Plastiape accepts no responsibility whatsoever for any changes to the drawings, specifications, designs, documents or wording, in whatever language, related to the Products that is provided to Plastiape by Liquidia.

23. Publicity.

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 (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 the Parties' respective policies); (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; or (iii) for Public Statements by Liquidia related to the use of Product(s) with its pharmaceutical products and the inclusion of Products in kits with Liquidia's products.

24. Force Majeure.

24.1 If by reason of Force Majeure, either Party is unable to carry out any of its obligations under this Agreement, that obligation is suspended during the continuance of the Force Majeure. Such non-performing Party shall exercise all reasonable efforts to eliminate the Force Majeure Event and to resume performance of its affected obligations as soon as practicable.

24.2 Such non-performance will be excused for six (6) months or as long as such event shall be continuing (whichever occurs sooner), provided that the non-performing Party gives prompt written notice to the other Party of the Force Majeure.

25. Notices.

25.1 Any notice, report or other instrument provided for in this Agreement will be deemed sufficiently given or delivered pursuant to this Agreement if directed to the Party for whom it is intended at the following addresses or such different address as that Party may have specified for the purpose by notice in writing to the other Party:

(a) if to Liquidia , at the address, or email address specified on page 1 with copy to Liquidia Technologies, Inc., Attn: Legal Department, 419 Davis Drive, Suite 100, Morrisville, NC 27560 USA or legal@liquidia.com;

(b) if to Plastiape, at the address, facsimile number or email address specified on page 1,

or as otherwise notified in writing to the other Party.

25.2 Notice will be deemed to have been given by the sender and received by the addressee:

(c) if by delivery in person, when delivered to the addressee;

(d) if by post, ten (10) business days from and including the date of posting;

(e) if by facsimile transmission, when the sender's machine generates a correct facsimile transmission report; or

(f) if by email, one (1) Business Day after sending to the correct email address.

26. Dispute Resolution and Jurisdiction.

26.1 If a dispute arises between the Parties out of or in relation to this Agreement ("Dispute"), either Party seeking to resolve the Dispute must do so strictly in accordance with the provisions of this clause. Compliance with the provisions of this clause is a condition precedent to seeking relief in any court in respect of the Dispute except as provided in clause 26.2.

26.2 A Party seeking to resolve a Dispute must notify the existence and nature of the Dispute to the other Party ("Notification"). Upon receipt of a Notification, the Parties must refer resolution of the dispute to their respective chief executive officers or nominees appointed by the chief executive officers.

26.3 If the Dispute has not resolved within thirty (30) days of receipt of the Notification, then either Party may initiate proceedings in accordance with clause 34 of this Agreement.

26.4 Nothing in this clause shall prevent either Party from seeking interlocutory relief, injunctive relief or equitable relief through any court of competent jurisdiction at any time.

27. Limitation of Liability.

27.1 In no event shall either Party be liable to the other Party for any indirect, special, incidental, consequential (except in connection with a breach of Section 18), statutory, punitive or exemplary damages arising under or in connection with this Agreement including, without limitation loss of business or profits or interruption of business, regardless of the nature of the claim or theory of recovery.

27.2 Notwithstanding anything to the contrary and to the extent legally permissible, neither Party's total liability to the other Party in respect of alleged direct damages or losses arising under or in connection with this Agreement, regardless of the nature of the claim or theory of recovery, shall exceed in aggregate over a contractual year, the price paid by Liquidia to Plastiape for Products.

27.3. Nothing in this Agreement shall limit or exclude (i) a Party's liability for fraud, death or personal injury caused by its negligence, unlawful actions, intentional misconduct or any matter in respect of which it would be unlawful for a Party to exclude or restrict its liability, or (ii) any indemnity claims hereunder relating to the matters described in clause (i) of this Section 27.3.

28. Relationship.

28.1 Each Party is an independent contractor.

28.2 The Parties are not principal and agent, partners, joint venturers, trustee and beneficiary, or employer and employee of each other.

28.3 Neither Party may:

(a) hold out their agents, contractors or employees as the agents, contractors or employees of the other Party;

(b) pledge the credit of the other Party; or

(c) contract for or on behalf of the other Party or make any other commitments on behalf of the other party.

28.4 For the avoidance of doubt, either Party's dealings with its customers are in no way binding on the other Party.

29. Assignment.

29.1 Subject to clause 29.2, without the consent of the other Party (not to be unreasonably withheld, conditioned or delayed), each Party must not:

(a) assign the benefits of this Agreement;

(b) mortgage, charge or otherwise encumber the benefit of this Agreement; or

(c) cause its obligations under this Agreement to be assumed by a third party.

29.2 Subject to Clause 17.1 the Parties acknowledge that each Party may assign its rights hereunder to any Affiliate of the Party or to any third party that acquires the Party, or substantially all the assets or business of the Party that relates to this Agreement; or in the case of Liquidia, to any third party that acquires or licenses the Liquidia product(s) that uses the Product.
29.3 Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties and each of their respective successors and assigns (whether by asset sale, merger or otherwise).

30. No Waiver.
30.1 A Party only waives a breach of this Agreement if the waiver is given in writing signed by that Party or its authorized representative.
30.2 A waiver is limited to the instance(s) referred to in writing. A waiver of compliance with any provision of this Agreement shall not constitute a waiver of any subsequent lack of compliance with such provision or of any other provision of this Agreement.
30.3 Failure, omission or delay by any Party to enforce compliance with any provision of this Agreement will not constitute a waiver of or otherwise affect the rights of that Party to use any remedy available to it in respect of the breach of any such provision. Any single or partial exercise of any right, power or privilege hereunder shall not preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder.

31. Costs.
Each Party must pay its own costs in respect of the costs of the negotiating, preparation and examination of this Agreement and any document required by this Agreement.

32. Entire Agreement.
When signed, this Agreement constitutes the entire agreement between the Parties in relation to its subject matter. This Agreement may not be contradicted by evidence of any prior or contemporaneous agreement, oral or written, and this Agreement may not be explained or supplemented by evidence of consistent additional terms. No previous course of dealing will be admissible to explain, modify or contradict the terms of this Agreement. This Agreement supersedes, merges, and voids all prior representations, statements, negotiations, understandings, proposed agreements, and other agreements, written or oral, relating to its subject matter.

33. Amendment.
This Agreement can only be amended, modified or supplemented by written agreement executed by all the Parties.

34. Governing Law.
34.1 This agreement is governed by the laws of England and Wales, excluding its conflict of laws provisions. In the event that any dispute, controversy, conflicts or claim ("Disputes") arising out of, or in relation to, this Agreement, cannot be settled by means of negotiations within 30 calendar days from the date of notification to the other Party about the presence of the dispute or conflict, the Parties shall submit all Disputes (including the validity, invalidity, breach, or termination thereof) to the competent court in London, United Kingdom. . The Parties agree that the competent court in London, United Kingdom is the most appropriate and convenient court to settle any Dispute and, accordingly, that they will not argue to the contrary.

