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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 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: 001-36485

ARDELYX, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**26-1303944**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No)
400 Fifth Avenue, Suite 210, Waltham, Massachusetts	**02451**
(Address of Principal Executive Offices)	(Zip Code)

(510) 745-1700
(Registrant's Telephone Number, Including Area Code)

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, par value $0.0001	ARDX	The Nasdaq Global Market

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, or 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 Exchange Act). Yes ☐ No ☒

The number of issued and outstanding shares of the registrant's Common Stock, $0.0001 par value per share, as of October 25, 2024, was 236,854,270.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

Unless the context requires otherwise, in this Quarterly Report on Form 10-Q the terms “Ardelyx”, “we,” “us,” “our” and “the Company” refer to Ardelyx, Inc.

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would,” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- whether any legislative, regulatory or judicial action is taken to further delay or prevent the inclusion of XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, into the ESRD prospective payment system (ESRD PPS) which would otherwise occur on January 1, 2025;
- the adequacy of reimbursement and coverage of XPHOZAH beginning January 1, 2025 for all patients, regardless of insurance coverage, in the event that legislative, regulatory or judicial action to further delay or prevent the inclusion of oral only drugs in the ESRD PPS is not taken;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital; and
- other risks and uncertainties, including those under the caption “Risk Factors.”

We have based these forward-looking statements largely on management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management’s beliefs and assumptions, and these forward-looking statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the “ITEM 1A. RISK FACTORS” section and elsewhere in this Quarterly Report on Form 10-Q. Except as required by law, we assume no obligation to update any forward-looking statement publicly, or to revise any forward-looking statement to reflect events or developments occurring after the date of this Quarterly Report on Form 10-Q, even if new information becomes available in the future. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in any such forward-looking statement.

SUMMARY OF PRINCIPAL RISKS ASSOCIATED WITH OUR BUSINESS

The principal risks and uncertainties affecting our business include the following:

- We have incurred losses in each year since our inception, and we expect to continue to incur operating losses in the future as we commercialize IBSRELA® and XPHOZAH®, incur manufacturing and development costs for tenapanor, and incur additional expenses related to our ongoing operations and our pursuit of future business opportunities and incur research and development costs.
- We will require additional financing for the foreseeable future as we invest in the commercialization of IBSRELA and XPHOZAH in the U.S. and incur additional expenses related to our ongoing operations. The inability to access necessary capital when needed on acceptable terms, or at all, could force us to reduce our efforts to commercialize IBSRELA or XPHOZAH, or to delay or limit our pursuit of other future business opportunities.
- We have generated limited revenue from product sales and may never be profitable for a full fiscal year.
- We are substantially dependent on the successful commercialization of IBSRELA, and there is no guarantee that we will maintain sufficient market acceptance for IBSRELA, grow market share for IBSRELA, secure and maintain adequate coverage and reimbursement for IBSRELA, or generate sufficient revenue from product sales of IBSRELA.
- There is no guarantee that we will achieve sufficient market acceptance for XPHOZAH, secure and maintain adequate coverage and reimbursement for XPHOZAH, or generate sufficient revenue from product sales of XPHOZAH.
- In the event that legislative, regulatory or judicial action to further delay or prevent the inclusion of oral only drugs in the ESRD prospective payment system (ESRD PPS) is not taken, XPHOZAH will become part of the ESRD PPS on January 1, 2025, after which time, coverage for XPHOZAH for Medicare beneficiaries will no longer be available under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted.

- IBSRELA and/or XPHOZAH may cause undesirable side effects or have other properties that could limit the commercial success of the product.
- Third-party payor coverage and reimbursement status of newly commercialized products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for IBSRELA and XPHOZAH could limit our ability to market those products and decrease our ability to generate revenue.
- We rely completely on third parties, including certain single-source suppliers, to manufacture IBSRELA and XPHOZAH. If they are unable to comply with applicable regulatory requirements, unable to source sufficient raw materials, experience manufacturing or distribution difficulties or are otherwise unable to manufacture sufficient quantities to meet demand, our commercialization of IBSRELA and XPHOZAH may be materially harmed.
- Our future results depend on contract manufacturing organizations (CMOs), many of whom are our single source manufacturers.
- Our operating activities may be restricted as a result of covenants related to the indebtedness under our loan and security agreement with SLR Investment Corp. (SLR), as amended, and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

The summary risk factors described above should be read together with the text of the full risk factors below in the section entitled “Risk Factors” and the other information set forth in this Quarterly Report on Form 10-Q, including our financial statements and the related notes, as well as in other documents that we file with the U.S. Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

NOTE REGARDING TRADEMARKS

ARDELYX®, IBSRELA®, and XPHOZAH® are trademarks of Ardelyx. All other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

ARDELYX, INC.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ARDELYX, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)

	September 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 47,429	$ 21,470
Short-term investments	142,973	162,829
Accounts receivable	53,195	22,031
Inventory	11,378	12,448
Prepaid commercial manufacturing	16,663	18,925
Prepaid expenses and other current assets	12,460	8,408
Total current assets	284,098	246,111
Inventory, non-current	73,780	37,039
Prepaid commercial manufacturing, non-current	—	4,235
Right-of-use assets	3,625	5,589
Property and equipment, net	1,028	1,009
Other assets	5,332	3,596
Total assets	$ 367,863	$ 297,579
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 15,824	$ 11,138
Accrued compensation and benefits	11,541	12,597
Current portion of operating lease liability	2,567	4,435
Deferred revenue	7,272	7,182
Accrued expenses and other current liabilities	33,295	15,041
Total current liabilities	70,499	50,393
Operating lease liability, net of current portion	1,218	1,725
Long-term debt	100,707	49,822
Deferred revenue, non-current	12,770	8,644
Deferred royalty obligation related to the sale of future royalties	24,372	20,179
Total liabilities	209,566	130,763
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Common stock, $0.0001 par value; 500,000,000 shares authorized; 236,890,431 and 232,453,190 shares issued and outstanding as of September 30, 2024 and December 31, 2023	24	23
Additional paid-in capital	1,048,073	1,012,773
Accumulated deficit	(889,985)	(846,204)
Accumulated other comprehensive income	185	224
Total stockholders' equity	158,297	166,816
Total liabilities and stockholders' equity	$ 367,863	$ 297,579

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

ARDELYX, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Product sales, net	$ 92,090	$ 22,285	$ 208,193	$ 51,949
Product supply revenue	5,322	2,092	7,461	5,354
Licensing revenue	20	32,014	56	32,790
Non-cash royalty revenue related to the sale of future royalties	809	—	1,776	—
Total revenues	98,241	56,391	217,486	90,093
Cost of goods sold:				
Cost of product sales	1,715	644	4,133	1,508
Other cost of revenue	14,013	7,048	28,159	11,210
Total cost of goods sold	15,728	7,692	32,292	12,718
Operating expenses:				
Research and development	15,310	8,637	38,651	26,012
Selling, general and administrative	64,970	32,664	182,618	86,653
Total operating expenses	80,280	41,301	221,269	112,665
Income (loss) from operations	2,233	7,398	(36,075)	(35,290)
Interest expense	(3,357)	(1,107)	(9,039)	(3,210)
Non-cash interest expense related to the sale of future royalties	(1,924)	(922)	(5,202)	(2,859)
Other income, net	2,282	1,460	6,766	4,308
Income (loss) before provision for income taxes	(766)	6,829	(43,550)	(37,051)
Provision for income taxes	43	200	231	214
Net income (loss)	$ (809)	$ 6,629	$ (43,781)	$ (37,265)
Net income (loss) per share of common stock - basic and diluted	$ (0.00)	$ 0.03	$ (0.19)	$ (0.17)
Shares used in computing net income (loss) per share - basic	235,911,399	222,782,229	234,516,305	214,976,555
Shares used in computing net income (loss) per share - diluted	235,911,399	227,894,335	234,516,305	214,976,555
Comprehensive income (loss):				
Net income (loss)	$ (809)	$ 6,629	$ (43,781)	$ (37,265)
Unrealized gains (losses) on available-for-sale securities	286	9	(39)	(147)
Comprehensive income (loss)	$ (523)	$ 6,638	$ (43,820)	$ (37,412)

