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, 2024

or

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

Commission File Number: 001-39724

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

Delaware	**85-1710962**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
419 Davis Drive, Suite 100 **Morrisville, North Carolina**	**27560**
(Address of Principal Executive Offices)	(Zip Code)

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

N/A

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	LQDA	The Nasdaq Stock Market LLC

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

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

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

Large Accelerated Filer ☐ Accelerated Filer ☐ Non-accelerated Filer ☒ Smaller Reporting Company ☒
Emerging Growth Company ☐

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

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

As of August 1, 2024, there were 76,793,694 shares of the registrant's common stock outstanding.

LIQUIDIA CORPORATION

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

Cautionary Note Regarding Forward-Looking Statements

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

- 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 FDA (as defined below) of and our ability to commercially launch YUTREPIA, including the potential impact of regulatory review, approval, and exclusivity developments which may occur for competitors, and the scope of any such approvals and the indications for which we receive approval;
- the timeline or outcome related to our patent litigation with United Therapeutics that was filed in the U.S. District Court for the District of Delaware, the *inter partes* reviews with the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, our litigation with United Therapeutics that was filed in the Superior Court for Durham County, North Carolina, the lawsuit filed by United Therapeutics against the FDA in the U.S. District Court for the District of Columbia, or any future litigation with United Therapeutics or any other third party, including any related rehearings or appeals;
- the timing and our business partners' ability to obtain and maintain regulatory clearance for the infusion pump that we are developing with Sandoz (as defined below) and Mainbridge (as defined below);
- the timing and our ability to obtain and maintain regulatory approval for L606, an investigational, liposomal formulation of treprostinil that we licensed from Pharmosa (as defined below);
- our ability to continue operations as a going concern without obtaining additional funding;
- our expectations regarding the size of the patient populations, market acceptance, third-party payor coverage 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 HCR (as defined below) and our ability to satisfy the covenants contained in the RIFA (as defined below);
- our ability to retain, attract and hire key personnel;
- prevailing economic, market and business conditions;
- our ability to predict, foresee, and effectively address or mitigate future developments resulting from health epidemics 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;
- 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 ongoing litigation involving United Therapeutics and the FDA and any future litigation with United Therapeutics, the FDA or any other third party;
- the effects on our company or our subsidiaries of future changes in law, including regulatory developments or legislative actions, including changes in healthcare, environmental and other laws and regulations to which we are subject, or judicial decisions overturning or establishing new legal precedents;
- 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, 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 and related contents of our planned regulatory filings and/or applications;
- 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 ability and 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;
- fluctuations in the trading price of our common stock;
- 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. 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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 133,093	$ 83,679
Accounts receivable, net	3,249	4,061
Inventory	7,212	—
Prepaid expenses and other current assets	3,707	2,159
Total current assets	147,261	89,899
Property, plant and equipment, net	6,387	4,480
Operating lease right-of-use assets, net	1,471	1,704
Indemnification asset, related party	7,194	6,707
Contract acquisition costs, net	7,621	7,922
Intangible asset, net	3,300	3,430
Goodwill	3,903	3,903
Other assets	224	287
Total assets	$ 177,361	$ 118,332
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,741	$ 1,396
Accrued expenses and other current liabilities	13,100	13,400
Revenue interest financing payable, current	4,154	2,615
Operating and finance lease liabilities, current	1,225	1,139
Total current liabilities	24,220	18,550
Litigation finance payable	6,929	6,707
Revenue interest financing payable, noncurrent	81,764	43,418
Operating and finance lease liabilities, noncurrent	1,726	2,364
Total liabilities	114,639	71,039
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock — 10,000,000 shares authorized, none outstanding	—	—
Common stock — $0.001 par value, 115,000,000 and 100,000,000 shares authorized as of June 30, 2024 and December 31, 2023, respectively, 76,414,548 and 68,629,575 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	76	69
Additional paid-in capital	560,614	476,322
Accumulated deficit	(497,968)	(429,098)
Total stockholders' equity	62,722	47,293
Total liabilities and stockholders' equity	$ 177,361	$ 118,332

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,	
	2024	2023	2024	2023
Revenue	$ 3,659	$ 4,786	$ 6,631	$ 9,279
Costs and expenses:				
Cost of revenue	1,493	671	2,960	1,325
Research and development	9,420	17,695	19,477	22,973
General and administrative	19,943	9,245	40,192	17,038
Total costs and expenses	30,856	27,611	62,629	41,336
Loss from operations	(27,197)	(22,825)	(55,998)	(32,057)
Other income (expense):				
Interest income	1,855	734	3,735	1,656
Interest expense	(2,600)	(1,426)	(5,124)	(2,550)
Loss on extinguishment of debt	—	—	(11,483)	(2,311)
Total other expense, net	(745)	(692)	(12,872)	(3,205)
Net loss and comprehensive loss	$ (27,942)	$ (23,517)	$ (68,870)	$ (35,262)
Net loss per common share, basic and diluted	$ (0.37)	$ (0.36)	$ (0.91)	$ (0.54)
Weighted average common shares outstanding, basic and diluted	76,435,831	64,788,482	75,914,869	64,722,818

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, 2023	68,629,575	$ 69	$ 476,322	$ (429,098)	$ 47,293
Issuance of common stock upon exercise of stock options	23,247	—	99	—	99
Issuance of common stock upon vesting of restricted stock units	383,133	—	—	—	—
Issuance of common stock under employee stock purchase plan	67,982	—	404	—	404
Issuance of common stock upon exercise of warrants	946	—	—	—	—
Sale of common stock, net	7,182,532	7	74,861	—	74,868
Stock-based compensation	—	—	4,524	—	4,524
Net loss	—	—	—	(40,928)	(40,928)
Balance as of March 31, 2024	76,287,415	$ 76	$ 556,210	$ (470,026)	$ 86,260
Issuance of common stock upon exercise of stock options	10,686	—	32	—	32
Issuance of common stock upon vesting of restricted stock units	116,447	—	—	—	—
Sale of common stock, net	—	—	—	—	—
Stock-based compensation	—	—	4,372	—	4,372
Net loss	—	—	—	(27,942)	(27,942)
Balance as of June 30, 2024	76,414,548	$ 76	$ 560,614	$ (497,968)	$ 62,722

	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

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,	
	2024	2023
Operating activities		
Net loss	$ (68,870)	$ (35,262)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	—	10,000
Stock-based compensation	8,896	5,051
Depreciation and amortization	1,069	1,158
Non-cash lease expense	233	187
Loss (gain) on disposal of property and equipment	3	(2)
Loss on extinguishment of debt	11,483	2,311
Accretion and non-cash interest expense	5,119	2,376
Changes in operating assets and liabilities:		
Accounts receivable, net	812	922
Inventory	(7,212)	—
Prepaid expenses and other current assets	(1,548)	760
Other noncurrent assets	63	47
Accounts payable	3,224	(380)
Accrued expenses and other current liabilities	(300)	(755)
Operating lease liabilities	(499)	(434)
Net cash used in operating activities	(47,527)	(14,021)
Investing activities		
Purchases of property, plant and equipment	(1,914)	(609)
Proceeds from the sale of property, plant and equipment	—	2
Net cash used in investing activities	(1,914)	(607)
Financing activities		
Proceeds from revenue interest financing, net	24,975	31,814
Principal payments on long-term debt	—	(20,000)
Payments for debt prepayment and extinguishment costs	—	(2,190)
Payments on revenue interest financing liability	(1,692)	(500)
Principal payments on finance leases	(53)	(130)
Receipts from litigation financing	222	101
Proceeds from sale of common stock, net of issuance costs	74,868	—
Proceeds from issuance of common stock under stock incentive plans	535	446
Net cash provided by financing activities	98,855	9,541
Net increase (decrease) in cash and cash equivalents	49,414	(5,087)
Cash and cash equivalents, beginning of period	83,679	93,283
Cash and cash equivalents, end of period	$ 133,093	$ 88,196
Supplemental disclosure of cash flow information		
Cash paid for interest	$ —	$ 360
Cash paid for operating lease liabilities	$ 655	$ 637
Non-cash increase in property, plant and equipment through accounts payable	$ 634	$ —
Non-cash increase in indemnification asset through accounts payable	$ 487	$ 101

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 rare cardiopulmonary diseases such as pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD"). 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 PAH and PH-ILD in the United States, as well as key stakeholders involved in the distribution and reimbursement of medicines to treat these patients. We established our commercial presence in the field to support Treprostinil Injection and have since expanded our presence to support the potential launch of YUTREPIA upon final approval, further validating our reputation as a company committed to supporting PAH and PH-ILD 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 and PH-ILD. 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 effort dry-powder inhaler ("DPI") and by achieving higher dose levels than the labeled doses of current inhaled therapies. In November 2021, the United States Food and Drug Administration ("FDA") tentatively approved our New Drug Application ("NDA") for YUTREPIA for the treatment of PAH. In July 2023, we filed an amendment to our NDA to add PH-ILD to the label for YUTREPIA. We are currently awaiting final action by the FDA with respect to our NDA.

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 and PH-ILD 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 believe that changes in any of the following areas could have a material adverse effect on our future financial position, results of operations, or cash flows: the ability to obtain future financing; advances and trends in new technologies and industry standards; results of clinical trials; regulatory approval, market acceptance and third-party payor coverage for our products; development of sales channels; certain strategic relationships; litigation or claims against us, including claims 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 or, if we do, the indications for which our products will be approved. If we are denied approval, approval is delayed, approval is for less than all of the indications we are seeking, 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, adding to the manufacturing risks we face. In the event of any failure by a supplier, we could be left without backup facilities. Any disruption from these manufacturers or suppliers could have a negative impact on our business, financial position and results of operations.

Liquidity and 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. We have financed our growth and operations through a combination of funds generated from revenues, the issuance of convertible preferred stock and common stock, bank borrowings, bank borrowings with warrants, the issuance of convertible notes and warrants, and revenue interest financing. Since inception, we have incurred recurring losses, including a net loss of $68.9 million for the six months ended June 30, 2024. As of June 30, 2024, we had an accumulated deficit of $498.0 million.

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 of such product candidates and pursue 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 Revenue Interest Financing Agreement with HealthCare Royalty Partners IV, L.P. ("HCR") dated January 9, 2023, as amended (the "RIFA") contains fixed quarterly payments and minimum cash covenants that require 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.

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. Based on our current plans, we expect that we will require additional capital to fund operations as well as to pursue in-licenses or acquisitions of other product candidates. If we 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 our business prospects, or we may be unable to continue operations.