35. Counterparts.

This Agreement may be executed in any number of counterparts, each of which will be deemed to be an original copy of this Agreement. A counterpart may be a facsimile or electronic signature, which shall constitute effective execution and delivery of this Agreement as to the Parties and may be used in lieu of the original Agreement for all purposes. Signatures of the Parties transmitted by facsimile or electronic transmission shall be deemed to be their original signatures for all purposes. Together all counterparts make up one instrument.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK;
THE SIGNATURE PAGE IMMEDIATELY FOLLOWS]

The Parties have caused this Agreement to be signed by their duly authorized representatives below, effective as of May 22nd, 2023 for all purposes.

| | |
|---|---|
| Liquidia Technologies, Inc. | Plastiape SpA |
| By: /s/ Rob Lippe | By: /s/ Alfredo Masuello |
| Name: Rob Lippe | Name: Alfredo Masuello |
| Title: Chief Operations Officer | Title: Managing Director |

SCHEDULE 1

[***]

**Exhibit 10.6**

**AMENDED AND RESTATED**
**COMMERCIAL MANUFACTURING SERVICES AND SUPPLY AGREEMENT**

This Amended and Restated Commercial Manufacturing Services and Supply Agreement (the "Agreement") is made and entered into as of July 13, 2023 ("Effective Date"), by and between Liquidia Technologies, Inc., with a principal place of business at 419 Davis Drive, Suite 100, Morrisville NC 27560 ("Customer"), and Lonza Tampa LLC f/k/a Xcelience, LLC, with principal place of business at 5415 West Laurel Street, Tampa, Florida 33607, USA ("Lonza"). Each of Lonza and Customer may be referred to herein individually as a "Party," and Lonza and Customer may be referred to collectively as the "Parties."

WHEREAS, Customer is engaged in the research and development of pharmaceutical products; and

WHEREAS, Lonza possesses the expertise to manufacture commercial pharmaceutical products; and

WHEREAS, Customer wishes to engage Lonza, and Lonza wishes to be engaged by Customer, to manufacture quantities of Product (defined below), pursuant to the terms and subject to the conditions of this Agreement for human pharmaceutical use in the Territory (defined below), and in accordance with cGMP (defined below); and

WHEREAS, Customer and Lonza are parties to that certain Commercial Manufacturing Services and Supply Agreement, dated as of November 12, 2020 (the "Original Agreement"); and

WHEREAS, Customer and Lonza desire to amend and restate the terms of the Original Agreement in their entirety as set forth in this Agreement.

NOW THEREFORE, in consideration of the representations, covenants and warranties set forth herein, and for other good and valuable consideration, the Parties agree as follows:

## 1. DEFINITIONS AND GENERAL MATTERS

1.1 **Defined Terms.** As used in this Agreement, the following words and phrases shall have the meanings set forth below.

- "Affiliate" means any Person who, directly or indirectly through one or more intermediaries, Controls, is Controlled by, or is under common Control with any other Person. For purposes of this definition, "Control" means (a) the direct or indirect legal or beneficial ownership of more than fifty percent (50%) of (i) the ownership interests in a Person or (ii) the outstanding voting rights in a Person or (b) the power to otherwise direct the business activities of a Person.

- "Annual Minimum Commitment" shall mean the minimum quantity of Product to be ordered by Customer in each Contract Year as set forth in Exhibit A, attached hereto.

- "Baseline Forecast" shall be set forth in Exhibit A, attached hereto.

- "Bulk Powder" means treprostinil processed by Customer using proprietary PRINT technology, also referred to as LIQ861.

- "Cancellation Fee" has the meaning given in Section 3.6.

- “Claim or Proceeding” means any third party claim, action, suit, proceeding or arbitration, including any governmental authority action or investigation for death, bodily injury or property damage.

- “Commencement Date” means the date of commencement of the Services.

- “Commercial Launch Date” means the date Customer receives notice from the FDA of Regulatory Approval.

- “Contract Year” means for Contract Year 1 (also sometimes referred to as Year 1) started on February 8th, 2022 and extends to the date of Regulatory Approval. After Contract Year 1, “Contract Year” means the period beginning on the date of Regulatory Approval and ending on the twelve (12) months anniversary thereafter and each 12-month period thereafter.

- “Current Good Manufacturing Practices” or “cGMPs” mean all applicable Laws in the Territory relating to manufacturing practices of medicinal products for human use promulgated by any relevant governmental authority, as may be updated, supplemented or amended from time to time.

- “Facility” means (i) for encapsulation, Lonza’s manufacturing facilities located at 5415 West Laurel Street, Tampa, Florida 33607, USA; (ii) for packaging, 4901 W Grace St, Tampa, Florida 33607, USA; or for storage and distribution, 5709 John’s Rd, Tampa, Florida 33634, USA.

- “FDA” means the U.S. Food and Drug Administration, and any successor agency thereof.

- “Hidden Defect” means those deviations from the Specifications that are not visible or readily identifiable at the time of delivery.

- “Law” means all applicable treaties, laws, and regulations in the Territory.

- “Losses” means any and all losses, fines, fees, settlements, payments, obligations, penalties, deficiencies, liabilities, damages, costs and expenses (including reasonable attorneys’ fees).

- “Person” means an individual, partnership, corporation, association, trust, joint venture, or unincorporated organization.

- “Price” means the price for Product referred to in Section 4.1.

- “Product” means the finished drug product for commercial sale and distribution to end users which complies with FDA approved labeling that is packed in the final market configuration that Lonza manufactures for Customer hereunder in accordance with cGMPs, containing the Bulk Powder and other Raw Materials identified in the Specifications for human pharmaceutical use in the Territory.

- “Quality Agreement” means the Quality Agreement, dated August 24, 2020 by and between the Parties, as amended from time to time.

- “Raw Materials” means any materials, other than Active Materials, as specified in the Specifications.

- “Regulatory Approval” means the receipt of all approvals, licenses, registrations or authorizations from the FDA necessary to market and sell the Product in the United States.

- "Services" means the commercial manufacturing services and related services to be performed by Lonza under this Agreement, particulars of which are set out in each Purchase Order.

- "SKU" means stock keeping units in Product weights of 5 mg of Bulk Powder, 10 mg of Bulk Powder, 15 mg of Bulk Powder, and 20 mg of Bulk Powder.

- "Specifications" means the release specifications for the manufacture, processing, bulk packaging, testing and testing procedures, shipping, storage and supply of the Product, any Raw Material requirements, analytical procedures and standards of quality control and quality assurance, established by the Parties for the Product. The Specifications include those specifications set forth in Exhibit D and such other specifications and requirements as may be set forth in the Quality Agreement.

- "Territory" means the United States of America, and any other countries or jurisdictions that are mutually agreed to by the Parties in writing.

- "Units" shall mean a finished labeled kit ready for commercial sale and distribution to end users which complies with the FDA approved labeling, containing 7 individual blister cards, containing 4 capsules in each blister card, a DPI and a package of cleaning brushes or other agreed upon packaging configuration.

1.2 **Exhibits.** The attached Exhibits are incorporated into and form part of this Agreement:

| | |
|---|---|
| EXHIBIT A | COMMERCIAL TERMS |
| EXHIBIT B | ENVIRONMENTAL AND HEALTH AND SAFETY INFORMATION |
| EXHIBIT C | SDS OF MATERIALS PROVIDED BY CUSTOMER |
| EXHIBIT D | SPECIFICATIONS |

## 2. TERM; FACILITY; AFFILIATES

2.1 **Term.** The term of this Agreement shall commence on the Effective Date and, subject to the rights of earlier termination contained in this Agreement, shall remain in effect for five (5) years from Regulatory Approval ("Initial Term"). The Initial Term may thereafter be extended for subsequent years upon the mutual written agreement of the Parties (the Initial Term, together with such subsequent periods, the "Term").

2.2 **Facility.** Lonza shall perform all manufacturing activities and all storage activities at the Facility. Lonza may use other facilities for the manufacture and storage of Product provided that (i) such facilities have been approved for such manufacture and storage by all applicable governmental authorities and (ii) Customer written approval is obtained prior to the use of such facilities, such approval not to be unreasonably withheld by Customer.

2.3 **Affiliates.** Lonza may instruct one or more of its Affiliates to perform any of Lonza's obligations contained in this Agreement and any particular Purchase Order (defined below in Section 3.2) as mutually agreed to by the Parties in writing, provided, however, that Lonza shall remain fully responsible in respect of those obligations. Such Affiliate shall be entitled to submit invoices to Customer for the specific Services performed by such Affiliate under the applicable Purchase Order. Any of said Affiliates so used by Lonza shall be subject to all of the terms and conditions applicable to Lonza under this Agreement and shall be entitled to all rights and protections afforded Lonza under this Agreement.