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

ARDELYX, INC.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
For the Three and Nine Months ended September 30, 2024 and 2023
(Unaudited)
(in thousands, except shares)

	Three Months Ended September 30, 2024					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of June 30, 2024	235,401,398	$ 23	$ 1,036,244	$ (889,176)	$ (101)	$ 146,990
Issuance of common stock under employee stock purchase plan	226,297	—	1,189	—	—	1,189
Issuance of common stock upon exercise of options	663,358	1	1,507	—	—	1,508
Issuance of common stock upon vesting of restricted stock units	599,378	—	—	—	—	—
Stock-based compensation	—	—	9,133	—	—	9,133
Unrealized gains on available-for-sale securities	—	—	—	—	286	286
Net loss	—	—	—	(809)	—	(809)
Balance as of September 30, 2024	236,890,431	$ 24	$ 1,048,073	$ (889,985)	$ 185	$ 158,297

	Nine Months Ended September 30, 2024					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2023	232,453,190	$ 23	$ 1,012,773	$ (846,204)	$ 224	$ 166,816
Issuance of common stock under employee stock purchase plan	479,609	—	2,227	—	—	2,227
Issuance of common stock for services	40,549	—	257	—	—	257
Issuance of common stock upon exercise of options	2,227,627	1	5,298	—	—	5,299
Issuance of common stock upon vesting of restricted stock units	1,689,456	—	—	—	—	—
Stock-based compensation	—	—	27,518	—	—	27,518
Unrealized losses on available-for-sale securities	—	—	—	—	(39)	(39)
Net loss	—	—	—	(43,781)	—	(43,781)
Balance as of September 30, 2024	236,890,431	$ 24	$ 1,048,073	$ (889,985)	$ 185	$ 158,297

	Three Months Ended September 30, 2023					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of June 30, 2023	217,862,921	$ 22	$ 947,380	$ (824,031)	$ (210)	$ 123,161
Issuance of common stock under employee stock purchase plan	269,739	—	670	—	—	670
Issuance of common stock upon exercise of options	28,227	—	40	—	—	40
Issuance of common stock upon vesting of restricted stock units	211,277	—	—	—	—	—
Issuance of common stock in at-the-market offerings	13,760,968	1	57,162	—	—	57,163
Stock-based compensation	—	—	3,489	—	—	3,489
Unrealized gains on available-for-sale securities	—	—	—	—	9	9
Net income	—	—	—	6,629	—	6,629
Balance as of September 30, 2023	232,133,132	$ 23	$ 1,008,741	$ (817,402)	$ (201)	$ 191,161

	Nine Months Ended September 30, 2023					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2022	198,575,016	$ 20	$ 878,500	$ (780,137)	$ (54)	$ 98,329
Issuance of common stock under employee stock purchase plan	435,708	—	808	—	—	808
Issuance of common stock for services	86,095	—	337	—	—	337
Issuance of common stock upon exercise of options	127,221	—	251	—	—	251
Issuance of common stock upon vesting of restricted stock units	634,351	—	—	—	—	—
Issuance of common stock in at-the-market offerings	32,274,741	3	119,245	—	—	119,248
Stock-based compensation	—	—	9,600	—	—	9,600
Unrealized losses on available-for-sale securities	—	—	—	—	(147)	(147)
Net loss	—	—	—	(37,265)	—	(37,265)
Balance as of September 30, 2023	232,133,132	$ 23	$ 1,008,741	$ (817,402)	$ (201)	$ 191,161

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

ARDELYX, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2024	2023
Operating activities		
Net loss	$ (43,781)	$ (37,265)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,548	930
Non-cash lease expense	2,973	2,690
Stock-based compensation	27,518	9,600
Non-cash interest expense	5,420	3,093
Non-cash royalty revenue related to the sale of future royalties	(1,776)	—
Other, net	(3,577)	(1,483)
Changes in operating assets and liabilities:		
Accounts receivable	(31,164)	(35,530)
Inventory	(35,671)	(19,152)
Prepaid commercial manufacturing	6,497	(3,609)
Prepaid expenses and other assets	(5,759)	(2,671)
Accounts payable	3,686	(3,123)
Accrued compensation and benefits	(1,056)	809
Operating lease liabilities	(3,388)	(2,880)
Accrued and other liabilities	19,695	6,466
Deferred revenue	4,216	1,126
Net cash used in operating activities	(54,619)	(80,999)
Investing activities		
Proceeds from maturities and redemptions of investments	120,354	36,264
Purchases of investments	(96,634)	(137,644)
Purchases of property and equipment	(418)	(301)
Net cash provided by (used in) investing activities	23,302	(101,681)
Financing activities		
Proceeds from 2022 Loan Agreement, net of issuance costs	49,750	—
Proceeds from issuance of common stock in at the market offering, net of issuance costs	—	119,248
Proceeds from issuance of common stock under equity incentive and stock purchase plans	7,526	1,059
Net cash provided by financing activities	57,276	120,307
Net increase (decrease) in cash and cash equivalents	25,959	(62,373)
Cash and cash equivalents at beginning of period	21,470	96,140
Cash and cash equivalents at end of period	$ 47,429	$ 33,767
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ 6,962	$ 2,692
Cash paid for income taxes	$ 272	$ 19
Supplementary disclosure of non-cash activities:		
Right-of-use assets obtained in exchange for lease obligations	$ 1,010	$ 339
Issuance of common stock for services	$ 257	$ 337

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

ARDELYX, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1. ORGANIZATION AND BASIS OF PRESENTATION

Ardelyx, Inc. (Company, we, us or our) is a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative first-in-class medicines that meet significant unmet medical needs. We developed a unique and innovative platform that enabled the discovery of new biological mechanisms and pathways to develop potent, and efficacious therapies that minimize the side effects and drug-drug interactions frequently encountered with traditional, systemically absorbed medicines. The first molecule we discovered and developed was tenapanor, a minimally absorbed, first-in-class, oral, small molecule therapy. Tenapanor, branded as IBSRELA®, is approved in the U.S. for the treatment of adults with irritable bowel syndrome with constipation (IBS-C). Tenapanor, branded as XPHOZAH®, is approved in the U.S. to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

We operate in one business segment, which is the development and commercialization of biopharmaceutical products.

Basis of Presentation

These condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) and pursuant to the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted. These condensed financial statements have been prepared on the same basis as our most recent annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary to present fairly our financial position, results of operations, changes in stockholders' equity, and cash flows for the interim periods presented.