Based on current operating plans and excluding any contribution from potential YUTREPIA product sales or external financing, we will not have sufficient cash and cash equivalents to fund operating expenses and capital requirements and meet our minimum cash covenants beyond one year from the issuance of these condensed consolidated financial statements, and therefore, the Company has concluded that there is substantial doubt about its ability to continue as a going concern. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

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, 2024 and for the three and six months ended June 30, 2024 and 2023 have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "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, 2024 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2024. 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. Certain amounts have been reclassified from the prior year presentation to conform to current presentation, specifically in relation to the balance sheet presentation of finance and operating leases. 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, 2023, which are included in our 2023 Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "2023 Annual Report on Form 10-K").

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the period. These estimates are based on historical experience and various other assumptions believed to be reasonable under the circumstances. We evaluate our estimates on an ongoing basis, including those related to the valuation of stock-based awards, certain accruals, the revenue interest financing payable, and intangible and contract acquisition cost amortization, and make 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, 2023 and 2022, which are included in our 2023 Annual Report on Form 10-K. There have been no material changes to our significant accounting policies during the six months ended June 30, 2024.

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, 2024, there were no newly adopted accounting pronouncements that

had a material impact on our condensed consolidated financial statements. As of June 30, 2024, 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. Our cash and cash equivalents are held at multiple accredited financial institutions. 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 95% and 99% of our accounts receivable, net at June 30, 2024 and December 31, 2023, respectively. As of June 30, 2024 and December 31, 2023, we have not recorded an allowance for credit losses.

Prelaunch Inventory

We capitalize prelaunch inventory prior to receiving regulatory approval if regulatory approval and subsequent commercialization of a product is probable and we also expect future economic benefit from the sales of the product to be realized. Prior to this conclusion, we expense prelaunch inventory as research and development expense in the period incurred. For prelaunch inventory that is capitalized, we consider a number of specific facts and circumstances, including the product’s shelf life, the product's current status in the development and regulatory approval process, results from related clinical trials, results from meetings with relevant regulatory agencies prior to the filing of regulatory applications, potential obstacles to the approval process, viability of commercialization and market trends. In late 2023, based on our assessment of the legal and regulatory process related to YUTREPIA, we concluded that we met the criteria to capitalize expenditures for prelaunch inventory. We capitalized $7.2 million of prelaunch inventory as of June 30, 2024 and none as of December 31, 2023. We do not have an allowance for inventory obsolescence as of June 30, 2024. If either regulatory approval or market acceptance post-approval of YUTREPIA do not occur at all or on a timely basis prior to the inventory shelf-life expiration, we may be required to write-off some or all prelaunch inventory, which could affect our financial condition and financial results.

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, 2024, 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, 2024 and concluded that no impairments had occurred.

Revenue Interest Financing Payable

We recognized a liability related to amounts received in January 2023, July 2023, and January 2024 pursuant to the RIFA under ASC 470-10, *Debt* and ASC 835-30, *Interest - Imputation of Interest*. The liability will be accreted under the effective interest method based upon the estimated amount of future payments to be made pursuant to the RIFA. If the timing or amounts of any estimated future payments change, we will prospectively adjust the effective interest and the related amortization of the liability and related issuance costs. A significant increase or decrease in these estimates could materially impact the liability balance and related interest expense. Amendments are assessed under ASC 470 to determine appropriate treatment as extinguishments or modifications.

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 in accordance with ASC 730, *Research and Development* and include facility-related costs related to research and development activities, direct costs from third parties, such as contract research organizations ("CROs"), contract manufacturing organizations (CMOs"), and consultants, as well as employee-related expenses, including salaries, benefits, and stock-based compensation. Research and development expenses also include costs of acquired product licenses and related technology rights where there is no alternative future use.

Accrued Research and Development Expenses

As part of the process of preparing the condensed consolidated financial statements, we are required to estimate accrued 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 condensed consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these 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. The financial terms of our agreements with CROs and CMOs 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 such 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.

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 9.

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,	
	2024	2023	2024	2023
Stock Options	9,436,272	9,506,827	9,503,896	9,454,756
Restricted Stock Units	3,072,986	1,773,919	3,027,450	1,682,701
Warrants	450,000	450,000	450,000	450,000
Total	12,959,258	11,730,746	12,981,346	11,587,457

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, 2024 and December 31, 2023:

June 30, 2024	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)	$ 127,294	$ —	$ —	$ 127,294

December 31, 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)	$ 79,912	$ —	$ —	$ 79,912

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 current liabilities approximate their fair values due to their short-term nature. The carrying value of 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. Inventory

Inventories are stated at the lower of average cost or net realizable value and consist of the following:

	June 30, 2024	December 31, 2023
Raw materials	$ 2,676	$ —
Work in process	4,536	—
Inventory	$ 7,212	$ —

Prelaunch Inventory

During the six months ended June 30, 2024, we capitalized costs of $7.2 million associated with the manufacture of YUTREPIA as a result of our determination that regulatory approval and subsequent commercialization is probable and we also expect future economic benefit from the sales of the product to be realized.

4. Property, Plant, and Equipment

Property, plant and equipment consisted of the following:

	June 30, 2024	December 31, 2023
Lab and build-to-suit equipment	$ 6,916	$ 6,834
Office equipment	19	19
Furniture and fixtures	241	241
Computer and other equipment	700	487
Leasehold improvements	11,420	11,409
Construction-in-progress	2,685	804
Total property, plant and equipment	21,981	19,794
Accumulated depreciation and amortization	(15,594)	(15,314)
Property, plant and equipment, net	$ 6,387	$ 4,480

We recorded depreciation and amortization expense related to property, plant and equipment of $0.2 million and $0.3 million for the three months ended June 30, 2024 and 2023, respectively, and of $0.4 million and $0.6 million for the six months ended June 30, 2024 and 2023, respectively.

5. Contract Acquisition Costs and Intangible Asset

Contract acquisition costs and intangible asset are summarized as follows:

	June 30, 2024			December 31, 2023		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Contract acquisition costs	$ 12,980	$ (5,359)	$ 7,621	$ 12,980	$ (5,058)	$ 7,922
Intangible asset	$ 5,620	$ (2,320)	$ 3,300	$ 5,620	$ (2,190)	$ 3,430

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 $0.2 million for the three months ended June 30, 2024 and 2023, respectively, and of $0.3 million and $0.4 million for the six months ended June 30, 2024 and 2023, respectively. We recorded amortization related to the intangible asset of $0.1 million and $0.1 million for the three months ended June 30, 2024 and 2023, respectively, and of $0.1 million and $0.2 million for the six months ended June 30, 2024 and 2023, respectively. Annual amortization over the next five years is expected to immaterially fluctuate from the 2024 amounts, consistent with changes to net profits to be recognized pursuant to the Promotion Agreement over the period.

6. 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") (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 (as defined below), all 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 RG Holdings, LLC ("PBM"). PBM is considered to be a related party as it is controlled by a major stockholder (which beneficially owns approximately 8.2% of Liquidia Corporation common stock as of August 1, 2024), 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, 2024 and December 31, 2023, 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, 2025.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2024	December 31, 2023
Accrued compensation	$ 6,603	$ 8,544
Accrued research and development expenses	1,586	2,902
Accrued inventory costs	2,248	—
Accrued other expenses	2,663	1,954
Total accrued expenses and other current liabilities	$ 13,100	$ 13,400

8. Stockholders' Equity

Common Stock

Issuance of Common Stock on January 4, 2024 from a Private Placement

On January 4, 2024, we entered into a common stock purchase agreement with Legend Aggregator, LP for the sale by us in a private placement (the "2024 Private Placement") of an aggregate of 7,182,532 shares of our common stock at a purchase price of $10.442 per share. The 2024 Private Placement closed on January 8, 2024, and we received gross proceeds of approximately $75.0 million, before deducting offering costs of less than $0.1 million.

Issuance of Common Stock on December 12, 2023 from an Underwritten Public Offering and Private Placement

In December 2023, we sold 3,491,620 shares of our common stock in an underwritten registered public offering at an offering price of $7.16 per share (the "2023 Offering") for net proceeds of approximately $25.0 million, before deducting offering costs of approximately $1.9 million.

Caligan Partners LP ("Caligan"), our largest stockholder, and Paul B. Manning, a member of our Board of Directors, participated in the 2023 Offering and purchased shares of common stock in an aggregate amount of approximately $10.0 million at the public offering price per share and on the same terms as the other purchasers in the 2023 Offering. Caligan purchased 1,117,318 shares of common stock in the 2023 Offering for an aggregate purchase price of $8.0 million and Paul B. Manning purchased 279,330 shares of common stock in the 2023 Offering for an aggregate purchase price of $2.0 million.

Concurrently with the 2023 Offering referenced above, we entered into a common stock purchase agreement with Roger Jeffs, our Chief Executive Officer, for the sale by us in a private placement of an aggregate of 139,665 shares of our common stock at a purchase price of $7.16 per share for gross proceeds of approximately $1.0 million.

Warrants

During the three months ended June 30, 2024 and 2023, 948 and no warrants to purchase shares of common stock were exercised, respectively. Outstanding warrants consisted of the following as of June 30, 2024:

Number of warrants		Exercise Price	Expiration Date
250,000	$	5.14	January 6, 2032
100,000	$	3.05	February 26, 2031
100,000	$	n/a[1]	February 26, 2031
64,624	$	0.02	December 31, 2026

1 These warrants were issued on February 26, 2021, in connection with our previously outstanding debt with Silicon Valley Bank. These warrants only became exercisable if there was additional funding under the loan agreement, and the exercise price of these warrants was to be set upon such potential additional funding. The additional funding never occurred, and the loan agreement has since been repaid and terminated. While these warrants technically remain outstanding, they are not, and will never be, exercisable.

9. 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, 2024, the number of shares of common stock available for issuance under the 2020 Plan automatically increased by 2,745,183 shares pursuant to the Evergreen Provision. As of June 30, 2024, there were 913,937 shares available for future grants under the 2020 Plan.

The 2020 Plan replaced all prior equity award plans and such plans have been discontinued. However, the awards outstanding under the prior equity award plans will continue to remain in effect in accordance with their terms. Awards that are forfeited under these prior plans upon cancellation, termination or expiration will not be available for grant under the 2020 Plan. As of June 30, 2024, a total of 635,280 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, 2024, a total of 26,650 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 on January 1 of each year through 2030, by the lesser of (a) 1.0% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, (b) 150,000 shares, or (c) an amount determined by the Board of Directors. On January 1, 2024, the number of shares of common stock available for issuance under the ESPP increased by 150,000 shares. As of June 30, 2024, a total of 639,155 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, 2024 and 2023, 67,982 and 81,281 shares were issued under the ESPP, respectively.