## 3. FORECASTS AND ORDERS

3.1 **Forecasts.** Each quarter by the 10th business day Customer shall submit to Lonza a good faith, estimated [***] rolling forecast of the quantity of Product that Customer expects to order for production commencing with the month following the month in which such forecast is provided ("Forecast"). Each Forecast shall be non-binding, with the exception of the Forecast for the nearest [***] of the Forecast, which shall be considered a firm order for Product ("Firm Order"). For clarity, Customer is obligated to purchase the volumes of Product that are included in the Firm Order regardless of whether Customer issues Purchase Order for such amounts. Lonza shall notify Customer immediately in writing if at any time Lonza has reason to believe that it will not be able to fill a Firm Order. No Forecast shall amend any previous Firm Order.

3.2 **Purchase Orders.** Customer shall submit a purchase order corresponding to the Firm Order ("Purchase Order") no less than [***] in advance of the requested delivery date for Product that is not subject to a previous Purchase Order. For the avoidance of doubt, Purchase Orders will be issued every quarter to include the next three (3) months of the Firm Order such that at any given time Customer has issued Purchase Orders for the nearest [***] period. Each Purchase Order shall specify the quantity of Product ordered, Customer' purchase order number, the requested delivery date, the invoice address, the shipping address and any further information necessary or reasonably requested by Lonza to facilitate the shipment of Product. Lonza shall acknowledge receipt of Purchase Orders within ten (10) business days. Customer shall be permitted to adjust the Product SKU allocation at the packaging level no later than [***] prior to the requested delivery date with revised Purchase Order to be issued if there are changes to the version submitted previously.

3.3 **Forms and Inconsistencies.** Any term or condition of a Purchase Order, acceptance form used by Lonza, or any other correspondence between the parties that is different from, inconsistent with or contrary to the terms and condition of this Agreement shall be void. All Purchase Orders submitted by Customer shall be deemed to incorporate and be subject to the terms and conditions of this Agreement. Lonza's failure to object to any provisions contained in any communication from Customer shall not be deemed a waiver of the provisions herein.

3.4 **Annual Minimum Commitment**. Customer undertakes to purchase from Lonza a minimum quantity of Product per Contract Year as set forth in the table entitled "Annual Minimum Commitment" on Exhibit A. If Customer fails to purchase such minimum quantity of Product, Customer shall make payment to Lonza within thirty (30) days following the applicable Contract Year end equal to [***]. In accordance with that certain letter agreement, dated February 8, 2022, by and between Customer and Lonza, all Product ordered by Customer after February 8, 2022 and prior to the commencement of the first Contract Year shall be credited towards Customer's Annual Minimum Commitment for the first Contract Year.

[***]

3.5 **Delayed Launch.** Commencing on [***], in the event that the Customer fails to commence ordering of Product under this Agreement for any reason whatsoever, any reason, then the Parties, in good faith will renegotiate the rights and obligations under this Agreement.

3.6 **Cancellation of a Binding Purchase Order**. Customer may cancel a binding Purchase Order upon written notice to Lonza, subject to the payment of a cancellation fee of one hundred percent (100%) of the cancelled Purchase Order (the "Cancellation Fee").

3.7 **Payment of Cancellation Fee**. Any Cancellation Fee shall be payable within [***] following the written notice of cancellation associated with the cancelled batch.

3.8 **Capacity Reservation; Capital Expenditures**. Lonza agrees, that subject to Customer meeting its Annual Minimum Purchases and its payment obligations herein, it (i) shall maintain capacity to manufacture the quantity of Product as set forth on Exhibit A hereto; and (ii) incur reasonable additional capital expenditures, at Lonza's cost, as determined in Lonza's sole discretion in order to meet its obligations under this Agreement.

3.9 **Continuous Improvement Program**. The Parties together shall use commercially reasonable efforts to identify and target any potential areas of cost reduction and process improvements (i.e., cycle time reductions, inventory reductions, yield improvements, collaborative procurement) relating to its obligations hereunder. Lonza and Customer shall meet from time to time, but at least annually, to review objectives and to share ideas for these improvements. As opportunities are identified along with potential cost and savings impact an implementation plan and project budget shall be jointly defined and agreed on by the Parties. The allocation of any costs and expenses for new capital equipment addition or investment necessary to the same implementation plan and the resulting modified process shall be agreed by both Parties, which will also include prior written regulatory assessment and approval by both the Parties. The resulting costs benefits will be shared equally between the two Parties. No price adjustment will be applied unless such cost improvement plans are agreed on, successfully implemented and applied on commercial scale for the Product.

## 4. PRICE; PAYMENT TERMS; TITLE

4.1 **Price.** Customer agrees to pay Lonza for the Product provided hereunder at the Price set forth on Exhibit A hereto.

4.2 **Taxes**. The Price is exclusive of taxes, which taxes shall be for the account of Customer. Taxes that Lonza is required by Law to collect from Customer, e.g., V.A.T., will be separately stated in Lonza's invoice and will be paid by Customer to Lonza.

4.3 **Payment Terms.** The payment terms are set forth in Exhibit A as [***] days from the date of invoice upon release of Product and with appropriate release documentation as set forth in Section 4.6 hereof. Lonza shall invoice Customer at the time Product is released by Lonza QA at the Facility. Each shipment shall constitute an independent transaction, and Customer shall pay for the same in accordance with the specified payment terms and without deduction or set-off.

4.4 **Late Payment Interest.** If Customer is in default of payment of any undisputed invoice on the due date, interest shall accrue on any amount overdue at the lesser of (i) one percent (1%) per month or (ii) the maximum rate allowable by applicable Law, interest to accrue on a day to day basis until full payment; and Lonza shall, at its sole discretion, and without prejudice to any other of its accrued rights, be entitled to suspend the provision of the Services and/or delivery of Product until all overdue amounts have been paid in full including interest for late payments.

4.5 **Price adjustments.**

4.5.1 Commencing on the first anniversary of the Effective Date, not more than once per Contract Year, Lonza may adjust the Price in accordance with the US Department of Labor's Bureau of Labor Statistics Pharmaceutical Preparations Index, ethical PCU 325414 (https://www.bls.gov/ppi) or any successor index, for the previous Contract Year. The new Price reflecting such adjustment shall be effective for any manufacture of Product for which the Commencement Date is on or after the date of Lonza's notice to Customer of the Price adjustment.

4.5.2 In addition to the above, the Price may be changed by Lonza, upon prior written consent of Customer, such consent shall not be unreasonable delayed or withheld (providing reasonable detail in support thereof), to reflect (i) a change in variable costs (such as energy) by more than [***] (based on the initial Price or any previously amended Price), or for a process adjustment or assumption changes, and (ii) any material change in an environmental, safety or regulatory standard that substantially impacts Lonza's cost and ability to perform the Services.

4.6 **Shipping Term; Title.** All Product shall be delivered ExW (as defined by Incoterms® 2010) the Facility. Title and risk of loss or damage to the Product shall pass to Customer at the time Product is released by Lonza's QA department together with appropriate release documentation as set forth in the Quality Agreement, according to the terms of shipment set forth in Exhibit A. Lonza shall provide necessary documentation to allow shipment from Lonza's premises to those detailed in the Purchase Order. Customer shall arrange for shipment and take delivery of such Product from the Facility, at Customer's expense, within fifteen (15) days after release of the Product by Lonza or pay applicable storage costs of [***] per pallet per month. Lonza shall provide storage on a bill and hold basis for such batch(es) at no charge for up to fifteen (15) days; provided that any additional storage beyond fifteen (15) days will be subject to availability and, if available, will be charged to Customer and will be subject to a separate bill and hold agreement. Within five (5) days following a written request from Lonza, Customer shall provide Lonza with a letter in form satisfactory to Lonza confirming the bill and hold status of each stored batch.