The accompanying condensed financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2023. The results for the three and nine months ended September 30, 2024 are not necessarily indicative of results to be expected for the entire year ending December 31, 2024, or for any other interim period or future year.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the amounts reported in the financial statements and accompanying notes thereto. On an ongoing basis, management evaluates its estimates, including those related to recognition of revenue, clinical trial accruals, contract manufacturing accruals, expected demand for inventory, fair value of assets and liabilities, income taxes and stock-based compensation. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances. Actual results could materially differ from those estimates.

Liquidity

As of September 30, 2024, we had cash, cash equivalents and short-term investments of approximately $190.4 million. We have incurred operating losses since inception in 2007 and our accumulated deficit as of September 30, 2024 is $890.0 million. We have addressed our operating cash flow requirements through cash generated from product sales of IBSRELA and XPHOZAH, proceeds from the sale of shares of our common stock under our at-the-market offering, the receipt of milestone payments from our collaboration partners and payments from our Japanese collaboration partner under the second amendment to our License Agreement, and funds from our loan agreements with SLR Investment Corp. (SLR), as amended. We believe our available cash, cash equivalents and short-term investments as of September 30, 2024 will be sufficient to fund our planned operations for at least a period of one year from the issuance of these condensed financial statements.

Summary of Significant Accounting Policies

Our significant accounting policies are described in Note 2 to our audited financial statements for the fiscal year ended December 31, 2023, included in our Annual Report on Form 10-K. There have been no material changes in our significant accounting policies as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Recent Accounting Pronouncements

New Accounting Pronouncements - Recently Adopted

We have adopted no new accounting pronouncements subsequent to filing our most recent Annual Report on Form 10-K.

Recent Accounting Pronouncements Not Yet Adopted

In October 2023, the Financial Accounting Standards Board (FASB) issued ASU No. 2023-06, Disclosure Improvements - Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative. The amendments in this Update modify the disclosure or presentation requirements of a variety of Topics in the Codification. The amendments are in response to the U.S. Securities and Exchange Commission's (SEC) Release No. 33-10532, Disclosure Update and Simplification, in which the SEC referred certain of its disclosure requirements that overlap with, but require incremental information to, generally accepted accounting principles to the FASB for potential incorporation into the Codification. For entities subject to the SEC's existing disclosure requirements and for entities required to file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer, the effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all other entities, the amendments will be effective two years later. For all entities, if by June 30, 2027, the SEC has not removed the applicable requirement from Regulation S-X or Regulation S-K, the pending content of the related amendment will be removed from the Codification and will not become effective for any entity. Management is currently assessing the impact of this standard on the Company's financial statements.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280) - Improvements to Reportable Segment Disclosures. This Update requires publicly traded entities to provide enhanced disclosures about significant segment expenses regularly reviewed by the chief operating decision maker, including public traded entities with a single reportable segment. The amendments in this update are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. Management is currently assessing the impact of this standard on the Company's financial statements.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740) - Improvements to Income Tax Disclosures, an amendment which modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendments in this Update provide more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. For public business entities, the amendments in this Update are effective for annual periods beginning after December 15, 2024. Early adoption is permitted on a prospective basis for annual financial statements that have not yet been issued or made available for issuance. Management is currently assessing the impact of this standard on the Company's financial statements.

NOTE 2. CASH, CASH EQUIVALENTS AND INVESTMENTS

Securities classified as cash, cash equivalents and short-term investments as of September 30, 2024 and December 31, 2023 are summarized below (in thousands):

	September 30, 2024			
		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 7,560	$ —	$ —	$ 7,560
Money market funds	39,869	—	—	39,869
Total cash and cash equivalents	47,429	—	—	47,429
Short-term investments:				
U.S. government-sponsored agency bonds	$ 53,052	$ 52	$ (6)	$ 53,098
U.S. treasury securities	36,697	47	(1)	36,743
Commercial paper	30,738	54	—	30,792
Corporate bonds	17,371	37	—	17,408
Asset-backed securities	2,975	3	—	2,978
Yankee bonds	1,955	—	(1)	1,954
Total short-term investments	142,788	193	(8)	142,973
Total cash, cash equivalents and investments	$ 190,217	$ 193	$ (8)	$ 190,402

	December 31, 2023			
		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 2,829	$ —	$ —	$ 2,829
Money market funds	18,641	—	—	18,641
Total cash and cash equivalents	21,470	—	—	21,470
Short-term investments:				
U.S. government-sponsored agency bonds	$ 101,892	$ 235	$ (34)	$ 102,093
Commercial paper	49,630	41	(17)	49,654
Asset-backed securities	8,628	2	(5)	8,625
U.S. treasury securities	2,455	2	—	2,457
Total short-term investments	162,605	280	(56)	162,829
Total cash, cash equivalents and investments	$ 184,075	$ 280	$ (56)	$ 184,299

Cash equivalents consist of money market funds with original maturities of three months or less at the time of purchase, and the carrying amount is a reasonable approximation of fair value. We invest our cash in high quality securities of financial and commercial institutions. These securities are carried at fair value, which is based on readily available market information, with unrealized gains and losses included in accumulated other comprehensive income (loss) within stockholders' equity on our balance sheets. We use the specific identification method to determine the amount of realized gains or losses on sales of marketable securities. Realized gains or losses have not been significant and are included in other income, net, in the statement of operations and comprehensive income (loss).

All of our available-for sale securities held as of September 30, 2024 and December 31, 2023 had contractual maturities of less than one year. Our available-for-sale securities are subject to a periodic impairment review. We consider a debt security to be impaired when its fair value is less than its carrying cost, in which case we would further review the investment to determine whether it is other-than-temporarily impaired. When we evaluate an investment for other-than-temporary impairment, we review factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, intent to sell, and whether it is more likely than not we will be required to sell the investment before the recovery of its cost basis. If an investment is other-than-temporarily impaired or subject to credit losses, we write it down through the statement of operations and comprehensive income (loss) to its fair value and establish that value as a new cost basis for the investment. Our unrealized losses as of September 30, 2024 and December 31, 2023 were not material. We determined that none of our available-for-sale securities were other-than-temporarily impaired as of September 30, 2024 and December 31, 2023, and no investment was in a continuous unrealized loss position for more than one year. As such, we believe that it is more likely than not that the investments will be held until maturity or a forecasted recovery of fair value.

NOTE 3. FAIR VALUE MEASUREMENTS

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

Level 1 – Valuations are based on quoted prices in active markets for identical assets or liabilities and readily accessible by us at the reporting date.

Level 2 – Valuations based on inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Valuations based on unobservable inputs for which there is little or no market data, which require us to develop our own assumptions.