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:	**2024**	**2023**	**2024**	**2023**
Cost of revenue	$ 57	$ —	$ 121	$ —
Research and development	826	578	1,837	1,159
General and administrative	3,489	1,921	6,938	3,892
Total stock-based compensation expense	$ 4,372	$ 2,499	$ 8,896	$ 5,051

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, 2024	
	Unamortized Expense	Weighted Average Remaining Recognition Period (Years)
Stock options	$ 11,456	1.8
Restricted and performance stock units	$ 29,166	2.7

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,	
	2024	2023
Expected dividend yield	—	—
Risk-free interest rate	3.98%	3.46% - 3.99%
Expected volatility	90%	91% - 95%
Expected life (years)	6.1	5.8 - 6.1

The weighted average fair value for options granted during the six months ended June 30, 2024 and 2023 was $9.84 and $5.09 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,	
	2024	2023
Expected dividend yield	—	—
Risk-free interest rate	5.27%	5.20%
Expected volatility	90%	64%
Expected life (years)	0.50	0.50

Stock Option Activity

Options generally vest over a four-year period in multiple tranches.

The following table summarizes stock option activity during the six months ended June 30, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	9,573,937	$ 4.80		
Granted	7,500	12.86		
Exercised	(33,933)	3.85		
Cancelled	(139,260)	5.54		
Outstanding as of June 30, 2024	9,408,244	$ 4.80	7.1	$ 67,980
Exercisable as of June 30, 2024	6,563,332	$ 4.52	6.7	$ 49,365
Vested and expected to vest as of June 30, 2024	9,043,468	$ 4.76	7.0	$ 65,681

The aggregate intrinsic value of stock options in the table above represents the difference between the $12.00 closing price of our common stock as of June 30, 2024 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 and/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.

The tax withholding method used for most RSUs is the sell-to-cover method, in which shares with a market value equivalent to the tax withholding obligation are sold on behalf of the holder of the RSUs upon vesting and settlement to cover the tax withholding liability and the cash proceeds from such sales are remitted to taxing authorities by us. In circumstances where the sell-to-cover method is not used, the holder of the RSUs is required to remit cash to us to cover the tax withholding liability and the cash is then remitted to taxing authorities by us.

A summary of unvested RSU awards outstanding as of June 30, 2024 and changes during the six months ended June 30, 2024 are as follows:

	Number of RSUs	Weighted Average Grant-Date Fair Value (per RSU)
Unvested as of December 31, 2023	1,657,978	$ 6.41
Granted	2,110,671	12.59
Vested	(499,580)	6.46
Forfeited	(75,328)	6.55
Unvested as of June 30, 2024	3,193,741	$ 10.48

RSUs granted during the six months ended June 30, 2024, included 520,526 performance-based RSUs granted to our executive officers. These performance-based RSUs vest upon the later of (a) time-based vesting conditions and (b) the first commercial sale of YUTREPIA in the United States and are considered probable of vesting. The time-based vesting condition means 25% of the performance-based RSUs vest one year after grant date and quarterly thereafter for three years, subject to the executive's continued service.

10. Revenue From Contracts With Customers

In August 2018, we entered into a Promotion Agreement with Sandoz under which we have the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection for the treatment of patients with PAH in the United States. We paid Sandoz $20 million at the inception of the Promotion Agreement in consideration for these rights. In exchange for conducting these commercial activities, we are entitled to receive a share of Net Profits (as defined within the Promotion Agreement) based on specified profit levels. The share of Net Profits received is subject to adjustments from Sandoz for certain items, such as distributor chargebacks, rebates, inventory returns, inventory write-offs and other adjustments. We expect to refund certain amounts to Sandoz through a reduction of the cash received from future Net Profits generated under the Promotion Agreement. As of June 30, 2024, a $0.5 million refund liability is offset against accounts receivable from Sandoz related to expected refund amounts. Approximately 96% and 97% of revenue during the three and six months ended June 30, 2024, respectively, was generated from the Promotion Agreement.

11. 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 our 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, 2024, 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	2024	2023	2024	2023
Operating lease cost:					
Fixed lease cost	Research and development	$ 175	$ 175	$ 350	$ 351
Fixed lease cost	General and administrative	20	20	39	39
Finance lease cost:					
Amortization of lease assets	Research and development	22	22	44	52
Interest on lease liabilities	Interest expense	2	4	4	9
Total Lease Cost		$ 219	$ 221	$ 437	$ 451

The weighted average remaining lease term and discount rates as of June 30, 2024 were as follows:

Weighted average remaining lease term (years):	
Operating leases	2.3
Finance leases	0.8
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 payments as of June 30, 2024 were as follows:

Year ending December 31:	Operating Leases	Finance Leases	Total
2024 (six months remaining)	$ 662	$ 57	$ 719
2025	1,356	64	1,420
2026	1,158	—	1,158
Total minimum lease payments	3,176	121	3,297
Less: interest	(343)	(3)	(346)
Present value of lease liabilities	$ 2,833	$ 118	$ 2,951

12. 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 existing obligations due to Silicon Valley Bank. This repayment resulted in a loss on extinguishment during the year ended December 31, 2023 of $2.3 million.

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. $10.0 million from the second tranche was funded on July 27, 2023.

On January 3, 2024, we entered into the Fourth Amendment to the RIFA pursuant to which HCR moved $25.0 million from the third tranche to the second tranche, such that the second tranche totals $35.0 million. The additional $25.0 million from the second tranche was funded on January 5, 2024. The remaining third tranche of $10.0 million and fourth tranche of $22.5 million can be funded in the future upon the mutual agreement of both parties.

As consideration for the Investment Amount and pursuant to the RIFA, we have agreed to pay HCR either (a) quarterly fixed payments and a one-time fixed payment or (b) 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 (as defined in the RIFA) has been funded.

We are currently required to make certain fixed quarterly payments to HCR which include an additional amount on a ratable basis to reflect the funding of additional amounts by HCR under the RIFA and a one-time fixed payment. As of June 30, 2024, we were required to pay $4.2 million within one year of the balance sheet date, which is classified as current in our condensed consolidated balance sheet. If the Third Investment Amount is not funded, our quarterly fixed payment will increase to $5.8 million beginning in the third quarter of 2025. Additionally, in the event that the Third

Investment Amount has not been funded by June 30, 2025, we will be obligated to pay an incremental one-time fixed payment of $23.8 million also during the third quarter of 2025.

If the Third Investment Amount is 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.

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.

The Fourth Amendment to the RIFA qualifies as a debt extinguishment and issuance of a new debt instrument in accordance with ASC 405-20, Extinguishments of Liabilities. We recorded a loss on extinguishment during the quarter ended March 31, 2024 of $11.5 million, equal to the fair value of the amended RIFA less the carrying value of the existing RIFA on January 5, 2024.

We recorded the total funds received from HCR of $42.5 million under the terms of the RIFA as a liability. The issuance costs, consisting primarily of legal fees, totaled $0.9 million and were recorded as a deduction of the carrying amount of the liability and are being amortized under the effective interest method over the estimated period the liability will be repaid. We estimated the total amount of payments over the life of the RIFA to determine the interest expense to record to accrete the liability to the amount ultimately due. For the three and six months ended June 30, 2024, we estimated an effective annual interest rate of approximately 12.3%. Over the course of the RIFA, the effective annual interest rate may be affected by potential changes in forecasted payments. On a quarterly basis, we will reassess the expected amount and timing of payments, recalculate the amortization and effective interest rate and adjust the accounting prospectively as needed.

The following table presents the changes in the RIFA payable during the six months ended June 30, 2024:

Balance as of December 31, 2023	$	46,033
Accretion		107
Amortization of issuance costs		2
Second tranche funding, net of fees		24,975
Balance as of January 5, 2024, prior to extinguishment	$	71,117
Loss on extinguishment		11,483
Balance as of January 5, 2024, after extinguishment	$	82,600
Accretion		5,010
Payments		(1,692)
Balance as of June 30, 2024	$	85,918
Less: current portion of revenue interest financing payable		(4,154)
Long-term portion of revenue interest financing payable	$	81,764

The expected annual payments on the revenue interest financing payable as of June 30, 2024 are as follows:

Year ending December 31:		
2024 (six months remaining)	$	2,077
2025		37,507
2026		23,214
2027		23,214
2028		23,214
2029		5,553
Total	$	114,779

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 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.

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 2025. 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 our 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, $0.2 million of which has been accrued as of June 30, 2024.

Employment Agreements and Executive Severance and Change in Control Plan

We have agreements with certain employees and an Executive Severance and Change in Control Plan which covers certain other 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 deliver bulk treprostinil powder, manufactured using our proprietary PRINT® technology, and Lonza encapsulates and packages it. The CSA was 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.

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

As of June 30, 2024, we have non-cancelable commitments for product manufacturing and supply costs of approximately $3.5 million.

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 condensed consolidated 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 "Original 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 Original 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 Original Hatch-Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Original 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 Original Hatch-Waxman Litigation. In September 2022, Judge Andrews entered a final

judgment in the Original 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 a petition for *inter partes* review with the Patent Trial and Appeal Board (the "PTAB") of the USPTO with respect to the '901 Patent, seeking a determination that the claims in the '901 Patent are invalid. 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. In June 2024, the Court of Appeals for the Federal Circuit affirmed the PTAB's decision regarding the '901 Patent.

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 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. In December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the '793 Patent to be unpatentable due to the existence of prior art cited by us in *inter partes* review proceedings. In January 2024, United Therapeutics filed a request for rehearing of the decision by the United States Court of Appeals for the Federal Circuit. The request for rehearing was denied in March 2024. In June 2024, United Therapeutics filed a petition for a writ of certiorari to seek an appeal with the United States Supreme Court. In July 2024, the Company was asked to respond to United Therapeutics' petition, with the response due on August 28, 2024. The petition remains pending and is expected to be considered in conference by the United States Supreme Court on September 30, 2024.

As a result of the decision by the United States Court of Appeals for the Federal Circuit with respect to the invalidity of the '793 Patent, in December 2023, the Company filed a motion for Judge Andrews to set aside the injunction he issued in the Original Hatch-Waxman Litigation. The motion was granted in March 2024, and the injunction on final approval by the FDA of YUTREPIA was set aside. United Therapeutics has appealed Judge Andrews' decision to set aside the injunction to the Federal Circuit. Briefing in the appeal remains ongoing, and the Federal Circuit has scheduled oral argument for September 3, 2024.