4.7 **Credit**. Lonza shall have the right to cancel any Purchase Order accepted by Lonza, or to delay the shipment of the Product ordered therein, if Customer fails to meet payment schedules or other credit or financial requirements established by Lonza. Customer agrees to make available to Lonza such statements of Customer's financial condition as Lonza may, from time to time, request. Lonza reserves the right at all times, either generally or with respect to any specific Purchase Order, to vary, change or limit the amount or duration of credit to be allowed to Customer.

## 5. OBLIGATIONS OF THE CUSTOMER

5.1 **Manufacture and Supply of Bulk Powder.** Customer shall comply with all applicable Laws related to the manufacture of Bulk Powder and the delivery of Bulk Powder to Lonza. Customer shall identify, qualify, purchase and deliver the Bulk Powder to the Facility. Customer shall be responsible for the quality of the Bulk Powder, Quality Assurance and management of Bulk Powder vendor relationship. Customer shall supply Lonza with the quantity of Bulk Powder required to manufacture the Product in the amount specified in Customer's Purchase Order, [***] (excluding material for lab testing and retain) ("Loss Allowance") to allow for normal waste and breakage calculated over a twelve (12) month period, not less than four (4) weeks prior to the Commencement Date. Delivery shall take place DDP Facility Incoterms 2010. Lonza shall not be responsible for any failure to deliver or any delivery delay of Product due to (i) the failure of Customer to deliver or cause delivery of Bulk Powder in the time specified in this Section, or (ii) the delivery of defective Bulk Powder, and Customer shall be responsible for all additional costs and expenses arising out of such delay or defect, including, if applicable, reasonable idle Facility capacity costs and any Cancellation Fees if such delay or defect results in Lonza not being able to manufacture Product in the manufacturing slots reserved for Customer at the Facility. In the event of any loss or damage to Bulk Powder while in the possession of Lonza in excess of the Loss Allowance due to Lonza's negligence, Lonza's liability to Customer related to or arising out of such loss shall be limited to the greater of (i) reimbursement of Customer for the most recent actual incurred manufacturing cost per kilo of Bulk Powder, up to [***]/kg, applied pro-rata to the amount of Bulk Powder concerned or (ii) [***] the value of the Purchase Order creating such liability.

5.2 **Health & Safety Data.** (a) Customer has provided to Lonza certain information relating to the Bulk Powder, attached hereto as Exhibit C. To the extent Customer has not provided the information in Exhibit C and to the extent it possesses the information, Customer shall provide to Lonza, prior to the shipment of any Bulk Powder to Lonza hereunder, the environmental, health and safety information described in Exhibit B as it relates to the Bulk Powder. To the extent the information contained in paragraphs 2 and 3 of Exhibit B has not yet been generated by Customer, tests, analyses and/or research necessary to collect such information and data shall be conducted, at the expense of Customer, by Customer internally or by an outside laboratory retained by Customer. Customer shall properly document all such test results and shall provide such documentation to Lonza prior to the delivery of any Bulk Powder to Lonza. If the data indicates that Lonza cannot safely manage the Bulk Powder without the addition of certain engineering controls or other changes to its facilities and/or equipment, the Parties will discuss cost allocation for required changes.

(b) Customer shall provide to Lonza promptly upon receipt by Customer (i) any information needed to clarify, correct, supplement or amend any of the information described in Exhibit B or provided in Exhibit C and (ii) any other information reasonably related to the environmental, health and safety implications, including employee health and safety, of the handling, manufacture, distribution, use and disposal of the Bulk Powder. Lonza shall not be responsible for any failure to deliver or delivery delay due to Customer's failure to deliver such results or documentation.

5.3 **Compliance with Law; Use and Disposal of Product.** Customer is responsible for (a) the use, packaging, labeling, distribution, marketing, promotion, sale and disposal of Product, including compliance with all present and future Laws related to the same; (b) communicating with any governmental authority concerning the Product, including without limitation with respect to the registration, classification or notification of a new Product or substance, or the use, packaging, labeling, distribution, marketing, promotion, sale or disposal of the same or any adverse events related to the Product (for the avoidance of doubt, Lonza may interact with governmental authorities for the purpose of fulfilling its obligations hereunder); (c) storing and handling Product in appropriate conditions following its delivery; and (d) determining the Specifications for the Product to permit its sale in each country in the world. Customer shall conduct all such activities at all times in compliance with applicable Laws. The Parties acknowledge and agree that Lonza has no control, role, or other form of influence in Customer's use, packaging, labeling, distribution, marketing, promotion, sale and disposal of Product, nor does it control or influence any payments or transfers of value that may be made by Customer to health care professionals, health care institutions, or any other customer or third party. Customer is responsible for participation and compliance in all government health care programs such as Medicare and Medicaid, and any rebate liability, mandatory pricing, or reporting obligations resulting therefrom.

5.4 **Additional Obligations.** Customer shall manage, direct and be responsible for all intellectual property decisions and being responsible for all litigation costs which result solely from the filing of the Products. Customer shall maintain pharmacovigilance infrastructure as required by a distributor of Product. Customer will own and control all regulatory approvals in the Territory (including all associated contents and correspondences) and applications therefore related to the Product and any other marketing authorizations within the Territory.

## 6. OBLIGATIONS OF LONZA AND CUSTOMER

6.1 **Materials.** Lonza shall be responsible for procuring Raw Materials identified in the Specifications other than the Bulk Powder. Lonza will destroy unused Bulk Powder following instructions

provided by Customer, consistent with Lonza's environmental, health and safety guidelines. Customer shall pay for the costs of destruction.

6.2 **Lonza Regulatory Obligations**. Lonza is responsible for (a) manufacturing and supplying the Product in compliance with all applicable Laws, including but not limited to environmental health and safety laws and cGMP, and (b) storing and handling Product in appropriate conditions before its delivery to Customer in accordance with Section 4.6. Lonza shall obtain and maintain during the Term all regulatory approvals necessary in the jurisdiction in which the Facility is located for Lonza to operate the Facility.

6.3 **Inspections and Audits**. Subject to the terms of the Quality Agreement, Customer and its representatives shall have the right to visit or audit, or request a reputable third party to visit or audit the Facility to verify that the documentation, equipment and material relating to the Product is maintained in accordance with applicable Laws and that Lonza is performing its obligations hereunder. Customer shall bear all costs related to any such audit, or inspection, above one (1) audit or inspection during a contiguous 12 month period. This Section 6.3 is subject in all cases to any such party executing a confidentiality agreement with Lonza, in form and substance reasonably acceptable to Lonza.

Subject to the terms of the Quality Agreement, Lonza will allow full access to any governmental regulatory inspection and shall promptly inform Customer of the results of such inspections to the extent such inspection directly affects Lonza's performance under this Agreement.

6.4 **Customer Regulatory Obligations.** Customer is responsible for compiling the registration dossiers (with reasonable and necessary assistance from Lonza), filing the marketing applications with the regulatory authorities in the Territory, and maintaining marketing authorizations for the Product and the costs associated with the same. Lonza shall reasonably assist Customer in obtaining and maintaining marketing authorizations for the Product. Customer is responsible for (a) the formulation, use, packaging, labeling, distribution and disposal of Product, including compliance with all Laws related to the same; (b) communicating with any governmental authority concerning the Product (for the avoidance of doubt, Lonza may interact with governmental authorities for the purpose of fulfilling legal obligations); and (c) storing and handling Product in appropriate conditions following its delivery; and (d) determining that the Product is permitted for human use. Customer is responsible for developing all Product labeling, and for labeling content.