The following table sets forth the fair value of our financial assets and liabilities that are measured or disclosed on a recurring basis by level within the fair value hierarchy (in thousands):

	September 30, 2024			
	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 39,869	$ 39,869	$ —	$ —
U.S. government-sponsored agency bonds	53,098	—	53,098	—
U.S. treasury securities	36,743	—	36,743	—
Commercial paper	30,792	—	30,792	—
Corporate bonds	17,408	—	17,408	—
Asset-backed securities	2,978	—	2,978	—
Yankee bonds	1,954	—	1,954	—
Total	$ 182,842	$ 39,869	$ 142,973	$ —

	December 31, 2023			
	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 18,641	$ 18,641	$ —	$ —
U.S. government-sponsored agency bonds	102,093	—	102,093	—
Commercial paper	49,654	—	49,654	—
Asset-backed securities	8,625	—	8,625	—
U.S. treasury securities	2,457	—	2,457	—
Total	$ 181,470	$ 18,641	$ 162,829	$ —
Liabilities:				
Derivative liability for exit fees	$ 675	$ —	$ —	$ 675
Total	$ 675	$ —	$ —	$ 675

Where quoted prices are available in an active market, securities are classified as Level 1. We classify money market funds as Level 1. When quoted market prices are not available for the specific security, we estimate fair value by using benchmark yields, reported trades, broker/dealer quotes and issuer spreads. We classify U.S. government-sponsored agency bonds, U.S. treasury securities, commercial paper, corporate bonds, asset-backed securities, and Yankee bonds as Level 2. In certain cases, where there is limited activity or less transparency around inputs to valuation, securities or derivative liabilities, such as the 2022 Exit Fee valuation as of December 31, 2023, as defined and discussed in *Note 9. Derivative Liabilities*, are classified as Level 3. The conditions for payment of the 2022 Exit Fee were met at the measurement date of June 30, 2024 and it was therefore valued at its full contractual amount of $1.0 million as of that date. The 2022 Exit Fee was included in accounts payable and accrued liabilities on the accompanying condensed balance sheets at $1.0 million and $0.7 million as of September 30, 2024 and December 31, 2023, respectively.

The carrying amounts reflected in the condensed balance sheets for accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values at both September 30, 2024 and December 31, 2023 due to their short-term nature.

Based on our procedures under the expected credit loss model, including an assessment of unrealized losses in our portfolio, we concluded that any unrealized losses on our marketable securities were not attributable to credit and, therefore, we have not recorded an allowance for credit losses for these securities as of September 30, 2024 and December 31, 2023.

Fair Value of Debt

The principal amount outstanding under our term loan facilities is subject to a variable interest rate. Therefore, we believe the carrying amount of the term loan facility approximates fair value as of September 30, 2024 and December 31, 2023. See *Note 8. Borrowing* for a description of the Level 2 inputs used to estimate the fair value of the liability.

The carrying value of the deferred royalty obligation related to the sale of future royalties approximates its fair value as of September 30, 2024 and December 31, 2023 and is based on our current estimates of future royalties and commercialization milestones expected to be paid to us by Kyowa Kirin Co., Ltd. (Kyowa Kirin) over the life of the agreement. See *Note 7. Deferred Royalty Obligation Related to the Sale of Future Royalties* for a description of the Level 3 inputs used to estimate the fair value of the liability.

NOTE 4. INVENTORY

Inventory as of September 30, 2024 and December 31, 2023 consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Raw materials	$ 25,992	$ 22,920
Work in process	57,335	24,582
Finished goods	1,831	1,985
Total	$ 85,158	$ 49,487
Reported as:		
Inventory	$ 11,378	$ 12,448
Inventory, non-current	73,780	37,039
Total	$ 85,158	$ 49,487

In addition to inventory, we had prepaid commercial manufacturing of $16.7 million and $23.2 million as of September 30, 2024 and December 31, 2023, respectively, which consisted of prepayments to third party contract manufacturing organizations, including prepayments of zero and $4.2 million as of September 30, 2024 and December 31, 2023 that are expected to be converted into inventory after 12 months.

NOTE 5. REVENUE

Total revenues during the three and nine months ended September 30, 2024 and 2023 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Product sales, net:				
IBSRELA	$ 40,638	$ 22,285	$ 104,444	$ 51,949
XPHOZAH	51,452	—	103,749	—
Total product sales, net	92,090	22,285	208,193	51,949
Product supply revenue	5,322	2,092	7,461	5,354
Licensing revenue	20	32,014	56	32,790
Non-cash royalty revenue related to the sale of future royalties	809	—	1,776	—
Total revenues	$ 98,241	$ 56,391	$ 217,486	$ 90,093

Revenue from customers who contributed greater than 10% of our total gross product revenue during the three and nine months ended September 30, 2024 and 2023 was as follows (as a percentage of total gross product revenue):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
BioRidge Pharma, LLC	53.4 %	19.5 %	49.3 %	19.2 %
AmerisourceBergen Drug Corporation	14.0 %	21.2 %	15.1 %	21.3 %
Cardinal Health	12.6 %	22.2 %	13.8 %	22.3 %
McKesson Corporation	13.2 %	18.4 %	13.2 %	19.0 %

The activities and ending reserve balances for each significant category of discounts and allowances, which constitute variable consideration, were as follows (in thousands):

	Discounts and Chargebacks	Rebates, Wholesaler and GPO Fees	Copay and Returns	Total
Balance as of December 31, 2023	$ 478	$ 4,234	$ 3,916	$ 8,628
Provisions	10,074	43,398	20,390	73,862
Credits/payments	(8,974)	(33,925)	(16,271)	(59,170)
Balance as of September 30, 2024	$ 1,578	$ 13,707	$ 8,035	$ 23,320

Adjustments to prior period provisions recorded in the current period were not material.

NOTE 6. COLLABORATION AND LICENSING AGREEMENTS

Kyowa Kirin Co., Ltd. (Kyowa Kirin)

In November 2017, we entered into an exclusive license agreement with Kyowa Kirin (2017 Kyowa Kirin Agreement), under which we granted Kyowa Kirin an exclusive license to develop and commercialize certain NHE3 inhibitors including tenapanor in Japan for the treatment of cardiorenal diseases and conditions, excluding cancer. We retained the rights to tenapanor outside of Japan, and also retained the rights to tenapanor in Japan for indications other than those stated above. Pursuant to the 2017 Kyowa Kirin Agreement, Kyowa Kirin is responsible for all costs and expenses incurred in the development and commercialization of tenapanor for all licensed indications in Japan. We are responsible for supplying the tenapanor drug substance for Kyowa Kirin's use in development and commercialization throughout the term of the 2017 Kyowa Kirin Agreement, provided that Kyowa Kirin may exercise an option to manufacture the tenapanor drug substance under certain conditions. In October 2022, we entered into a Commercial Supply Agreement with Kyowa Kirin to further define the obligations of the parties with respect to the commercial supply of tenapanor drug substance (2022 Kyowa Kirin Supply Agreement). As detailed below under the heading *Deferred Revenue* we have received advanced payments from Kyowa Kirin for the manufacturing of tenapanor drug substance that will be used to satisfy Kyowa Kirin needs.

We assessed these arrangements in accordance with Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606) and related amendments (ASC 606) and concluded that the contract counterparty, Kyowa Kirin, is a customer. Under the terms of the 2017 Kyowa Kirin Agreement, we received $30.0 million in upfront license fees, which was recognized as revenue when the agreement was executed. Based on our assessment, management determined that the license and the manufacturing supply services were its material performance obligations at the inception of the 2017 Kyowa Kirin Agreement, and as such, each of the performance obligations is distinct.

We may be entitled to receive up to $55.0 million in total development and regulatory milestones, of which $35.0 million has been received and recognized as revenue as of September 30, 2024. We may also be eligible to receive approximately ¥8.5 billion for commercialization milestones, or approximately $59.8 million at the currency exchange rate on September 30, 2024, as well as reimbursement of costs plus a reasonable overhead for the supply of product and royalties on net sales throughout the term of the agreement. As discussed in *Note 7. Deferred Royalty Obligation Related to the Sale of Future Royalties*, the future royalties and commercial milestone payments we may receive under the 2017 Kyowa Kirin Agreement are remitted to HealthCare Royalty Partners IV, L.P. (HCR) upon receipt pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement (HCR Agreement). The variable consideration related to the remaining milestone payments was fully constrained at September 30, 2024.