In connection with an amendment to our NDA filed in July 2023 to add PH-ILD as an indication for YUTREPIA, the Company provided a new notice of the paragraph IV certification 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, in September 2023, United Therapeutics filed a second complaint for patent infringement against us in the U.S. District Court for the District of Delaware (Case No. 1:23-cv-00975-RGA) (the "New Hatch-Waxman Litigation"), again asserting infringement by the Company of the '793 Patent. In November 2023, the U.S. Patent and Trademark Office (the USPTO) issued U.S. Patent No. 11,826,327, or the '327 Patent, entitled "Treatment for Interstitial Lung Disease", to United Therapeutics. On November 30, 2023, United Therapeutics filed an amended complaint in the New Hatch-Waxman Litigation asserting infringement of the '327 Patent by the practice of YUTREPIA based on the amended NDA. In January 2024, the Company filed an answer, counterclaims and a partial motion to dismiss the claims related to the '793 Patent as a result of the decision by the United States Court of Appeals for the Federal Circuit to affirm the PTAB's finding that the '793 patent is unpatentable. In February 2024, United Therapeutics stipulated to the dismissal of the claims in the New Hatch-Waxman Litigation related to the '793 Patent. In February 2024, United Therapeutics also filed a motion seeking a preliminary injunction to prevent us from manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling YUTREPIA for the treatment of PH-ILD. Briefing on the motion is complete and a hearing on the motion

was held in April 2024. Judge Andrews denied the motion for a preliminary injunction in May 2024. Discovery in the case remains ongoing.

FDA Litigation

In February 2024, United Therapeutics filed a complaint against the FDA in the U.S. District Court for the District of Columbia, challenging the FDA's acceptance of our amended NDA for review (the "FDA Litigation"). The Company intervened and became a party to the lawsuit in March 2024. In March 2024, United Therapeutics filed a motion for a temporary restraining order in the FDA Litigation, seeking to enjoin the FDA from approving our NDA for YUTREPIA with respect to the indication to treat PH-ILD. United Therapeutics' motion was denied in March 2024. In May 2024, both the Company and the FDA filed motions to dismiss United Therapeutics' complaint. Briefing on the motions to dismiss has been completed, and the motion remains pending.

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 Robert Roscigno ("Dr. Roscigno") 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 2024, Dr. Roscigno filed a motion for summary judgment with respect to all claims, but the motion was denied in July 2024. In addition, in July 2024, the Company filed a motion for summary judgment with respect to all claims. Briefing on the Company's motion is in process.

In May 2024, United Therapeutics filed a second complaint in the Superior Court in Durham County, North Carolina, against Dr. Roscigno, alleging that he breached prior employment agreements with United Therapeutics by failing to assign to United Therapeutics his interest in patents obtained by the Company that relied upon or benefitted from certain inventions, discoveries, materials, authorship, derivatives and results developed by Dr. Roscigno while he was employed by United Therapeutics. The Company was also named as a defendant in this new lawsuit. As part of the lawsuit, United Therapeutics alleges that Dr. Roscigno misappropriated certain intellectual property of United Therapeutics which led to the development of YUTREPIA. The complaint also seeks declaratory judgement such that all right, title and interest in and to any patentable or unpatentable inventions, discoveries, and ideas made or conceived by Dr. Roscigno while employed by the company should be assigned and transferred to United Therapeutics because they involved the use of United Therapeutics' confidential information. On July 30, 2024, the Company filed a motion to dismiss all claims. Briefing on the motion is in progress.

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. A trial to determine the amount of damages due from United Therapeutics to Sandoz with respect to the breach of contract claim was held from late April to early May 2024, and closing arguments were held in June 2024. The parties are awaiting a decision from the Court.

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

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

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

Objective

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our condensed consolidated financial statements and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the three and six months ended June 30, 2024 as compared to the three and six months ended June 30, 2023. Also refer to our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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 rare cardiopulmonary diseases such as pulmonary arterial hypertension ("PAH") and pulmonary hypertension associated with interstitial lung disease ("PH-ILD"). 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 PAH and PH-ILD in the United States, as well as key stakeholders involved in the distribution and reimbursement of medicines to treat these patients. We established our commercial presence in the field to support Treprostinil Injection and have since expanded our presence to support the launch of YUTREPIA upon final approval, further validating our reputation as a company committed to supporting PAH and PH-ILD 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 and PH-ILD. 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 effort dry-powder inhaler ("DPI") and by achieving higher dose levels than the labeled doses of current inhaled therapies. In November 2021, the United States Food and Drug Administration ("FDA") tentatively approved our New Drug Application ("NDA") for YUTREPIA for the treatment of PAH. In July 2023, we filed an amendment to our NDA to add PH-ILD to the label for YUTREPIA. We are currently awaiting final action by the FDA with respect to our NDA.

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 Biopharm. L606 is currently being evaluated in an open-label study in the United States for treatment of PAH and PH-ILD with a planned pivotal study for the treatment of PH-ILD.

Since inception, we have incurred significant operating losses. Our net loss was $68.9 million for the six months ended June 30, 2024 and $78.5 million and $41.0 million for the years ended December 31, 2023 and 2022, respectively. As of June 30, 2024, we had an accumulated deficit of $498.0 million. 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 of such product candidates and pursue 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 Revenue Interest Financing Agreement with HealthCare Royalty Partners IV, L.P. ("HCR") dated January 9, 2023, as amended (the "RIFA") contains fixed quarterly payments and minimum cash covenants that require 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.

Our future funding requirements will be heavily determined by the timing of the potential commercialization of YUTREPIA and the resources needed to support the development of our product candidates. We expect that we will require additional capital to fund operations as well as to pursue in-licenses or acquisitions of other product candidates. If we 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 our business prospects, or we may be unable to continue operations.

Based on current operating plans and excluding any contribution from YUTREPIA product sales or external financing, we will not have sufficient cash and cash equivalents to fund operating expenses and capital requirements and meet our minimum cash covenants beyond one year from the issuance of these condensed consolidated financial statements, and therefore, the Company has concluded that there is substantial doubt about its ability to continue as a going concern. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

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. In May 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. We are 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. In December 2022, we entered into a Device Development and Supply Agreement (the "Pump Development Agreement") with Mainbridge Health Partners, LLC ("Mainbridge") and 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 2025. Revenue will continue to be impacted or at risk until new components or alternative pumps are available.

Cost of Revenue

Cost of revenue consists of (i) an allocation of the cost of our sales force associated with calling on physicians and hospital pharmacies involved in the treatment of PAH with Treprostinil Injection, as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection and (ii) 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 unless objective and persuasive evidence exists that regulatory approval and subsequent commercialization of a product candidate is probable and where we also expect the future economic benefit from the sales of the product candidate to be realized;
- 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;
- costs of acquired product licenses and related technology rights where there is no alternative future use; and
- allocated facility-related costs.

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

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

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals. 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 can 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 equivalents. 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 interest accretion and amortization of debt discounts and issuance costs to interest expense.

Results of Operations

Three and Six Months Ended June 30, 2024 compared with the Three and Six Months Ended June 30, 2023

The following table summarizes the results of our operations for the three and six months ended June 30, 2024 and 2023, 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,		$	%
	2024	2023	Change	Change	2024	2023	Change	Change
Revenue	$ 3,659	$ 4,786	$ (1,127)	(24)%	$ 6,631	$ 9,279	$ (2,648)	(29)%
Costs and expenses:								
Cost of revenue	1,493	671	822	123 %	2,960	1,325	1,635	123 %
Research and development	9,420	17,695	(8,275)	(47)%	19,477	22,973	(3,496)	(15)%
General and administrative	19,943	9,245	10,698	116 %	40,192	17,038	23,154	136 %
Total costs and expenses	30,856	27,611	3,245	12 %	62,629	41,336	21,293	52 %
Loss from operations	(27,197)	(22,825)	(4,372)	19 %	(55,998)	(32,057)	(23,941)	75 %
Other income (expense):								
Interest income	1,855	734	1,121	153 %	3,735	1,656	2,079	126 %
Interest expense	(2,600)	(1,426)	(1,174)	82 %	(5,124)	(2,550)	(2,574)	101 %
Loss on extinguishment of debt	—	—	—	* %	(11,483)	(2,311)	(9,172)	397 %
Total other expense, net	(745)	(692)	(53)	8 %	(12,872)	(3,205)	(9,667)	302 %
Net loss and comprehensive loss	$ (27,942)	$ (23,517)	$ (4,425)	19 %	$ (68,870)	$ (35,262)	$ (33,608)	95 %

* Not meaningful

Revenue

Revenue was $3.7 million for the three months ended June 30, 2024, compared to $4.8 million for the three months ended June 30, 2023. Revenue related primarily to the Promotion Agreement. The decrease of $1.1 million was primarily due to the impact of lower sales quantities in the current year as compared to the same period in the prior year.

Revenue was $6.6 million for the six months ended June 30, 2024, compared to $9.3 million for the six months ended June 30, 2023. Revenue related primarily to the Promotion Agreement. The decrease of $2.7 million was primarily due to the impact of lower sales quantities in the current year as compared to the same period in the prior year.

Cost of Revenue

Cost of revenue was $1.5 million for the three months ended June 30, 2024, compared to $0.7 million for the three months ended June 30, 2023. Cost of revenue related to the Promotion Agreement as noted above. The increase from the prior year was primarily due to our sales force expansion during the fourth quarter of 2023.

Cost of revenue was $3.0 million for the six months ended June 30, 2024, compared to $1.3 million for the six months ended June 30, 2023. Cost of revenue related to the Promotion Agreement as noted above. The increase from the prior year was primarily due to our sales force expansion during the fourth quarter of 2023.

Research and Development Expenses

Research and development expenses were $9.4 million for the three months ended June 30, 2024, compared to $17.7 million for the three months ended June 30, 2023. The decrease of $8.3 million or 47% 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 recorded during the three months ended June 30, 2023. Additionally, there was a $1.4 million decrease in expenses related to our YUTREPIA program driven by expensing prelaunch inventory costs in the prior year. These decreases were offset by a $1.7 million increase in clinical expenses related to our L606 program and a $1.5 million increase in personnel expenses (including stock-based compensation) related to increased headcount.

Research and development expenses were $19.5 million for the six months ended June 30, 2024, compared to $23.0 million for the six months ended June 30, 2023. The decrease of $3.5 million or 15% 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 recorded during the three months ended June 30, 2023. This decrease was offset by a $3.5 million increase in personnel expenses (including stock-based compensation) related to increased headcount and a $3.1 million increase in clinical expenses related to our L606 program.

General and Administrative Expenses

General and administrative expenses were $19.9 million for the three months ended June 30, 2024, compared to $9.2 million for the three months ended June 30, 2023. The increase of $10.7 million or 116% was primarily due to a $6.3 million increase in personnel expenses (including stock-based compensation) driven by higher headcount and expansion of our sales force in the fourth quarter of 2023, a $2.2 million increase in commercial and consulting expenses in preparation for the potential commercialization of YUTREPIA, and a $0.9 million increase in legal fees related to our ongoing YUTREPIA-related litigation.