6.5 **Adverse Events.** Lonza shall promptly notify and forward to Customer any information concerning any potentially serious or unexpected side effect, injury, toxicity or sensitivity reaction or any unexpected incidence or other adverse experience related to the Product (an "Adverse Experience") reported to it. Customer agrees that it shall be solely responsible to review, analyze and respond to any Adverse Experience. Lonza shall have no obligation with respect to an Adverse Experience other than the obligation to notify Customer.

6.6 **Debarment.** Lonza certifies that it has not been debarred, and has not been convicted of a crime that could lead to debarment, under the Generic Drug Enforcement Act and that it will use its reasonable efforts not to employ any person or entity that has been debarred or convicted to perform any services under this Agreement. Lonza shall promptly notify Customer in writing of any breach or expected breach of this Section 6.6 and its remedy thereto.

## 7. REPRESENTATIONS AND WARRANTIES

7.1 **Regarding the Product.** Lonza represents and warrants to Customer that, as of the date of delivery to Customer, the Product released by Lonza has been manufactured (a) in conformity with the Specifications and Quality Agreement and (b) in all material respects in accordance with cGMP.

7.2 **Rejection of Product; Disposal of Rejected Shipments**. (a) Customer may reject any Product that does not meet the warranties set forth in Section 7.1 ("Non-Complying Product") by providing written notice of rejection to Lonza within thirty (30) days following Lonza's release of the Product for delivery hereunder; provided that such period for rejection shall in the case of Hidden Defects in the Product be two years following Lonza's release of the Product for delivery hereunder. Failure by Customer to provide notice of rejections within the applicable timeframe shall constitute irrevocable acceptance of the Product by Customer.

(b) Lonza shall have the right to examine and test any Product that Customer claims to be a Non-Complying Product and shall notify Customer in writing of the results of such examination.

(c) In the event the Parties cannot agree as to whether or not any shipment of Product is a Non-Complying Product, the Parties shall appoint a third party, a mutually acceptable independent reputable laboratory to complete and report the relevant testing within thirty (30) days, the findings of which shall be binding on the Parties, absent manifest error. The Parties shall ensure that such independent laboratory is bound to the Parties by obligations of confidentiality no less exacting than those applying between the Parties. Expenses of such laboratory testing shall be borne by the Party whose position is determined to have been in error or, if the laboratory cannot place the fault noticed and complained about, then the Parties shall share equally the expenses of the laboratory.

(d) Customer agrees that Lonza shall have no liability if the Non-Complying Product is due to any action or inaction on the part of Customer, any Affiliate of Customer or any third party under contract with or subject to the control or direction of Customer or any Affiliate of Customer.

7.3 **Remedy for Non-Complying Product**. Customer shall return any shipments of Non-Complying Product (or portions thereof) rejected pursuant to Section 7.2 to Lonza at Lonza's expense. As Lonza's sole liability and Customer' sole remedy with respect to such Non-Complying Product, upon Customer's request, Lonza shall re-perform the Services hereunder and replace such rejected Non-Complying Product as soon as practicable, but no later than one hundred eighty (180) days from date of Bulk Powder manufacture with additional Bulk Powder supplied by Customer at Customer's cost but at no additional charge (including any freight charge) to Customer. The provisions of this Section 7.3 shall survive termination or expiration of this Agreement, provided that, subsequent to the termination or expiration of this Agreement, Lonza may, in lieu of replacing any rejected or missing quantities of Product, elect in its sole discretion to reimburse Customer for the amounts paid by Customer to Lonza for such rejected quantities of Non-Complying Product (including any applicable freight charges).

7.4 **Disclaimer of Other Warranties.** EXCEPT AS STATED IN THIS ARTICLE 7 LONZA MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AND TO THE FULLEST EXTENT PERMITTED UNDER APPLICABLE LAW LONZA SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

7.5 Lonza advises, and Customer acknowledges that, the Products resulting from the Services performed under this Agreement may not be used in the production, encapsulation, packaging or marketing of any product which is in violation of any applicable Laws or with any person or entity on any applicable government sanction, restricted party or denial list without a license or otherwise in violation of applicable Laws.

7.6 Customer represents and warrants that the Products will not be made available to any person or entity on any sanction, restricted party or denied party list of the United States of America,

Switzerland, the European Union or United Nations without a license or otherwise in violation of applicable Laws.

## 8. MANUFACTURING STANDARDS

8.1 **Quality Agreement.** The Parties have delivered and executed a Quality Agreement relating to the manufacture of the Product. Specifications and Product conformance shall be set forth in the Quality Agreement. Lonza shall manufacture and supply the Product in accordance with the Quality Agreement as reasonably updated by the Parties from time to time, notably to take into consideration any marketing authorization(s) for the Product. If there are any conflicts between the Quality Agreement and this Agreement, the provisions of this Agreement shall govern and control, with the exception that the Quality Agreement shall control with respect to all matters relating to the quality and disposition of the Product.

8.2 **Modifications in Specifications.** Any changes to the Specifications shall be agreed between the Parties in writing. Costs for amendments to the Specifications (including without limitation any additional Product or procurement costs) shall be borne by the Customer.

8.3 **Modifications in Materials.** Customer shall notify Lonza of any change related to the Bulk Powder that may affect the validated process including but not limited to supplier changes, process changes, regulatory changes, and environment health safety characteristics. Customer should provide to Lonza a written notification of such change at least ninety (90) days before implementation of the change. If the change warrants validation batches, then the costs associated with such change will be borne by the Customer.

## 9. INDEMNIFICATION

9.1 **Indemnification of Customer**. Lonza shall indemnify, defend and hold Customer, its Affiliates and their respective officers, directors, employees and agents (each, a "Customer Indemnified Party") harmless from and against any and all Losses suffered, incurred or sustained by any Customer Indemnified Party, by reason of any Claim or Proceeding to the extent arising out of or resulting from Lonza's: (i) breach of the representation and warranties in this Agreement or (ii) negligence or willful misconduct in connection with this Agreement; provided however, that Lonza shall have no obligation of indemnity hereunder with respect to any Losses to the extent caused by the negligence or willful misconduct on the part of Customer.

9.2 **Indemnification of Lonza**. Customer shall indemnify, defend and hold Lonza, its Affiliates and their respective directors, officers, employees and agents (each, a "Lonza Indemnified Party") harmless from and against any and all Losses suffered, incurred or sustained by any Lonza Indemnified Party, by reason of any Claim or Proceeding to the extent arising out of or resulting from Customer's (i) breach of the representation and warranties in this Agreement; (ii) negligence or willful misconduct in connection with this Agreement; (iii) the use, packaging, labeling, distribution, marketing, promotion, sale and disposal of Product or Bulk Powder; or (iv) resulting from the inherent risk of the Product or Bulk Powder; provided however, that Customer shall have no obligation of indemnity hereunder with respect to any Losses to the extent caused by the negligence or willful misconduct on the part of Lonza.

Customer shall also indemnify, defend and hold each Lonza Indemnified Party harmless from and against any and all claims, suits, and/or proceedings (including any assertion of an intellectual property right, regardless of whether the assertion has been or will be adjudicated), as well as all damages, losses, liabilities, and expenses (including reasonable attorneys' fees and costs), of whatever nature resulting from, arising out of, or relating to a claim or allegation that the Product, or any part thereof, or any intellectual

property, information or material supplied by or on behalf of Customer infringes, misappropriates, or otherwise violates a patent, copyright, trade secret, trademark or other intellectual property right of any third party.