In April 2022, we entered into a second amendment to the 2017 Kyowa Kirin Agreement (2022 Amendment). Under the terms of the 2022 Amendment, we and Kyowa Kirin agreed to a reduction in the royalty rate payable to us by Kyowa Kirin upon net sales of tenapanor for hyperphosphatemia in Japan. The royalty rate will be reduced from the high teens to low double digits for a two-year period of time following the first commercial sale in Japan, and then to mid-single digits for the remainder of the royalty term. As discussed in *Note 7. Deferred Royalty Obligation Related to the Sale of Future Royalties*, the future commercial milestones and royalties we may receive under the 2017 Kyowa Kirin Agreement will be remitted to HCR pursuant to the HCR Agreement. As consideration for the reduction in the royalty rate, Kyowa Kirin agreed to pay us up to an additional $40.0 million payable in two tranches, with the first payment due following Kyowa Kirin's filing with the Japanese Ministry of Health, Labour and Welfare (MHLW) of its application for marketing approval for tenapanor and the second payment due following Kyowa Kirin’s receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan, both of which occurred as of September 30, 2023.

In October 2022, we announced that Kyowa Kirin submitted a New Drug Application (NDA) to the Japanese MHLW for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $35.0 million for milestone payments and payments under the 2022 Amendment. We received these payments during the fourth quarter of 2022 and recorded them as licensing revenue on our condensed statement of operations and comprehensive income (loss).

In September 2023, we announced that Kyowa Kirin received approval from the Japanese MHLW for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $30.0 million for milestone payments and payments under the 2022 Amendment. We received these payments in October 2023 and recorded them as licensing revenue on our condensed statement of operations and comprehensive income (loss) when earned during the three months ended September 30, 2023. In February 2024, Kyowa Kirin announced the launch of tenapanor, marketed as PHOZEVEL®, for patients in Japan. During the three and nine months ended September 30, 2024, we recognized $0.8 million and $1.8 million, respectively, of non-cash royalty revenue related to the sale of future royalties which we remit to HCR upon receipt in accordance with the HCR Agreement.

During the three and nine months ended September 30, 2024, we recognized $5.3 million and $7.5 million, respectively, of product supply revenue pursuant to the 2017 Kyowa Kirin Agreement. During the three and nine months ended September 30, 2023, we recognized $2.1 million and $5.4 million, respectively, of product supply revenue pursuant to the 2017 Kyowa Kirin Agreement.

Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (Fosun Pharma)

In December 2017, we entered into an exclusive license agreement with Fosun Pharma (Fosun Agreement) for the development, commercialization and distribution of tenapanor in China for both hyperphosphatemia and IBS-C. We assessed these arrangements in accordance with ASC 606 and concluded that the contract counterparty, Fosun Pharma, is a customer. Under the terms of the Fosun Agreement, we received $12.0 million in upfront license fees which was recognized as revenue when the agreement was executed. Based on our assessment, we determined that the license and the manufacturing supply services represented the material performance obligations at the inception of the agreement and, as such, each of the performance obligations are distinct.

We may be entitled to receive development and commercialization milestones of up to $113.0 million, of which $8.0 million has been received and recognized as revenue as of September 30, 2024, as well as reimbursement of cost plus a reasonable overhead for the supply of product and tiered royalties on net sales ranging from the mid-teens to 20%. The variable consideration related to the remaining development milestone payments was fully constrained at September 30, 2024.

In July 2023, we announced that an NDA for tenapanor had been accepted for review by China’s Center for Drug Evaluation of the National Medical Products Administration (NMPA) for the control of serum phosphorus in adult patients with CKD on hemodialysis. This acceptance triggered a $2.0 million milestone payment to us under the terms of the Fosun Agreement. We received this payment during the third quarter of 2023 and recorded it as licensing revenue on our condensed statement of operations and comprehensive income (loss) when earned during the three months ended September 30, 2023. In October 2023, we announced that the U.S. FDA had approved XPHOZAH to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. This triggered an additional $3.0 million milestone payment to us under the terms of the Fosun Agreement, which was received during the first quarter of 2024. Also, in October 2023, we announced that Fosun Pharma received approval from the Hong Kong Department of Health for the marketing application for tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C).

During the three and nine months ended September 30, 2024, we did not recognize a material amount of revenue pursuant to the Fosun Agreement. During the three and nine months ended September 30, 2023, we recognized $2.0 million of licensing revenue pursuant to the Fosun Agreement.

Knight Therapeutics, Inc. (Knight)

In March 2018, we entered into an exclusive license agreement with Knight Therapeutics, Inc., (Knight Agreement) for the development, commercialization and distribution of tenapanor in Canada for hyperphosphatemia and IBS-C. We assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Knight, is a customer. Based on our assessment, we determined that the license and the manufacturing supply services were the material performance obligations at the inception of the agreement and, as such, each of the performance obligations are distinct.

Under the terms of the Knight Agreement, we received a $2.3 million non-refundable, one-time upfront payment in March 2018 and may be eligible to receive additional development and commercialization milestone payments worth up to CAD 22.2 million, or approximately $16.4 million at the currency exchange rate on September 30, 2024, of which $0.7 million has been received and recognized as revenue as of September 30, 2024. We are also eligible to receive royalties ranging from the mid-single digits to the low twenties throughout the term of the agreement, and a transfer price for manufacturing services. The variable consideration related to the remaining development milestone payments was fully constrained at September 30, 2024.

During the three and nine months ended September 30, 2024 and 2023, we did not recognize a material amount of revenue pursuant to the Knight Agreement.

AstraZeneca AB (AstraZeneca)

In June 2015, we entered into a termination agreement with AstraZeneca (AstraZeneca Termination Agreement) pursuant to which we have agreed to pay AstraZeneca (i) future royalties at a royalty rate of 10% of net sales of tenapanor or other NHE3 products by us or our licensees, and (ii) 20% of non-royalty revenue received from a new collaboration partner should we elect to license, or otherwise provide rights to develop and commercialize tenapanor or other NHE3 products, up to a maximum of $75.0 million in aggregate for (i) and (ii). As of September 30, 2024, to date in aggregate, we have recognized $50.3 million of the $75.0 million, which has been recorded as other cost of revenue on our condensed statements of operations and comprehensive income (loss). During the three and nine months ended September 30, 2024, we recognized $10.0 million and $22.7 million, respectively, as other cost of revenue related to the AstraZeneca Termination Agreement. During the three and nine months ended September 30, 2023 we recognized $5.7 million and $8.7 million, respectively, as other cost of revenue related to the AstraZeneca Termination Agreement.