General and administrative expenses were $40.2 million for the six months ended June 30, 2024, compared to $17.0 million for the six months ended June 30, 2023. The increase of $23.2 million or 136% was primarily due to a $12.2 million increase in personnel expenses (including stock-based compensation) driven by higher headcount and expansion of our sales force in the fourth quarter of 2023, a $4.5 million increase in commercial and consulting expenses in preparation for the potential commercialization of YUTREPIA, and a $4.0 million increase in legal fees related to our ongoing YUTREPIA-related litigation.

Other Income (Expense)

Total other expense, net was $0.7 million for both the three months ended June 30, 2024 and 2023. There was a $1.2 million increase in interest expense attributable to the higher borrowings under the RIFA as compared to the prior year and a $1.1 million increase in interest income attributable to higher money market balances.

Total other expense, net was $12.9 million for the six months ended June 30, 2024, compared with $3.2 million for the six months ended June 30, 2023. The increase of $9.7 million was primarily driven by a $9.2 million increase in loss on extinguishment of debt resulting from the Fourth Amendment to the RIFA, which was executed in January 2024, and a $2.6 million increase in interest expense attributable to the higher borrowings under the RIFA compared to the prior year. These increases were offset by a $2.1 million increase in interest income attributable to higher money market balances.

Liquidity and Capital Resources

Sources of Liquidity

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, 2024 and December 31, 2023, we had cash and cash equivalents of $133.1 million and $83.7 million,

respectively. As of June 30, 2024, we had stockholders' equity of $62.7 million and an accumulated deficit of $498.0 million.

In January 2024, we sold 7,182,532 shares of our common stock in a private placement (the "2024 Private Placement") at a purchase price of $10.442 per share for gross proceeds of approximately $75.0 million, before deducting offering expenses of less than $0.1 million.

In December 2023, we sold 3,491,620 shares of our common stock in an underwritten registered public offering at an offering price of $7.16 per share for gross proceeds of approximately $25.0 million, before deducting offering costs of approximately $1.9 million.

In December 2023, we also entered into a common stock purchase agreement with Roger Jeffs, our Chief Executive Officer, for the sale by us in a private placement of an aggregate of 139,665 shares of our common stock at a purchase price of $7.16 per share for gross proceeds of approximately $1.0 million.

In January 2023, we entered into a Revenue Interest Financing Agreement with HealthCare Royalty Partners IV, L.P. ("HCR"), as amended (the "RIFA"), 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, $22.2 million of which was used to satisfy in full and retire our previously outstanding debt with Silicon Valley Bank, 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. On January 5, 2024 an additional $25.0 million of the Investment Amount was funded. See Note 12 to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for information regarding repayment.

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, the indications, if any, for which YUTREPIA is approved and the resources needed to support the development of our product candidates. Based on our current plans, we expect that we will require additional capital. See Note 1 to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for information regarding our ability to continue as a going concern.

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,	
	2024	**2023**
Net cash provided by (used in):		
Operating activities	$ (47,527)	$ (14,021)
Investing activities	(1,914)	(607)
Financing activities	98,855	9,541
Net increase (decrease) in cash and cash equivalents	$ 49,414	$ (5,087)

Operating Activities

Net cash used in operating activities increased $33.5 million to $47.5 million for the six months ended June 30, 2024 compared to $14.0 million for the six months ended June 30, 2023. The increase was primarily due to $27.8 million higher net loss adjusted for non-cash items and unfavorable working capital changes of $5.7 million.

Investing Activities

Net cash used in investing activities was $1.9 million for the six months ended June 30, 2024 compared to $0.6 million for the six months ended June 30, 2023. During both the six months ended June 30, 2024 and 2023, net cash used in investing activities related to property, plant and equipment purchases.

Financing activities

Net cash provided by financing activities was $98.9 million during the six months ended June 30, 2024, compared to $9.5 million during the six months ended June 30, 2023. During the six months ended June 30, 2024, we received $74.9 million net proceeds from the 2024 Private Placement, $25.0 million net proceeds from the RIFA, and $0.5 million from the issuance of common stock under stock incentive plans. These inflows were offset by $1.7 million in payments under the RIFA. During the six months ended June 30, 2023, we received $31.8 million net proceeds from the RIFA of which $22.2 million was used to repay our indebtedness to Silicon Valley Bank.

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, $0.2 million of which was accrued as of June 30, 2024.

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 2025. 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. 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.

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 our proprietary PRINT® technology, and Lonza will encapsulate and package the Product. Under the terms of the Agreement, 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.

In addition, we have entered into a multi-year supply agreement with LGM Pharma, LLC ("LGM") to supply 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.

As of June 30, 2024, we have non-cancelable commitments for product supply and manufacturing costs of approximately $3.5 million.

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 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 have agreements with certain employees and an Executive Severance and Change in Control Plan which covers certain other employees which require 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 condensed 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 condensed 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 condensed 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 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

We recognized a liability related to amounts received in January 2023, July 2023, and January 2024 pursuant to the RIFA with HCR under ASC 470-10, *Debt* and ASC 835-30, *Interest - Imputation of Interest*. The liability will be accreted under the effective interest method based upon the estimated amount of future payments to be made pursuant to the RIFA. If the timing or amounts of any estimated future payments change, we will prospectively adjust the effective interest and the related amortization of the liability. A significant increase or decrease in these estimates could materially impact the liability balance and related interest expense. See Note 12 to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for additional information.

Prelaunch Inventory

We capitalize prelaunch inventory prior to receiving regulatory approval if regulatory approval and subsequent commercialization of a product is probable and we also expect future economic benefit from the sales of the product to be realized. Prior to this conclusion, we expense prelaunch inventory as research and development expense in the period incurred. For prelaunch inventory that is capitalized, we consider a number of specific facts and circumstances, including the product's historical shelf life, the product's current status in the development and regulatory approval process, results from related clinical trials, results from meetings with relevant regulatory agencies prior to the filing of regulatory applications, potential obstacles to the approval process, viability of commercialization and market trends. In late 2023, based on our assessment of the legal and regulatory process related to YUTREPIA, we concluded that we met the criteria to capitalize expenditures for prelaunch inventory. We capitalized $7.2 million of prelaunch inventory as of June 30, 2024 and none as of December 31, 2023. We do not have an allowance for inventory obsolescence as of June 30, 2024. If either regulatory approval or market acceptance post-approval of YUTREPIA do not occur at all or on a timely basis prior to the inventory shelf-life expiration, we may be required to write-off some or all prelaunch inventory, which could affect our financial condition and financial results.

Smaller Reporting Company

As a "smaller reporting company," as defined under 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.

We will be able to take advantage of these scaled disclosures for so long as (i) our common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter. To the extent we take advantage of any reduced disclosure obligations, it may make it harder for investors to analyze the Company's results of operations and financial prospectus in comparison with other public companies. Until we cease to be a smaller reporting company, the scaled-back disclosure in our SEC filings will result in less information about our company being available than for other public companies.

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, 2024, 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, 2024.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2024 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.

For information on our legal proceedings, see Note 14 "Legal Proceedings" to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

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 will depend on our ability to fund future operations and capital requirements with potential sales of any approved product candidates and/or with additional capital from external financing.
- 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) for some or all of the indications for which we are seeking approval or may not be commercialized successfully.
- United Therapeutics has initiated multiple lawsuits against us in which it has claimed that YUTREPIA is infringing its patents, two separate lawsuits against us that we and a former United Therapeutics employee, who later joined us as an employee, conspired to misappropriate and use certain trade secrets and confidential information of United Therapeutics and engaged in unfair or deceptive trade practices, and a separate lawsuit against the FDA seeking to challenge the FDA's acceptance of our amended NDA for YUTREPIA. United Therapeutics has sought injunctive relief in several of these lawsuits. These lawsuits, and other lawsuits that United Therapeutics may file in the future, may result in our company being further delayed in its efforts to commercialize YUTREPIA, may limit the indications for which YUTREPIA is approved or may result in substantial damage claims against us if we launch YUTREPIA and we are later found to infringe. Even where we have been successful in defending these lawsuits, outcomes could be overturned on rehearing or appeal.
- 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 indicated its intention to discontinue service and maintenance of CADD-MS 3 infusion pumps. Although we believe that

the quantity of CADD-MS 3 infusion pumps available will be sufficient to serve patients through 2025, the availability of such pumps may terminate earlier than anticipated. 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 Healthcare Royalty Partners IV, L.P., or 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 or third-party payor coverage.
- 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. In addition, we may experience unexpected challenges as we ramp up our manufacturing capacity to meet demand or during commercial manufacturing, which may result in our inability to supply sufficient quantities of product to meet demand.
- Our business and operations may be adversely affected by the effects of health epidemics.
- 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 will depend on our ability to fund future operations and capital requirements with potential sales of any approved product candidates and/or with additional capital from external financing.

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, 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. We do not expect to generate significant revenue unless and until we are able to obtain marketing approval for and successfully commercialize one or more of our 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. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. 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 will depend on our ability to fund future operations and capital requirements with potential sales of any approved product candidates and/or with additional capital from external financing. We may seek additional funding through public or private financings, debt financing or collaboration. Our inability to obtain funding, 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 $68.9 million during the six months ended June 30, 2024, and $78.5 million and $41.0 million during the years ended December 31, 2023 and 2022, respectively. We also had negative operating cash flows for each of these periods. As of June 30, 2024, we had an accumulated deficit of $498.0 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 expect 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. 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. 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 fail to obtain financing 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 in January 2023 at the initial closing, $10.0 million of the Investment Amount was funded in July 2023 in connection with our entry into a license agreement with Pharmosa, $25.0 million of the Investment Amount was funded in January 2024. The third tranche of $10.0 million and the fourth tranche of $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, the January 2024 Private Placement, our December 2023 public equity offering, the December 2023 Private Placement 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, 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 the January 2024 Private Placement, our December 2023 public equity offering, the December 2023 Private Placement, 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.

Changes to existing tax laws, or challenges to our tax positions could adversely affect our business and financial condition.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions could materially affect our tax obligations.

For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures in the year incurred and instead requires taxpayers to capitalize and subsequently amortize such expenditures over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. In January 2024, the U.S. House of Representatives passed the Tax Relief for American Families and Workers Act, which would retroactively repeal for 2022 and 2023, and defer until 2026, the requirement to capitalize research and development expenditures for research activities conducted in the United States. Uncertainty exists as to whether the bill will be enacted into law. As another example, in August 2022, the Inflation Reduction Act of 2022 was enacted, and, among other things, included a new 15% alternative minimum tax on the adjusted financial statement income of certain large corporations for tax years beginning after December 31, 2022. To

the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes could adversely impact our business, results of operations and financial position.

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 in connection with the development of our product candidates and commercialization of any approved products.

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, or the ANDA, for and controls Treprostinil Injection and is responsible among other things for the compliant manufacture, distribution, labeling, and advertising of Treprostinil Injection. As a result, we are dependent on Sandoz to manufacture and supply Treprostinil Injection, and are 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, or cGMPs; 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. 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. 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.