9.3 **Indemnification Procedures**. In the event that any Claim or Proceeding is asserted or imposed against a Party, and such Claim or Proceeding involves a matter which is subject to a claim for indemnification under this Article 9, then such Party (the "Indemnified Party") shall promptly give written notice to the other Party (the "Indemnifying Party") of such Claim or Proceeding. The Indemnifying Party shall assume, at its cost and expense, the defense of such Claim or Proceeding through its legal counsel selected and reasonably acceptable to the Indemnified Party, except that the Indemnified Party may, at its option and expense, select and be represented by separate counsel. The Indemnifying Party shall have control over the Claim or Proceeding, including the right to settle; provided, however, that the Indemnifying Party shall not, absent the prior written consent of the Indemnified Party, consent to the entry of any judgment or enter into any settlement that (1) provides for any relief other than the payment of monetary damages for which the Indemnifying Party shall be solely liable, and (2) where the claimant or plaintiff does not release the Indemnified Party, its Affiliates and their respective directors, officers, employees, agents and representatives, as the case may be, from all liability in respect thereof. In no event shall the Indemnified Party be liable for any claims that are compromised or settled in violation of this Section.

9.4 **Waiver of Certain Losses.** IN NO EVENT SHALL LONZA OR ITS AFFILIATES BE LIABLE TO CUSTOMER OR ITS AFFILIATES FOR ANY LOSS OF OPPORTUNITY, LOSS OF PROFITS, LOSS OF ANTICIPATED SALES, OR FOR ANY PUNITIVE, INCIDENTAL, CONSEQUENTIAL, INDIRECT OR SPECIAL LOSSES OR DAMAGES WHETHER OR NOT FORESEEABLE, OR WHETHER OR NOT LONZA HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OF ANY KIND HOWEVER CAUSED, WHETHER BASED ON CONTRACT, NEGLIGENCE, INDEMNITY OR OTHER THEORY OF LAW, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT (OR THE TERMINATION HEREOF) OR ANY PURCHASE ORDER, AS APPLICABLE.

9.5 **Limitation of Liability.** Notwithstanding any other provision in this Agreement or a Purchase Order, as applicable, the total liability, in the aggregate, of Lonza and its Affiliates, to Customer and anyone claiming by or through Customer, for any and all claims, losses, costs, damages or fees, including without limitation, attorneys' fees resulting from or in any way related to this Agreement or a Purchase Order from any cause or causes shall not exceed [***] the purchase price of the Product with respect to which damages are claimed.

9.6 **Insurance.** Each Party shall, during the Term and for five (5) years after the later of (i) delivery of the last Product manufactured, or (ii) Services provided under this Agreement, obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance including, but not limited to product liability coverage in the amount of at least five (5) million USD per claim. Each Party shall provide the respective other Party with a certificate of such insurance upon reasonable request.

## 10. CONFIDENTIALITY

10.1 **Non-disclosure and Non-use.** Neither Party shall disclose to any third party nor use for its own purposes (other than those contemplated by this Agreement) any information of the other Party that is not in the public domain and that was disclosed to it by the other Party in connection with this Agreement ("Confidential Information"). For purposes of this Agreement, Confidential Information shall mean all proprietary information, trade secrets, business plans, pharmaceuticals, materials, operations, equipment, processes, methods, strategies and systems, and financial information, prices, materials, building techniques

and any drawings, specifications, designs and other information or data, or any fact with respect to any of the foregoing relating to this Agreement or the preceding agreements and work conducted by and between the Parties and relating to the Product prior to entering this Agreement. If information is disclosed in written form, the receiving Party's obligations of non-disclosure and non-use shall apply only to information which is, at the time of the disclosure, identified in writing by the disclosing party as being "Confidential", or that which the receiving Party should reasonably know is confidential due to its nature and the work begin conducted between the Parties. Notwithstanding the above, either Party may disclose Confidential Information to those of its and its Affiliates' directors, officers, employees, agents, consultants, representatives and advisors (collectively, "Agents") and to those approved subcontractors who have a need to know for the purposes of this Agreement. Each Party shall ensure that all of its Agents and subcontractors are bound by confidentiality obligations no less stringent than those stated herein. The receiving Party shall be liable for any failure of any of its Agents and subcontractors to (a) maintain the confidentiality of the disclosing Party's Confidential Information, or (b) otherwise comply with the terms of this Article 10 to the same extent as the receiving Party is obligated to do so.

10.2 **Exclusion of Confidential Information.** The obligations of confidentiality and non-use set forth in Section 10.1 shall not apply to Confidential Information that: (a) is or becomes part of the public domain without a violation of this Agreement; (b) was already in possession of a receiving Party or its Affiliates at the time of receipt from the disclosing Party, as shown by documentary evidence, without violating an obligation of confidentiality; (c) after the date of this Agreement is received from a third party whose direct or indirect source is not the disclosing Party; or (d) the receiving Party can demonstrate was independently developed by or for the receiving Party or its Affiliates without the use or reliance on the disclosing Party's Confidential Information or violating the terms of this Agreement.

10.3 **Information Required by Law.** If the receiving Party is requested to disclose the Confidential Information of the disclosing Party or the substance of this Agreement in connection with a legal or administrative proceeding or otherwise to comply with a requirement under applicable Law, the receiving Party will, to the extent legally permissible, give the disclosing Party prompt written notice of such request so that the disclosing Party may seek an appropriate protective order or other remedy, or waive compliance with the relevant provisions of this Agreement. If the disclosing Party seeks a protective order or other remedy, the receiving Party, at the disclosing Party's expense, will cooperate with and assist the disclosing Party in such efforts. If the disclosing Party fails to obtain a protective order or waives compliance with the relevant provisions of this Agreement, the receiving Party will disclose only that portion of the Confidential Information which its legal counsel determines it is required by applicable Law to disclose.

10.4 **Confidentiality Period.** All obligations of confidentiality under this Article 10 will terminate seven (7) years after the expiration or termination of this Agreement; provided however that the obligations of confidentiality for Confidential Information identified as a trade secret will survive indefinitely until such trade secret information no longer qualifies as a trade secret.

10.5 **Publicity.** Neither Party shall use or reference in any advertising, sales promotion, press release or other communication, the endorsement, direct or indirect quote, code, drawing, logo, trademark, specification, or picture of the other Party or the other Party's Affiliates without the prior written consent of the other Party. Customer and Lonza agree to coordinate external communications (e.g., a joint press release) regarding the Parties' collaboration promptly following execution of this Agreement. Notwithstanding anything herein, Lonza acknowledges that Customer is a publicly traded entity and as such has certain reporting requirements related to material events and contracts, of which this Agreement may be material to Customer.

10.6 **Document Retention.** In case of termination of this Agreement, all technical documents

of Customer shall be returned in original form without retaining any copies except for such copies as are required for regulatory purposes. All executed documents of exhibit and commercial batches shall be kept by Lonza as per regulatory requirements and shall be destroyed after the applicable retention period without retaining any copies.

10.7 **Reservation of Rights**. Except as specifically set forth herein, this Agreement does not (i) give either Party any license, right, title, interest in or ownership to any Confidential Information of the other Party; or (ii) grant any license, ownership or other right under any intellectual property rights except that solely necessary to carry out the activities contemplated by this Agreement.

## 11. INTELLECTUAL PROPERTY

11.1 All claims, expenses or damages (including attorneys' fees) in connection with any litigation instituted by a third party relating to a claim or claims of infringement of patents against either of the Parties, relating to or arising from the filings and/or the manufacturing, marketing, use or offer to sell of the Products in the Territory shall be the responsibility of Customer. Lonza shall support Customer with all necessary relevant information required by Customer for intellectual property evaluation and in case of any related legal notice and/or litigation, to the extent of providing supporting data and information related to such legal notice and/or litigation.

11.2 Customer acknowledges that it shall be solely and fully responsible for doing any and all freedom to operate assessments regarding possible infringement of third party intellectual property rights for any and all products and processes for any Product which it makes, has made, uses, sells, offers for sale or imports, except for any processes that are proprietary to Lonza or that Lonza conducts under a license right.

11.3 The marketing of Products shall be carried out by Customer under its own trademark. A Party shall acquire no rights or license on the other Party’s trademarks, unless such other Party provides prior written consent under separate written agreement signed by an authorized officer of such Party.