Deferred Revenue

The following tables present changes in our current and non-current deferred revenue balances during the reporting period, which are all attributable to the 2017 Kyowa Kirin Agreement (in thousands):

	2024		2023	
	Current	Non-Current	Current	Non-Current
Balance at January 1,	$ 7,182	$ 8,644	$ 4,211	$ 9,025
Amounts invoiced as prepayments for product supply	2,654	8,212	1,182	4,530
Decrease for revenue recognized for product supply	(6,650)	—	(4,586)	—
Reclassify amounts to be recognized in the next twelve months	4,086	(4,086)	3,265	(3,265)
Balance at September 30,	$ 7,272	$ 12,770	$ 4,072	$ 10,290

NOTE 7. DEFERRED ROYALTY OBLIGATION RELATED TO THE SALE OF FUTURE ROYALTIES

In June 2022, we and HealthCare Royalty Partners IV, L.P. (HCR) entered into a Royalty and Sales Milestone Interest Acquisition Agreement (HCR Agreement). Under the terms of the HCR Agreement, HCR has agreed to pay us up to $20.0 million in exchange for the royalty payments and commercial milestone payments (collectively, the Royalty Interest Payments) that we may receive under our 2017 License Agreement with Kyowa Kirin based upon Kyowa Kirin's net sales of tenapanor in Japan for hyperphosphatemia. As consideration for the sale of the Royalty Interest Payments, HCR paid to us a $10.0 million upfront payment in June 2022 and a $5.0 million payment, which we received in October 2023, as a result of Kyowa Kirin's receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan. We are eligible to receive another $5.0 million payment in the event net sales by Kyowa Kirin in Japan exceed a certain annual target level by the end of 2025.

The HCR Agreement is effective until terminated by the mutual agreement of the parties and contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to prosecution, maintenance, defense and enforcement of certain patent rights in Japan, restrictions regarding our ability to forgive, release or reduce any Royalty Interest Payments due to us under the 2017 Kyowa Kirin Agreement, to create or incur any liens with respect to the Royalty Interest Payments, the 2017 Kyowa Kirin Agreement or certain patents, or to sell, license or transfer certain patents in the field and territory described in the 2017 Kyowa Kirin Agreement.

In addition, the HCR Agreement contains customary events of default with respect to which we may incur indemnification obligations to HCR for any losses incurred by HCR and related parties as a result of the event of default, subject to a specified limitation of liability cap. Under the HCR Agreement, an event of default will occur if, among other things, any of the representations and warranties included in the HCR Agreement proves not to have been true and correct in all material respects, at the time it was made, we breach any of our covenants under the HCR Agreement, subject to specified cure periods with respect to certain breaches, we are in breach or default under the 2017 Kyowa Kirin Agreement in any manner which is likely to cause a material adverse effect on the Royalty Interest Payments, the occurrence of a termination of the 2017 Kyowa Kirin Agreement under certain circumstances or we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings, or we are unable to pay our debts as they become due.

The $10.0 million upfront payment from HCR received in June 2022 and the $5.0 million payment received in October 2023 have been recorded as a deferred royalty obligation related to the sale of future royalties (deferred royalty obligation) on our balance sheets. Due to our ongoing manufacturing obligations under the 2017 Kyowa Kirin Agreement, we account for the proceeds as imputed debt and therefore will recognize royalties earned under the arrangement as non-cash royalty revenue. Non-cash interest expense will be recognized over the life of the HCR Agreement using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of future royalty payments to be received from Kyowa Kirin. As part of the sale, we incurred approximately $0.4 million in transaction costs, which, along with the deferred royalty obligation, are being amortized to non-cash interest expense over the estimated life of the HCR Agreement using the effective interest method. As future royalties are remitted to us by Kyowa Kirin, and subsequently from us to HCR, the balance of the deferred royalty obligation will be effectively repaid over the life of the HCR Agreement. There are a number of factors that could materially affect the fair value of the deferred royalty obligation. Such factors include, but are not limited to, the amount and timing of potential future royalty payments to be received from Kyowa Kirin under the 2017 Kyowa Kirin agreement, changing standards of care, the introduction of competing products, manufacturing or other delays, intellectual property matters, adverse events that result in governmental health authority imposed restrictions on the use of the drug products, significant changes in foreign exchange rates as the royalties remitted to HCR are made in U.S. dollars while the underlying sales of the products by Kyowa Kirin are made in Japanese yen, and other events or circumstances that could result in reduced royalty payments from Kyowa Kirin, which are not within our control, and all of which would result in a reduction of non-cash royalty revenues and the non-cash interest expense over the life of the deferred royalty obligation. We periodically assess the estimated royalty payments from Kyowa Kirin and, to the extent that the amount or timing of such payments is materially different than our original estimates, we prospectively adjust the imputed interest rate and the related amortization of the deferred royalty obligation. As of September 30, 2024, our effective interest rate used to amortize the liability is 33.3%. During the three and nine months ended September 30, 2024, we recognized $1.9 million and $5.2 million, respectively, of non-cash interest expense related to the deferred royalty obligation. During the three and nine months ended September 30, 2023, we recognized $0.9 million and $2.9 million, respectively, of non-cash interest expense related to the deferred royalty obligation. As of September 30, 2024, we have received $1.0 million royalty payments from Kyowa Kirin and the deferred royalty obligation has been reduced accordingly.

NOTE 8. BORROWING

Solar Capital and Western Alliance Bank Loan Agreement

In May 2018, we entered into a loan and security agreement (as amended on October 9, 2020, March 1, 2021, May 5, 2021, and July 29, 2021) (2018 Loan Agreement) with Solar Capital Ltd. and Western Alliance Bank (collectively, the 2018 Lenders). The 2018 Loan Agreement provided for a loan facility for up to $50.0 million with a maturity date of November 1, 2022 (2018 Loan). As of the Closing Date for the 2022 Loan, as discussed below, we owed $25.0 million in principal payments from the 2018 Loan, which we repaid in full at that time.

As discussed in *Note 9. Derivative Liabilities*, in connection with entering into the 2018 Loan Agreement, we entered into an agreement pursuant to which we agreed to pay $1.5 million in cash upon the occurrence of certain conditions (2018 Exit Fee). Our obligations for the 2018 Exit Fee remained outstanding following the full repayment of the 2018 Loan in February 2022 until October 2023 when we received approval from the U.S. FDA for XPHOZAH to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. This triggered our obligation to pay the 2018 Exit Fee to the 2018 Lenders and we subsequently paid the 2018 Exit Fee in October 2023.

SLR Investment Corp. Loan Agreement

On February 23, 2022 (Closing Date), we entered into a loan and security agreement (2022 Loan Agreement) with SLR Investment Corp. as collateral agent (Agent or SLR), and the lenders listed in the 2022 Loan Agreement (collectively, the 2022 Lenders). The 2022 Loan Agreement was subsequently amended in August 2022 (the First Amendment), February 2023 (the Second Amendment) and October 2023 (the Third Amendment). We concluded that the First Amendment, the Second Amendment and the Third Amendment were each modifications to the 2022 Loan Agreement.

The 2022 Loan Agreement, as amended by the First Amendment and the Second Amendment, provided for a senior secured loan facility, with $27.5 million (Term A Loan) funded on the Closing Date and an additional $22.5 million which was funded upon our election in October 2023 (Term B Loan, and together with the Term A Loan, the 2022 Original Loans). The 2022 Term A Loan funds were used to repay the 2018 Loan with the 2018 Lenders.

The Third Amendment, among other things, (1) provided us with the option to draw an additional $50.0 million of committed capital by March 15, 2024 (the Term C Loan) provided we have drawn the Term B Loan; and (2) provided us with the option to draw up to an additional $50.0 million of uncommitted capital by December 31, 2026, subject to approval by the Agent’s investment committee (the Term D Loan). In February 2024, we provided the Agent with notice of our decision to draw the Term C Loan to support the commercial launch of XPHOZAH and received the proceeds of the Term C Loan in March 2024.