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 has indicated that they will no longer support the CADD-MS 3 infusion pump. Although we believe that the number of available CADD-MS 3 infusion pumps will be sufficient to serve patients through 2025, it is possible that the availability of CADD-MS 3 infusion pumps could end earlier. Due to this limitation in the availability of pumps, specialty pharmacies will limit the number of patients that they place on subcutaneous Treprostinil Injection therapy in order to ensure that patients placed on subcutaneous administration of Treprostinil Injection will not have to discontinue such treatment due to the unavailability of pumps. Until we are able to obtain a pump to replace the CADD-MS 3, 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.

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 subcutaneous 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 at multiple banking institutions that may exceed the Federal Deposit Insurance Corporation, or the 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, 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 its patents and that we have misappropriated its trade secrets and confidential information and has initiated a lawsuit against the FDA challenging the FDA's acceptance of our amended NDA for YUTREPIA for review, which may result in our company being further delayed in its efforts to commercialize YUTREPIA and may limit the indications for which YUTREPIA is approved.

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"Original 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 Original 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 Original Hatch-Waxman Litigation were held in March 2022. In August 2022, Judge Andrews, who was presiding over the Original 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 Original Hatch-Waxman Litigation. In September 2022, Judge Andrews entered a final judgment in the Original 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 a petition for *inter partes* review with the Patent Trial and Appeal Board, or the PTAB, of the USPTO with respect to the '901 Patent, seeking a determination that the claims in the '901 Patent are invalid. 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. On June 27, 2024, the United States Court of Appeals for the Federal Circuit affirmed the PTAB's decision with respect to the '901 patent.

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 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. In December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the '793 Patent to be unpatentable due to the existence of prior art cited by us in *inter partes* review proceedings. In January 2024, United Therapeutics filed a request for rehearing of the decision by the United States Court of Appeals for the Federal Circuit. The request for rehearing was denied on March 12, 2024. In June 2024, United Therapeutics filed a petition for a writ of certiorari to seek an appeal with the United States Supreme Court. In July 2024, the Company was asked to respond to United Therapeutics' petition, with the response due on August 28, 2024. The petition remains pending and is expected to be considered in conference by the United States Supreme Court on September 30, 2024.

As a result of the decision by the United States Court of Appeals for the Federal Circuit with respect to the invalidity of the '793 Patent, in December 2023, we filed a motion for Judge Andrews to set aside the injunction he issued in the Original Hatch-Waxman Litigation. The motion was granted in March 2024, and the injunction on final approval by the FDA of YUTREPIA was set aside. United Therapeutics has appealed Judge Andrews' decision to set aside the

injunction to the Federal Circuit. Briefing in the appeal remains ongoing, and the Federal Circuit has scheduled oral argument for September 3, 2024.

In connection with an amendment to our NDA filed in July 2023 to add PH-ILD as an indication for YUTREPIA, we provided a new notice of the paragraph IV certification 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, in September 2023, United Therapeutics filed a second complaint for patent infringement against us in the U.S. District Court for the District of Delaware (Case No. 1:23-cv-00975-RGA) (the "New Hatch-Waxman Litigation"), again asserting infringement by the Company of the '793 Patent. In November 2023, the U.S. Patent and Trademark Office (the USPTO) issued U.S. Patent No. 11,826,327, or the '327 Patent, entitled "Treatment for Interstitial Lung Disease", to United Therapeutics. On November 30, 2023, United Therapeutics filed an amended complaint in the New Hatch-Waxman Litigation asserting infringement of the '327 Patent by the practice of YUTREPIA based on the amended NDA. In January 2024, we filed an answer, counterclaims and a partial motion to dismiss the claims related to the '793 Patent as a result of the decision by the United States Court of Appeals for the Federal Circuit to affirm the PTAB's finding that the '793 patent is unpatentable. In February 2024, United Therapeutics stipulated to the dismissal of the claims in the New Hatch-Waxman Litigation related to the '793 Patent. In February 2024, United Therapeutics also filed a motion seeking a preliminary injunction to prevent us from manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling YUTREPIA for the treatment of PH-ILD. Briefing on the motion for preliminary injunction is ongoing, and the motion remains pending. Judge Andrews denied the motion for a preliminary injunction in May 2024. Discovery in the case remains ongoing.

Although we do not believe United Therapeutics is entitled to a new 30-month stay or a preliminary injunction in connection with the New Hatch-Waxman Litigation, it is possible that the Court could rule that a new mandatory 30- month delay has been triggered with respect to the approval of the 505(b)(2) NDA application or that a preliminary injunction is warranted.

In February 2024, United Therapeutics also filed a lawsuit against the FDA, challenging the FDA's acceptance of our amended NDA for review (the "FDA Litigation"). In March 2024, United Therapeutics filed a motion for a temporary restraining order in the FDA Litigation, seeking to enjoin the FDA from approving our NDA for YUTREPIA with respect to the indication to treat PH-ILD. United Therapeutics' motion was denied in March 2024. In May 2024, both we and the FDA filed motions to dismiss United Therapeutics' complaint. Briefing on the motions to dismiss has been completed. Although we do not believe the arguments of United Therapeutics have merit, it is possible that the Court could rule that the FDA must reject the amendment to the YUTREPIA NDA to add PH-ILD to the label, in which case we may be required to later file a supplement to our NDA to add PH-ILD to the label. If we are required to file a supplement to add PH-ILD to the label for YUTREPIA, although we do not believe United Therapeutics would be entitled to a new 30-month stay, it is possible that the FDA or a Court could rule that a new mandatory 30-month delay has been triggered with respect to the supplement.

In addition, United Therapeutics may seek to assert newly issued patents against us, including U.S. Patent Number 11,723,887, and may seek to enjoin the FDA from granting final approval to YUTREPIA or enjoin us from launching YUTREPIA through one or more additional legal proceedings.

As a result of this 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. In addition, if United Therapeutics is successful in any of its appeals or requests for rehearing, we may be unable to commercialize YUTREPIA until the expiration of United Therapeutics' patents, which could materially harm our business. For example, in the event the United States Supreme Court was to overturn or vacate the United States Court of Appeals for the Federal Circuit's affirmance of the PTAB's invalidation of the '793 Patent, it is possible that Judge Andrews could reinstitute his injunction in the Original Hatch-Waxman Litigation, which could either prevent the FDA from granting final approval for YUTREPIA for either PAH or PH-ILD or force the FDA to revoke any prior approval for YUTREPIA for such indications. Also, although United Therapeutics' initial requests for injunctive relief have been denied, if United Therapeutics is successful in obtaining a preliminary injunction or temporary restraining order in the New Hatch-Waxman Litigation or the FDA Litigation, we could be limited to commercializing YUTREPIA only for the PAH indication for an extended time period.

In December 2021, United Therapeutics filed a complaint in the Superior Court in Durham County, North Carolina, alleging that we and Robert Roscigno ("Dr. Roscigno"), 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 2024, Dr. Roscigno filed a motion for summary judgment on all claims, but the motion was denied in July 2024. In addition, in July 2024, the Company filed a motion for summary judgment with respect to all claims. Briefing on the Company's motion is in process.

In May 2024, United Therapeutics filed a second complaint in the Superior Court in Durham County, North Carolina, against Dr. Roscigno, alleging that he breached prior employment agreements with United Therapeutics by failing to assign to United Therapeutics his interest in patents obtained by the Company that relied upon or benefitted from certain inventions, discoveries, materials, authorship, derivatives and results developed by Dr. Roscigno while he was employed by United Therapeutics. The Company was also named as a defendant in this new lawsuit. As part of the lawsuit, United Therapeutics alleges that Dr. Roscigno misappropriated certain intellectual property of United Therapeutics which led to the development of YUTREPIA. The complaint also seeks declaratory judgement such that all right, title and interest in and to any patentable or unpatentable inventions, discoveries, and ideas made or conceived by Dr. Roscigno while employed by the company should be assigned and transferred to United Therapeutics because they involved the use of United Therapeutics' confidential information. On July 30, 2024, the Company filed a motion to dismiss all claims. Briefing on the motion is in progress.

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 or other correspondence with the FDA, as United Therapeutics has recently done, 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 prostacyclin analog therapies that are either currently marketed or in clinical development:

- Tyvaso (treprostinil), marketed by United Therapeutics, has been approved for the treatment of PAH in the United States since 2009 and for PH-ILD since 2021. 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.

- Tyvaso DPI (treprostinil), 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.

- 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. In May 2024, Insmed reported positive topline safety and tolerability data as well as certain exploratory efficacy endpoints from the Phase 2 PH-ILD. Based on these Phase 2 results, Insmed is pursuing discussions with global regulatory authorities on the design of a Phase 3 study in PH-ILD to initiate in 2025. 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.

- Ventavis® (iloprost), marketed by Actelion, a division of Johnson & Johnson, has been approved for the treatment of PAH in the United States since 2004.

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 versions 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.
- ***Activin signaling inhibitor,*** such as sotatercept marketed by Merck & Co.

Merck & Co's injectable sotatercept, with a brand name of Winrevair, was approved by the FDA in March 2024 and is a potential first-in-class molecule that targets the proliferation of cells in the pulmonary arterial wall. Its clinical use is developing, and 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.

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., and Gossamer Bio, Inc., among others.

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 Investigation 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 the event United Therapeutics sought and was able to obtain one or more regulatory exclusivities with respect to Tyvaso DPI, it could significantly delay our ability to obtain final approval for YUTREPIA. Even if the FDA does not recognize any new regulatory exclusivity for United Therapeutics, United Therapeutics could challenge the FDA's decision and seek an injunction to prevent approval of YUTREPIA in on or more indications until such challenge has been decided.

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.

One or more products that are competitive with YUTREPIA could also obtain approval for additional indications or broader conditions of use. These additional indications and broader conditions of use could be protected by one or more patents or regulatory exclusivities, preventing YUTREPIA from obtaining approval for the same indications or conditions of use. For instance, if Liquidia is prevented from launching or selling YUTREPIA for the treatment of PH-ILD in connection with the patent litigation related to the '327 patent or the lawsuit that United Therapeutics filed against the FDA, Tyvaso and Tyvaso DPI would have broader labels than YUTREPIA. In addition, United Therapeutics

is currently studying Tyvaso for the treatment of idiopathic pulmonary fibrosis, an indication for which it has received an orphan drug designation. Thus, even if YUTREPIA is approved, such competitive products could 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 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 or adequate third-party payor coverage.