11.4 Lonza shall assign and hereby does so assign to Customer all rights, title and interest in all data, discoveries, inventions, improvements, new uses, processes, copyrights, trade secrets, techniques and compounds (“Inventions”), whether patentable or not, arising from work performed under the Agreement and related to or enabled by Customer’s Product. Lonza shall timely communicate in full detail and disclose to Customer all data, information, reports, results and other work product collected, generated, prepared or derived by Lonza during the course of services performed under this Agreement.

## 12. TERMINATION

12.1 **Breach; Insolvency.** If either Party is in material breach of any of its obligations, including its representations, warranties or covenants, under this Agreement, and fails to remedy such breach within ninety (90) days (thirty (30) days for non-payment) of receipt of written notice from the other Party, the non-breaching Party may terminate this Agreement with immediate effect with written notice of termination to the breaching Party, without liability to the other Party and without prejudice of any other rights or remedies; provided however, that if the breaching party is diligently pursuing in good faith the remedy of the breach at the expiration of such ninety (90) day cure period, then, at the consent of the non-breaching party which consent shall not be unreasonably withheld or delayed, such ninety (90) day cure period shall be extended as reasonably required to effect the cure. Subject to any limitations under applicable Law, either Party shall have the right to terminate this Agreement by giving notice to the other Party in the event that the other Party becomes insolvent or goes into bankruptcy, liquidation or receivership, or is admitted to the benefits of any procedure for the settlement of debts or becomes a party to dissolution proceedings. For purposes of clarity, Lonza shall have the right to terminate this Agreement in the event Customer (i)

breaches its payment obligations and fails to cure in such aforementioned cure period; or (ii) becomes insolvent.

12.2 **Termination by Customer.**

12.2.1 **Termination for FDA Rejection.** In the event that the application for Regulatory Approval for the Product is rejected by the FDA with no commercially viable method to resubmit an application for Regulatory Approval or secure Regulatory Approval of the Product, and such FDA decision is not caused by the fault of Customer, this Agreement may be terminated by Customer upon sixty (60) days' prior written notice to Lonza. If this Agreement is terminated in accordance with this Section 12.2.1, Customer agrees to pay Lonza an amount equal to [***] of Lonza's documented out-of-pocket expenditures for capital equipment purchased solely for Customer's program after the Effective Date, not to exceed [***] in the aggregate.

12.2.2 **Termination for Withdrawal of Regulatory Approval.** In the event Customer withdraws its Regulatory Approval or the FDA issues a final non-appealable order to the Customer to withdraw its Regulatory Approval, Customer may terminate this Agreement upon sixty (60) days' prior written notice to Lonza.

12.3 **Termination by Lonza.**

12.3.1 **Termination for FDA Delay.** In the event that the FDA does not issue a letter indicating that the application for Regulatory Approval for the Product is approved by December 31, 2024, this Agreement may be terminated by Lonza upon one hundred twenty (120) days' prior written notice to Customer. If this Agreement is terminated in accordance with this Section 12.3.1, Customer agrees to pay Lonza an amount equal to [***] of Lonza's documented out-of-pocket expenditures for capital equipment purchased solely for Customer's program after the Effective Date, not to exceed [***] in the aggregate.

**12.4 Consequences of Termination.**

12.4.1 In the event of termination herein, except in the event that Customer terminates for Lonza's breach in accordance with Section 12.1 above, (a) Lonza shall be compensated for: (i) Services rendered up to the date of termination, including in respect of any Product in-process; and (ii) all costs incurred through the date of termination, including Raw Materials costs for Raw Materials used or purchased for use in connection with the Purchase Orders; and (b) all Purchase Orders shall be deemed cancelled and Customer shall pay the Cancellation Fee (in accordance with the terms of this Agreement) in respect of such cancelled manufacturing of Product due under Section 3.6, without proration of the final Contract Year. In the case of termination by Lonza for Customer's material breach, Cancellation Fees shall be calculated as of the date of written notice of termination.

12.4.2 In the event of termination by Customer for Lonza's material breach in accordance with Section 12.1 above, Lonza shall be compensated for (i) Services rendered up to the date of termination, including in respect of any Product in-process and (ii) all costs incurred through the date of termination, including Raw Materials costs for Raw Materials used or purchased for use in connection with the Project Plan.

12.5 **Environmental Effects; Health and Safety.** Lonza reserves the right to terminate immediately this Agreement if, for any reason, (a) Lonza determines that the information provided by Customer pursuant to Section 5.2 is incomplete, inadequate, or inaccurate to protect the environment or the

health, safety and well-being of Lonza's employees (or those of its Affiliate) or (b) Lonza determines that continued performance of the Services hereunder may adversely affect the environment or the health, safety and well-being of Lonza's employees (or those of its Affiliate).

12.6 **Survival.** Termination or expiration of this agreement shall not relieve either Party of any liabilities, rights or obligations accruing prior to such termination or expiration. In the event of any termination or expiration of this Agreement, the provisions of this Section 12.6, and Sections 4, 5.2, 5.3, 6.1, 7, 9, 10, 15.1, and 15.3 shall survive such termination or expiration, together with any other provision hereof that by its terms survives termination or expiration hereof and any other obligations that have accrued prior to the termination or expiration of this Agreement.

## 13. NOTICES

13.1 Notices hereunder shall be deemed given as of the date sent. All notices shall be in writing mailed via a reputable overnight courier, addressed as follows, or to such other address as may be designated from time to time:

If to Lonza: Lonza Tampa LLC
5415 West Laurel Street
Tampa, Florida 33607
Attention: Managing Director

Copy to: Lonza, Inc.
412 Mt. Kemble Avenue, Suite 200S
Morristown, New Jersey 07960
Attention: General Counsel, North America

If to Customer: Liquidia Technologies, Inc.
419 Davis Drive, Suite 100
Morrisville, North Carolina 27560
Attention: Legal

## 14. FORCE MAJEURE

14.1 If Lonza is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure and gives written notice thereof to Customer specifying the matters constituting Force Majeure together with such evidence as Lonza reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, Lonza shall be excused from the performance or the punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue, following the end of the Force Majeure event, Lonza promptly resume performance under this Agreement upon removal of the Force Majeure; provided that, (i) if such Force Majeure persists for a period of [***] or more, Customer may terminate this Agreement by delivering written notice to Lonza.

14.2 "Force Majeure" shall be deemed to include any reason or cause beyond Lonza's reasonable control affecting the performance by Lonza of its obligations under the Agreement, including, but not limited to, any cause arising from or attributable to acts of God, pandemic event, strike, lockouts, labor troubles, restrictive governmental orders or decrees, riots, insurrection, war, terrorists acts, or the inability of Lonza to obtain any required raw material, energy source, equipment, labor or transportation, at reasonable prices and on terms deemed by Lonza to be reasonably practicable, from Lonza's usual sources of supply .

14.3 With regard to Lonza, any such event of Force Majeure affecting services or production at its Affiliates or suppliers that prohibit Lonza from otherwise performing under this Agreement shall be regarded as an event of Force Majeure.

## 15 MISCELLANEOUS

15.1 **Entire Agreements; Amendments; Waivers.** The terms and provisions contained in this Agreement and all Exhibits hereto constitute the entire agreement between the Parties with respect to the commercial terms and conditions related to the commercial supply of Product, superseding all prior and contemporaneous agreements or understandings between the Parties with respect to the commercial terms and conditions related to the Product, including the Original Agreement. The Original Agreement is superseded in its entirety by this Agreement. In the event of a conflict between the terms of the Agreement, any Exhibit and the Quality Agreement, the terms of this Agreement shall control. Any amendments of this Agreement must be in writing and signed by the Parties. A waiver of any breach or failure to enforce any of the terms or conditions of this Agreement shall in no way affect, limit or waive a Party's rights at any time to enforce strict compliance therafter with every term or condition of this Agreement.