As discussed in *Note 15. Subsequent Events*, on October 29, 2024, we entered into a Fourth Amendment (the Fourth Amendment) to the 2022 Loan Agreement by and between us and the 2022 Lenders. The Fourth Amendment, among other things, (1) provided for the immediate draw of the Term D Loan in a principal amount of $50.0 million on the closing date of the Fourth Amendment and (2) provides us with the option to draw an additional $50.0 million of committed capital by June 30, 2025 (the Term E Loan and together with the Term A, B, C and D Loans, the Five 2022 Loans).

Under the Fourth Amendment, the maturity date for the Five 2022 Loans is extended from March 1, 2027 to July 1, 2028 (the Maturity Date). The interest rate for each of the Term A Loan and the Term B Loan is 7.95% plus a SOFR value equal to 0.022% plus the 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator’s Website, subject to a SOFR floor of one percent. The interest rate for the Term C Loan is 4.25% plus a SOFR value equal to 0.022% plus the 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator’s Website, subject to a SOFR floor of 4.7%. The interest rate for each of the Term D Loan and the Term E Loan is 4.00% plus a SOFR value equal to 0.022% plus the 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website, subject to a SOFR floor of 4.7%.

In addition, pursuant to the Fourth Amendment, the period under which we are permitted to make interest-only payments on the Five 2022 Loans was extended to the Maturity Date.

We paid fees of $0.2 million, upon the closing of the Term A Loan, $0.1 million on the funding date of the Term B Loan, $0.3 million on the funding date of the Term C Loan and $0.3 million on the funding date of the Term D Loan in October 2024. In addition, we will be obligated to pay 0.5% of the aggregate original principal amount of the Term E Loan commitment, which shall be due on the earliest of (1) the funding of the Term E Loan, (2) June 30, 2025, and (3) the prepayment, refinancing, substitution or replacement of any of the Five 2022 Loans on or prior to the date immediately preceding June 30, 2025.

We are obligated to pay a final fee equal to 4.95% of the aggregate original principal amount of the Five 2022 Loans, to the extent such loans are funded, upon the earliest to occur of the maturity date, the acceleration of the Five 2022 Loans, and the prepayment, refinancing, substitution, or replacement of the Five 2022 Loans.

We may voluntarily prepay all amounts outstanding under the Five 2022 Loans, subject to a prepayment premium of (i) 3% of the outstanding principal amount of the Five 2022 Loans if prepaid prior to or on October 17, 2024, (ii) 2% of the outstanding principal amount of the Five 2022 Loans if prepaid after October 17, 2024 through and including October 17, 2025, or (iii) 1% of the outstanding principal amount of the Five 2022 Loans if prepaid after October 17, 2025 and prior to the maturity date. The Five 2022 Loans are secured by substantially all of our assets, except for our intellectual property and certain other customary exclusions. Additionally, as discussed in *Note 9. Derivative Liabilities*, in connection with the 2022 Original Loans, we entered into an agreement whereby we agreed to pay an exit fee in the amount of 2% of the 2022 Original Loans funded (2022 Exit Fee). We paid the 2022 Exit Fee to the Lender in October 2024.

The 2022 Loan Agreement, as amended, contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock or to redeem capital stock. We have agreed to not allow our cash, cash equivalents and available-for-sale investments to be less than the eighty percent (80%) of the outstanding balance of the Five 2022 Term Loans for any period in which our net revenue from the sale of any products, calculated on a trailing six (6) month basis and tested monthly, is less than sixty percent (60%) of the outstanding balance of the Five 2022 Loans.

In addition, the 2022 Loan Agreement, as amended, contains customary events of default that entitle the Agent to cause our indebtedness under the 2022 Loan Agreement to become immediately due and payable, and to exercise remedies against us and the collateral securing the Five 2022 Term Loans, including our cash. Under the 2022 Loan Agreement, an event of default will occur if, among other things, we fail to make payments under the 2022 Loan Agreement, we breach any of our covenants under the 2022 Loan Agreement, subject to specified cure periods with respect to certain breaches, certain Lenders determine that a material adverse change has occurred, we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings, we are unable to pay our debts as they become due or we default on contracts with third parties which would permit the holder of indebtedness to accelerate the maturity of such indebtedness or that could have a material adverse change on us. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal to 4% per annum will apply to all obligations owed under the 2022 Loan Agreement. We have classified the 2022 Original Loan balance as a non-current liability as of September 30, 2024 due to principal repayment on July 1, 2028. We have concluded that the provisions that could cause acceleration of the principal repayments are remote.

As of September 30, 2024, our future payment obligations related to the 2022 Loan, excluding interest payments and the 2022 final fee, were as follows (in thousands):

Total repayment obligations	$	104,950
Less: Unamortized discount and debt issuance costs		(944)
Less: Unaccreted value of final fee		(3,299)
Long-term debt		100,707
Less: Current portion of long-term debt		—
Long-term debt, net of current portion	$	100,707

NOTE 9. DERIVATIVE LIABILITIES

2018 Exit Fee

In May 2018, in connection with entering into the 2018 Loan Agreement, we entered into an agreement pursuant to which we agreed to pay $1.5 million in cash (2018 Exit Fee) upon any change of control transaction in respect of the Company or if we obtain both (i) U.S. FDA approval of XPHOZAH and (ii) U.S. FDA approval of IBSRELA, which was obtained on September 12, 2019 (2018 Exit Fee Agreement). Notwithstanding the February 2022 prepayment of the 2018 Loan, our obligation to pay the 2018 Exit Fee would have expired on May 16, 2028. We concluded that the 2018 Exit Fee was a freestanding derivative which was recorded at fair value as a derivative liability included in accrued expense and other current liabilities on the condensed balance sheets.

In October 2023, we received approval from the U.S. FDA for XPHOZAH to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. This triggered our obligation to pay the 2018 Exit Fee to the 2018 Lenders, which we paid in October 2023.

2022 Exit Fee

In February 2022, in connection with entering into the 2022 Original Loans, we entered into an agreement, whereby we agreed to pay an exit fee in the amount of 2% of the 2022 Original Loan funded (2022 Exit Fee) upon (i) any change of control transaction or (ii) our achievement of net revenue from the sale of any products equal to or greater than $100.0 million, measured on a six (6) months basis (Revenue Milestone), tested monthly at the end of each month. The Term C and Term D Loans do not result in payment of an additional exit fee. Notwithstanding the prepayment or termination of the 2022 Loan, the 2022 Exit Fee will expire on February 23, 2032. We concluded that the 2022 Exit Fee is a freestanding derivative which should be accounted for at fair value on a recurring basis. The estimated fair value of the 2022 Exit Fee was recorded as a derivative liability and included in accounts payable and accrued expenses and other current liabilities on the accompanying condensed balance sheets as of September 30, 2024 and December 31, 2023, respectively. As of September 30, 2024 and December 31, 2023, the estimated fair value of the 2022 Exit Fee was $1.0 million and $0.7 million, respectively. During the three months ended June 30, 2024, we achieved the Revenue Milestone and we paid the $1.0 million 2022 Exit Fee to the Agent in October 2024.

The fair value of the derivative liability was determined using a discounted cash flow analysis and was classified as a Level 3 measurement within the fair value hierarchy since our valuation utilized significant unobservable inputs prior to June 30, 2024. Specifically, the key assumptions included in the calculation of the estimated fair value of the 2022 Exit Fee derivative liability included: (i) our estimates of both the probability and timing of achieving the Revenue Milestone and (ii) the probability and timing of funding the Term B Loan, which was dependent upon (a) approval by the U.S. FDA for our NDA for the control of serum phosphorus in adult patients with CKD on dialysis by November 30, 2023, and (b) achievement of certain product revenue milestone targets. As of September 30, 2024, uncertainty around all of the noted valuation estimates had been removed, as the Term B Loan had been funded, the U.S. FDA had approved our NDA for the control of serum phosphorus in adult patients with CKD on dialysis prior to November 30, 2023, and we had achieved the Revenue Milestone.