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 or third-party payor coverage, we may not be able to generate sufficient revenue to become profitable. The degree of market acceptance and third-party payor coverage 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 or sufficient third-party payor coverage, 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. In addition, during 2023, we significantly increased the size of our sales force in anticipation of a potential launch of YUTREPIA. However, if we experience continued delays in the approval of YUTREPIA, we may be unable to retain our sales force. Moreover, we cannot

assure you that we will be successful in further building or effectively managing 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. If the commercial launch of a drug candidate for which we recruit or have recruited 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;
- 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, commercialization 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. Our inability to obtain sufficient product liability insurance at an acceptable cost and/or scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with our collaborators. The market for insurance coverage is increasingly expensive, and the costs of insurance coverage will increase as our clinical programs and commercialization efforts increase in size. 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.

Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources, adversely affect or eliminate the prospects for commercialization or sales of a product that is the subject of any such claim, and could have a material adverse effect on our business, financial condition, results of operations, and growth prospects.

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, and this product candidate may fail to receive final marketing approval (in a timely manner or at all), may fail to receive approval for one or more indications for which we have sought approval 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. However, United Therapeutics has invested considerable time and resources in an effort to block final approval of YUTREPIA, and expectations related to final FDA approval and projected product launch timelines are impacted by ongoing litigation following lawsuits filed by United Therapeutics. For instance, Judge Andrews issued an order in the Original Hatch-Waxman Litigation enjoining the FDA from issuing a final approval for the YUTREPIA NDA until the expiration of the '793 Patent in 2027. While Judge Andrews set aside the injunction after a December 2023 decision by the United States Court of Appeals for the Federal Circuit affirming an earlier decision by the PTAB to invalidate all claims of the '793 Patent, United Therapeutics has appealed Judge Andrews' decision to set aside the injunction. In the event such appeal or United Therapeutics' appeal to the United States Supreme Court of the decision invalidating the '793 Patent are successful, Judge Andrews may reinstitute the injunction, in which case the final approval of YUTREPIA may be blocked or, if it has already been granted, revoked. Furthermore, in connection with an amendment to our NDA filed on July 24, 2023 to add PH-ILD as an indication for YUTREPIA, we provided a new notice of the paragraph IV certification 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, in September 2023, United Therapeutics filed the New Hatch-Waxman Litigation, again asserting infringement by the Company of the '793 Patent, which lawsuit was amended on November 30, 2023, to add claims asserting infringement of the '327 Patent. Although the claims related to the '793 Patent were subsequently withdrawn, in February 2024, United Therapeutics also filed a motion seeking a preliminary injunction to prevent us from manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling YUTREPIA for the treatment of PH-ILD. That motion for preliminary injunction was denied, but United Therapeutics may still seek injunctive relief in the future. In February 2024, United Therapeutics also commenced the FDA Litigation, seeking to enjoin the FDA from approving our NDA for YUTREPIA with respect to the indication to treat PH-ILD. Although we do not believe United Therapeutics is entitled to any injunction or temporary restraining order in the New Hatch-Waxman Litigation or the FDA Litigation, it is possible that the Court could rule that the FDA must reject the amendment to the YUTREPIA NDA to add PH-ILD to the label or that, even if YUTREPIA has launched for both PAH and PH-ILD, the Company must remove PH-ILD from the label for YUTREPIA.

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. For instance, United Therapeutics recently filed a citizen petition related to the supplier of the active pharmaceutical ingredient for YUTREPIA in an attempt to prevent or delay the approval of YUTREPIA. It is possible that the issues raised in the citizen petition could delay the completion of FDA's review of the NDA for YUTREPIA. In addition, the FDA has not yet issued even tentative 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 or conduct additional inspections. If any additional issues were identified in such information requests or inspections or if FDA

determines that we failed to include required CMC information in the NDA for our products, including YUTREPIA, we may be delayed in obtaining final approval or may be unable to obtain final approval. Furthermore, responses to FDA's requests 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 regulatory 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. It is also possible that recent decisions by the United States Supreme Court, eliminating court deference to decisions by administrative agencies, may delay any final decisions from the FDA as it considers how to implement this new ruling into its decision-making process.

If we successfully obtain marketing approvals 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, even if such products are approved by the FDA, they may not achieve a sufficient level of market acceptance or third-party payor coverage, 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 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, that the drug CMC data or device biocompatibility data for our product candidates otherwise do not support approval or that additional CMC data or information for our product candidates must be submitted for review;

- 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 risk evaluation and mitigation strategies, or 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 a variety of factors, including, 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 pandemics 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 citizen petitions or other correspondence with the FDA or lawsuits against 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. For instance, United Therapeutics has a lawsuit against the FDA and recently filed a citizen petition in an attempt to prevent or delay the approval of YUTREPIA. 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 or for certain indications 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. In December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the '793 Patent to be unpatentable due to the existence of prior art cited by us in *inter partes* review proceedings. As a result of this decision by the United States Court of Appeals for the Federal Circuit with respect to the invalidity of the '793 Patent, in December 2023, we filed a motion for Judge Andrews to set aside the injunction he issued in the Original Hatch-Waxman Litigation. The motion was granted in March 2024, and the injunction on final approval by the FDA of YUTREPIA was set aside. However, United Therapeutics has appealed Judge Andrews' decision to set aside the injunction to the Federal Circuit.

Also, in connection with an amendment to our NDA filed in July 2023 to add PH-ILD as an indication for YUTREPIA, we provided a new notice of the paragraph IV certification 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, in September 2023, United Therapeutics filed the New Hatch-Waxman Litigation, again asserting infringement by the Company of the '793 Patent, which lawsuit was amended on November 30, 2023, to add claims asserting infringement of the '327 Patent. In February 2024, United Therapeutics filed a motion seeking a preliminary injunction to prevent us from manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling YUTREPIA for the treatment of PH-ILD. Although the motion for preliminary injunction was denied, United Therapeutics may still seek injunctive relief and other remedies.

In addition, United Therapeutics may seek to assert newly issued patents against us, including U.S. Patent Number 11,723,887, and may seek to enjoin the FDA from granting final approval to YUTREPIA or enjoin us from launching YUTREPIA.

It is also not uncommon for a manufacturer of an approved product, such as United Therapeutics, to file a citizen petition or other correspondence with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products or to take other actions, such as engaging in litigation with the FDA to enjoin approval of a competing product. If successful, such petitions, correspondence or litigation can significantly delay, or even prevent, the approval of the new product. For example, United Therapeutics is currently pursuing litigation under the Administrative Procedures Act, seeking to require the FDA to reject our amendment to the YUTREPIA NDA to add PH-ILD to the label. In addition, United Therapeutics recently filed a citizen petition related to the supplier of the active pharmaceutical ingredient for YUTREPIA in an attempt to prevent or delay the approval of YUTREPIA. Even if the FDA ultimately denies the petition and prevails in such litigation, the FDA may substantially delay approval while it considers and responds to the petition or correspondence and is engaged in litigation or the FDA may be temporarily enjoined by a court from granting approval until the court has ruled on United Therapeutics' requests.

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. 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, Smiths Medical has indicated that they will no longer support the CADD MS-3. Although we believe that the number of available CADD-MS 3 infusion pumps will be sufficient to continue serving patients through the end of 2025, we are relying upon Mainbridge for the development of new pumps for the subcutaneous administration of Treprostinil Injection to replace the CADD MS-3. If we are unable to identify options to maintain the availability of the existing CADD MS-3 pumps until the new pumps are cleared by the FDA, 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. Also, we are currently evaluating devices to use for the administration of L606. If we are unable to identify a device to use for our L606 program, establish an agreement with the manufacturer of that device for the supply of such devices or obtain adequate quantities of that device in a timely manner or at all, we may be unable to successfully develop L606 or to do so in a timely manner.

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. However, in December 2023, the United States Court of Appeals for the Federal Circuit affirmed the earlier decision by the PTAB, which found all claims of the '793 Patent to be unpatentable due to the existence of prior art cited by us in *inter partes* review proceedings. As a result of this decision by the United States Court of Appeals for the Federal Circuit with respect to the invalidity of the '793 Patent, in December 2023, we filed a motion for Judge Andrews to set aside the injunction he issued in the Original Hatch-Waxman Litigation. The motion was granted in March 2024, and the injunction on final approval by the FDA of YUTREPIA was set aside. United Therapeutics has appealed Judge Andrews' decision to set aside the injunction to the Federal Circuit.

In addition, in connection with an amendment to our NDA filed in July 2023 to add PH-ILD as an indication for YUTREPIA, a new notice of the paragraph IV certification was 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 filed the New Hatch-Waxman Litigation, in which it sought a preliminary injunction. While the motion for a preliminary injunction was denied, United Therapeutics may still seek injunctive relief in the New Hatch-Waxman Litigation. Although we do not believe United Therapeutics is entitled to a preliminary injunction in connection with the New Hatch-Waxman Litigation, it is possible that the Court could enjoin us from commercializing YUTREPIA for the treatment of PH-ILD.

In addition, United Therapeutics may seek to assert newly issued patents against us, including U.S. Patent Number 11,723,887, and may seek to enjoin the FDA from granting final approval to YUTREPIA or enjoin us from launching YUTREPIA, including through temporary restraining orders or injunctions that they may seek in the FDA Litigation.

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, limit the label of our products to fewer indications than intended, 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 matter 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.

Questions may also arise as to the ownership of our patents. For instance, in May 2024, United Therapeutics filed a complaint in the Superior Court in Durham County, North Carolina, in which it is seeking declaratory judgement such that all right, title and interest in and to any patentable or unpatentable inventions, discoveries, and ideas made or conceived by Dr. Roscigno while employed by the Company should be assigned and transferred to United Therapeutics because they involved the use of United Therapeutics' confidential information. If successful, United Therapeutics could obtain an ownership interest in our patents, which may either limit our ability to prevent United Therapeutics from using out patented inventions or even allow United Therapeutics to prevent us from using our own patented inventions.

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 payment, 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.

We may experience unexpected challenges as we ramp up our manufacturing capacity to meet demand or during commercial manufacturing, which may result in our inability to supply sufficient quantities of product to meet demand.

The manufacturing process for our products is complex, due in part to strict regulatory requirements. A failure of our quality control systems in our facilities or those of our CMOs could cause problems to arise in connection with facility operations for a variety of reasons, including equipment malfunction, viral contamination, failure to follow specific manufacturing instructions, protocols and standard operating procedures, problems with raw materials or environmental factors. Such problems could affect production of a single batch or a series of batches, requiring the destruction of products, or could halt manufacturing operations altogether. For instance, as we scale up the manufacture of YUTREPIA, we are adjusting the speed and temperature at which our blister packs are sealed to reduce the risk of the product being exposed to moisture. Our failure to meet required quality standards may result in our failure to timely deliver products to our customers in sufficient quantities to meet demand, which in turn could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, damage to our reputation and relationships with patients, health care providers and third-party payors, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches. With respect to our commercial manufacturing, if problems are not discovered before the product is released to the market, we may be subject to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation, the cost of which could be significant.