15.2 **Successors and Assigns.** Neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, provided, however that (a) either Party may assign this Agreement to (i) any Affiliate of such Party or (ii) any third party in connection with the sale or transfer (by whatever method) of all or substantially all of the assets of the business related to this Agreement, and (b) Lonza shall be entitled to sell, assign and/or transfer its trade receivables resulting from this Agreement without the consent of the Customer. For purposes of this Section 15.2, the terms "assign" and "assignment" shall include, without limitation (i) the sale of fifty percent (50%) or more of the outstanding stock of such Party to an Affiliate of such Party or an unrelated entity or natural person, (ii) the sale or transfer or other assignment of all or substantially all of the assets of the Party or the line of business or Product to which this Agreement relates, and (iii) a merger, consolidation, acquisition or other form of business combination. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

15.3 **Independent Contractor.** The relationship of the Parties under this Agreement is that of independent contractors and nothing contained herein shall be construed to create a partnership, joint venture or agency relationship between Customer and Lonza, nor shall either Party be authorized to bind the other in any way.

15.4 **Governing Law; Dispute Resolution.** This Agreement is governed in all respects by the laws of the State of New York, without regard to its conflicts of laws principles. The Parties agree to submit to the exclusive jurisdiction of the courts located in the Southern District of New York. The Parties shall have the right to proceed to a suitable jurisdiction for the purpose of enforcing a judgment, award, or order (including without limitation seeking specific performance) and injunctive reliefs.

15.5 **Severability.** If any provision of this Agreement is or becomes at any time illegal, invalid or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected or impaired thereby. The Parties undertake to substitute any illegal, invalid or unenforceable provision by a provision which is as far as possible commercially equivalent considering the legal interests and the purpose of this Agreement.

15.6 **Counterparts; Electronic Signatures.** This Agreement may be executed in one or more counterparts, and by the Parties in separate counterparts, each of which when so executed shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement, to the

extent signed and delivered by electronic means, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

15.7 **No Third Party Beneficiaries.** No third party including any employee of a Party shall have or acquire any rights by reason of this Agreement whether by way of statute or otherwise.

15.8 **Miscellaneous**. The division of this Agreement into articles, sections, subsections and exhibits, and the insertion of headings, are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless expressly provided herein or unless the context otherwise requires, all references to the singular shall include the plural and vice versa. Any reference herein to a "day" or "days" shall be references to a calendar day or days. Any period of days specified in this Agreement ending on a Saturday, Sunday or public holiday shall automatically be extended to the first business day in the country of manufacture ending after such Saturday, Sunday or public holiday.

15.9 **Construction.** Each of the Parties agrees that it has read and had the opportunity to review this Agreement with its legal counsel and, accordingly, the rule of construction that any ambiguity contained in this Agreement shall be construed against the drafting Party shall not apply.

[Signature Page(s) Follow]

**IN WITNESS WHEREOF,** the Parties have executed this Agreement as of the Effective Date.

| **LIQUIDIA TECHNOLOGIES, INC.** | **LONZA TAMPA LLC** |
|---|---|
| By: /s/ Rob Lippe | By: /s/Filipe Tomas |
| Name: Rob Lippe | Name: Filipe Tomas |
| Title: Chief Operations Officer | Title: Head of Account Management, NA |
| Date: July 14, 2023 | Date: July 14, 2023 |

**EXHIBIT A**
**COMMERCIAL TERMS**

**Price:**

| Price per Unit* (US$) regardless of individual capsule strength | Capsules/Batch | Theoretical Number of Units per Batch |
|---|---|---|
| [***] | [***] | [***] |
| [***] | [***] | [***] |
| [***] | [***] | [***] |
| [***] | [***] | [***] |
| [***] | [***] or greater | [***] |

* Price includes full conversion costs and cost of empty capsule shells and all packaging components except Patient Inserts, Desiccants, Brushes, and Inhalers. All packaging components are priced at cost plus 10% handling fee.

**Annual Minimum Commitment:**

| Contract Year | Annual Minimum Purchase (in capsules) |
|---|---|
| 1 | [***]; equivalent to [***] of Baseline Forecast |
| 2 | [***] of the Baseline Forecast |
| 3 | [***] of the Baseline Forecast |
| 4 | [***] of the Baseline Forecast |
| 5 | [***] of the Baseline Forecast |

**Absolute Annual Minimum Commitments (if Baseline Forecast is adjusted, the minimum volumes will not be lower than these numbers):**

| Contract Year | Absolute Annual Minimum Purchase (in capsules) |
|---|---|
| 1 | [***] |
| 2 | [***] |
| 3 | [***] |
| 4 | [***] |
| 5 | [***] |

**Lonza Capacity Guaranty:**

| Contract Year | Capacity Guaranty (in capsules) |
|---|---|
| 1 | [***]; equivalent to Baseline Forecast PLUS [***] |
| 2 | Baseline Forecast PLUS [***] |
| 3 | Baseline Forecast PLUS [***] |
| 4 | Baseline Forecast |
| 5 | Baseline Forecast |

**Shipping Terms:**

Delivery terms shall be Ex-Works from Lonza's Facility.

**Payment Terms:**

[***] from the date of invoice upon release of Product and the appropriate release documentation as set forth in Section 4.6 hereof. For the avoidance of doubt, payment terms are further described in Section 4.2 hereof.

**Currency:**

US$

**Baseline Forecast:**

[***]

**EXHIBIT B**
**ENVIRONMENTAL AND HEALTH AND SAFETY INFORMATION**

1. Safety Data Sheets (or the equivalent) for any drug substance, intermediate, pharmaceutical blend, or final drug product ("Material(s)") provided to Lonza by Customer;

2. Any occupational exposure limit (OEL) or occupational exposure control technique applicable to the formulation of the Material(s) (e.g. occupational exposure band, hazard classification, etc.), including any OEL or occupational exposure control technique applicable to the manufacture of dietary supplement, drug substance or drug product, whether established by Customer or its contract manufacturer, regardless of whether it is required by any governmental authority;

3. Any monograph or compilation of data upon which the OEL or occupational exposure control technique for the Material(s), its precursors, or intermediates, is based;

4. Any medical tests used to evaluate any biological condition or function of workers who may have been exposed to the Material(s), its precursors, or intermediates (to the extent such information is or becomes available);

5. Any biological exposure indices associated with the Material(s) or its precursors or intermediates (to the extent such information is or becomes available);

6. Any modeling related to any releases to the environment of the Material(s), its precursors, or intermediates (to the extent such information is or becomes available);

7. Any test results related to the identification of health or physical hazards, or understanding of the ecotoxicity of the Material(s), its precursors, or intermediates (to the extent such information is or becomes available);

8. Any quantitative or qualitative assessment of the environmental impact of the Material's use, manufacture, storage, transportation, or disposal (to the extent such information is or becomes available);

9. Any summary of the known physical and chemical properties, pharmacology, pharmacokinetics, and clinical and nonclinical toxicology data submitted to a government agency to obtain pre-marketing approval of the Material(s) (to the extent such information is or becomes available);

10. Any reports of adverse reactions by employees or others exposed to the Material(s), its precursors, or intermediates, during its manufacture, storage or transportation (to the extent such information is or becomes available); and

11. Any process safety information, including but not limited to process hazard analyses and off-site consequences analyses related to a licensed process (to the extent such information is or becomes available).

**EXHIBIT C**
**SAFETY DATA SHEETS (SDS)**

October 2020 CONFIDENTIAL

**EXHIBIT D**
**SPECIFICATIONS**

[***]

October 2020 CONFIDENTIAL

**Exhibit 31.1**

**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: August 10, 2023

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

**Exhibit 31.2**

**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: August 10, 2023

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

**Exhibit 32.1**

**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 June 30, 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: August 10, 2023

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

**Exhibit 32.2**

**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 June 30, 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: August 10, 2023

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