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, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, 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, 2024, 76,793,694 shares of our Common Stock were outstanding, of which 66,790,209 shares of Common Stock, or 87.0% of our outstanding shares as of August 1, 2024, are freely tradable without restriction or further registration under the Securities Act, provided however, some of these shares are held by persons deemed to be "affiliates" under the Securities Act, including our officers and directors, as well as our principal stockholders, and may not be sold except: (i) in compliance with Rule 144 under the Securities Act or (ii) pursuant to any other applicable exemption under the Securities Act. The remaining 10,003,485 shares held by our stockholders as of August 1, 2024 have not been registered under the Securities Act and may be only be sold (i) pursuant to an effective registration statement under the Securities Act covering the sale of those shares, (ii) in compliance with Rule 144 under the Securities Act or (iii) pursuant to any other applicable exemption under the Securities Act.

Shares issued upon purchase under the employee stock purchase plan or upon the exercise of stock options or vesting of restricted stock units 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. We have 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.

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 pursuant to the Promotion Agreement;
- 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 (and, if approved, the scope of the indications for which such product candidates are approved) or any failure to obtain such approvals;
- our involvement in significant lawsuits, such as stockholder litigation, litigation involving the FDA, including the FDA Litigation, or litigation related to intellectual property, including *inter partes* review proceedings and Hatch-Waxman litigation with originator companies or others which may hold patents, including the ongoing litigation in connection with the patents, trade secrets and confidential information 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 39.0% of our capital stock as of August 1, 2024. 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 internal controls over financial reporting. See Item 4. Controls and Procedures for additional information.

Because we are a "smaller reporting company," we may take advantage of certain scaled disclosures available to us, resulting in holders of our securities receiving less Company information than they would receive from a public company that is not a smaller reporting company.

We are a "smaller reporting company" as defined under Rule 12b-2 of the Exchange Act. As of December 31, 2023, we are no longer an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012. As a smaller reporting company, we may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our Common Stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and our Common Stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter. Based on the closing price of our common stock on June 30, 2024, we will remain a smaller reporting company through at least the end of 2025. To the extent we take advantage of any reduced disclosure obligations, it may make it harder for investors to analyze the Company's results of operations and financial prospectus in comparison with other public companies.

As a smaller reporting company, we are permitted to comply with scaled-back disclosure obligations in our SEC filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We have elected to adopt the accommodations available to smaller reporting companies. Until we cease to be a smaller reporting company, the scaled-back disclosure in our SEC filings will result in less information about our company being available than for other public companies.

If investors consider our Common Stock less attractive as a result of our election to use the scaled- back disclosure permitted for smaller reporting companies, there may be a less active trading market for our Common Stock and our share price may be more volatile.

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 (iv) 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.

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.

The extent to which health epidemics impact 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 severity and duration of future outbreaks, 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 any such health epidemic. These impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent any health epidemic 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. Changes and instability in global economic conditions and geopolitical matters could have a material adverse effect on our business, financial condition and results of operations.

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 periods of high inflation globally. We are continuing to monitor inflation, the situation in Ukraine and global capital markets and assessing its potential impact on our business.

The global economy has been, and may continue to be, negatively impacted by Russia's invasion of Ukraine. As a result of Russia's invasion of Ukraine, the U.S., the European Union, the United Kingdom, and other G7 countries, among other countries, have imposed substantial financial and economic sanctions on certain industry sectors and parties in Russia. Broad restrictions on exports to Russia have also been imposed. These measures include: (i) comprehensive financial sanctions against major Russian banks; (ii) additional designations of Russian individuals with significant business interests and government connections; (iii) designations of individuals and entities involved in Russian military activities; and (iv) enhanced export controls and trade sanctions limiting Russia's ability to import various goods. Russian military actions and the resulting sanctions could continue to adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds.

In addition, on October 7, 2023, Hamas militants and members of other terrorist organizations infiltrated Israel's southern border from the Gaza Strip and conducted a series of terror attacks on civilian and military targets. Thereafter, Hamas launched extensive rocket attacks on Israeli population and industrial centers located along the Israeli border with the Gaza Strip. Shortly following the attack, Israel's security cabinet declared war against Hamas and launched an aerial bombardment of various targets within the Gaza Strip. The Israeli government subsequently called for the evacuation of over one million residents of the northern part of the Gaza Strip and initiated ground operations in the Gaza Strip. It is possible that other terrorist and/or regional organizations will join the hostilities as well, including Hezbollah in Lebanon, and Palestinian military organizations in the West Bank, resulting in a widening of the conflict. The intensity and duration of Israel's current war against Hamas is difficult to predict as are such war's economic implications on the global economy.

Furthermore, because of current geopolitical tensions, the Biden administration has recently signed multiple executive orders regarding China. One particular executive order titled Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, signed on September 12, 2022, will likely impact the pharmaceutical industry to encourage U.S. domestic manufacturing of pharmaceutical products. Moreover, there have been Congressional legislative proposals, such as the recent bill titled the Biosecure Act, to discourage contracting with Chinese companies on the development or manufacturing of pharmaceutical products. Any additional executive orders or legislative action regarding or potential sanctions on China could materially impact our current manufacturing partners.

Although our business has not been materially impacted by these geopolitical tensions to date, such matters may affect our business and it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which such matters may impact our business. The extent and duration of the military action, sanctions 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.

The U.S. political and economic environment could materially impact our business operations and financial performance, and uncertainty surrounding the potential legal, regulatory and policy changes by a new U.S. presidential administration may directly affect us and the global economy.

The political and economic environment in the U.S. and elsewhere has resulted in and will continue to result in some uncertainty. Changing regulatory policies because of the changing political environment could impact our regulatory and compliance costs and future revenues, all of which could materially and adversely affect our business, financial condition and operating results. Failure to adapt to or comply with evolving regulatory requirements or investor or stakeholder expectations and standards could negatively impact our reputation, ability to do business with certain partners, access to capital and our stock price.

Further, a change in the U.S. presidential administration and congressional seat turnover following the 2024 election cycle may result in increased regulatory and economic uncertainty. Changes in federal policy by the executive branch and regulatory agencies may occur over time through the new presidential administration's and/or Congress's policy and

personnel changes, which could lead to changes involving the level of oversight and focus on the pharmaceutical industry; however, the nature, timing and economic and political effects of such potential changes remain highly uncertain. Any future changes in federal and state laws and regulations, as well as the interpretation and implementation of such laws and regulations, could affect us in substantial and unpredictable ways. At this time, it is unclear what laws, regulations and policies may change and whether future changes or uncertainty surrounding future changes will adversely affect our operating environment and therefore our business, financial condition and results of operations.

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, or 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.

We are subject to risks related to information technology systems, including cyber-security risks; successful cyber-attacks or technological malfunctions can result in, among other things, financial losses, the inability to process transactions, the unauthorized release of confidential information and reputational risk, all of which would negatively impact our business, financial condition or results of operations.

Our use of technology is critical to our continued operations. We are susceptible to operational, financial and information security risks resulting from cyber-attacks or technological malfunctions. Successful cyber-attacks or technological malfunctions affecting us, our CMOS or our business partners can result in, among other things, financial losses, the inability to process transactions, the unauthorized release of confidential or proprietary information and reputational risk. As cybersecurity threats continue to evolve, we may be required to use additional resources to continue to modify or enhance protective measures or to investigate security vulnerabilities, which could have a material adverse effect on our business, financial condition or results of operations.

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. We also plan to conduct clinical trials and may in the future conduct business in jurisdictions outside of the United States, which may cause us to become subject to transparency law and privacy regulations in those jurisdictions as well.

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

- The federal Anti-Kickback Statute, or 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, or the 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 FCA. 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 Section 5(a) of the Federal Trade Commission Act, the Federal Trade Commission 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 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. In addition, if we engage in business activities outside of the United States, including clinical trials that we plan to conduct outside of the United States, we may become subject to privacy and data security laws in those additional jurisdictions in which we operate or conduct clinical trials.

- 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, or the 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, 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, 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.

Recently enacted and future legislation and other legal developments may increase the difficulty and cost for us to obtain marketing approval of and commercialize our products and product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our product candidates are the following:

- establishment of a new pathway for approval of lower-cost biosimilars to compete with biologic products;
- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, enacted in August 2011, required sequestration that included aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2032, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will increase in future years of the sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' Medicaid Drug Rebate Program rebate liability, effective January 1, 2024. Under current law enacted as part of the ACA, drug manufacturers' Medicaid Drug Rebate Program rebate liability is capped at 100% of the average manufacturer price for a covered outpatient drug. We expect that other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to price our products at what we consider to be a fair or competitive price, generate revenue, attain profitability, or commercialize our product candidates, if approved.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly active in implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. In response to the executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our ability to price our products appropriately, which could negatively impact our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

There is also a great degree of uncertainty regarding how the recent U.S. Supreme Court decisions, including Loper Bright Enterprises v. Raimondo, 603 U.S. ___ (2024) and Corner Post, Inc. v. Board of Governors of the Federal Reserve System, 603 U.S. ___ (2024), will impact FDA's enforcement and decision-making authority. Loper Bright explicitly overturned Chevron deference, which previously gave judicial deference to administrative action by agencies in the executive branch. United Therapeutics has raised the U.S. Supreme Court's abolishment of Chevron deference as a rationale for overturning PTAB's invalidation of the '793 Patent. Further, the Supreme Court's decision in Corner Post may result in challenges to FDA decisions by new litigants long into the future, resulting in greater uncertainty about our continued 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, or 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.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects.

We believe that climate change has the potential to negatively affect our business and results of operations, cash flows and prospects. We are exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well-being) associated with climate change. These risks can be either acute (short-term) or chronic (long-term).

The adverse impacts of climate change include increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat. Extreme weather and sea-level rise pose physical risks to our facilities as well as those of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption caused by such natural disasters and extreme weather events. Other potential physical impacts due to climate change include reduced access to high-quality water in certain regions and the loss of biodiversity, which could impact future product development. These risks could disrupt our operations and its supply chain, which may result in increased costs.

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us.

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 5. Other Information

Rule 10b5-1 Trading Plans

During the three months ended June 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any "non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K.

During the three months ended June 30, 2024, the Company did not adopt or terminate a Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K).

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 No.	Document
3.1	Certificate of Second Amendment of Certificate of Incorporation of Liquidia Corporation (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed with the SEC on June 21, 2024).
10.1	Liquidia Corporation Amended and Restated Executive Severance and Change in Control Plan (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on May 14, 2024).
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 7, 2024

LIQUIDIA CORPORATION

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

DATE: August 7, 2024

LIQUIDIA CORPORATION

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