Changes in the fair value of recurring measurements are presented as other income, net in our condensed statements of operations and comprehensive income (loss) and were as follows for the nine months ended September 30, 2024 and 2023 (in thousands):

	2024	2023
Fair value of exit fee derivative liabilities at January 1,	$ 675	$ 1,656
Changes in estimated fair value:		
2018 Exit Fee	—	273
2022 Exit Fee	325	126
Fair value of exit fee derivative liabilities at September 30,	$ 1,000	$ 2,055

NOTE 10. LEASES

All of our leases are operating leases and each contain customary rent escalation clauses. Certain of the leases have both lease and non-lease components. We have elected to account for each separate lease component and the non-lease components associated with that lease component as a single lease component for all classes of underlying assets.

The following table provides additional details of our facility leases presented in our condensed balance sheets (dollars in thousands):

Facilities	**September 30, 2024**	**December 31, 2023**
Right-of-use assets	$ 3,625	$ 5,589
Current portion of lease liabilities	2,567	4,435
Operating lease liability, net of current portion	1,218	1,725
Total lease liabilities	$ 3,785	$ 6,160
Weighted-average remaining life (years)	1.7	1.6
Weighted-average discount rate	6.6 %	6.8 %

The lease costs, which are included in operating expenses in our condensed statements of operations and comprehensive income (loss), were as follows (in thousands):

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2024	**2023**	**2024**	**2023**
Operating lease expense	$ 1,067	$ 1,061	$ 3,204	$ 3,127
Cash paid for operating lease	$ 1,229	$ 1,119	$ 3,594	$ 3,316

The following table summarizes our undiscounted cash payment obligations for our operating lease liabilities as of September 30, 2024 (in thousands):

Remainder of 2024	$ 1,255
2025	1,660
2026	702
2027	238
2028	124
Thereafter	21
Total undiscounted operating lease payments	4,000
Imputed interest expenses	(215)
Total operating lease liabilities	3,785
Less: Current portion of operating lease liability	(2,567)
Operating lease liability, net of current portion	$ 1,218

NOTE 11. STOCKHOLDERS' EQUITY

At-the-Market Offering Agreements

In July 2020, we filed a registration statement on Form S-3, which became effective in August 2020 (2020 Registration Statement). In August 2021, we filed a prospectus supplement under the 2020 Registration Statement for the offering, issuance and sale by us of up to a maximum aggregate offering price of $150.0 million of our common stock that may be issued and sold, from time to time, under a sales agreement (2021 Open Market Sales Agreement) we entered into with Jefferies LLC (Jefferies), pursuant to which we may, from time to time, sell up to $150.0 million in shares of our common stock through Jefferies. Pursuant to the 2021 Open Market Sales Agreement, Jefferies, as our sales agent, receives a commission of up to 3.0% of the gross sales price for shares of common stock sold under the 2021 Open Market Sales Agreement. As of March 2023, we had received the maximum gross proceeds of $150.0 million under the 2021 Open Market Sales Agreement at a weighted average share price of approximately $1.57 per share, which included 15.5 million shares of our common stock for which we received gross proceeds of $51.9 million at a weighted average share price of approximately $3.35 during the quarter ended March 31, 2023.

In January 2023, we filed a registration statement on Form S-3, which became effective in January 2023 (2023 Registration Statement), containing (i) a base prospectus for the offering, issuance and sale by us of up to a maximum aggregate offering price of $250.0 million of our common stock, preferred stock, debt securities, warrants and/or units, from time to time in one or more offerings; and (ii) a prospectus supplement for the offering, issuance and sale by us of up to a maximum aggregate offering price of $150.0 million of our common stock that may be issued and sold, from time to time, under a sales agreement with Jefferies, deemed to be "at-the-market offerings" (2023 Open Market Sales Agreement). Pursuant to the 2023 Open Market Sales Agreement, Jefferies, as sales agent, may receive a commission of up to 3.0% of the gross sales price for shares of common stock sold under the 2023 Open Market Sales Agreement. During the nine months ended September 30, 2024, we completed no sales pursuant to the 2023 Open Market Sales Agreement. As of September 30, 2024, we have sold 16.8 million shares of our common stock and received gross proceeds of $70.0 million at a weighted average sales price of approximately $4.17 per share under the 2023 Open Market Sales Agreement.

NOTE 12. EQUITY INCENTIVE PLANS

Stock-based compensation expense recognized for stock options, restricted stock units (RSUs), and our employee stock purchase program (ESPP) are recorded as operating expenses in our condensed statements of operations and comprehensive income (loss), as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Selling, general and administrative	$ 6,199	$ 2,574	$ 20,305	$ 6,965
Research and development	2,934	915	7,213	2,635
Total	$ 9,133	$ 3,489	$ 27,518	$ 9,600

As of September 30, 2024, our total unrecognized stock-based compensation expense, net of estimated forfeitures, and average remaining vesting period, included the following (dollars in thousands):

	Unrecognized Compensation Expense	Average Remaining Vesting Period (Years)
Stock option grants	$ 59,155	2.8
RSU grants	$ 51,963	3.1
ESPP	$ 394	0.4

Stock Options

A summary of our stock option activity and related information for the nine months ended September 30, 2024 is as follows (in thousands, except dollar amounts):

	Number of Shares		Weighted-Average Exercise Price per Share
Balance at December 31, 2023	22,168	$	4.20
Options granted	8,738	$	8.20
Options exercised	(2,228)	$	2.38
Options forfeited or canceled	(510)	$	5.46
Balance at September 30, 2024	28,168	$	5.57
Exercisable at September 30, 2024	14,030	$	5.49

Restricted Stock Units

A summary of our RSUs activity and related information for the nine months ended September 30, 2024 is as follows (in thousands, except dollar amounts):

	Number of RSUs		Weighted-Average Grant Date Fair Value Per Share
Non-vested restricted stock units at December 31, 2023	3,646	$	3.09
Granted	6,646	$	8.20
Vested	(1,724)	$	5.76
Forfeited	(285)	$	5.35
Non-vested restricted stock units at September 30, 2024	8,283	$	6.55

Employee Stock Purchase Plan

During the nine months ended September 30, 2024, we sold approximately 0.5 million shares of our common stock under the ESPP. The shares were purchased by employees at an average purchase price of $4.64 per share resulting in proceeds to us of approximately $2.2 million.

Issuance of Common Stock for Services

Under Our Amended and Restated Non-Employee Director Compensation Program, members of our board of directors may elect to receive shares of our stock in lieu of their cash fees. During the nine months ended September 30, 2024, we issued 41 thousand shares of our common stock to members of the board of directors in accordance with the program.

NOTE 13. NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share is calculated by dividing net income (loss) by the weighted-average number of common shares outstanding during the period and excludes any dilutive effects of stock-based awards and warrants. Diluted net income (loss) per common share is computed giving effect to all potential dilutive common shares, including common stock issuable upon exercise of stock options, and unvested restricted common stock and stock units. As we had net losses for the nine months ended September 30, 2024 and 2023, all potential common shares were determined to be anti-dilutive during those periods.

The following table sets forth the computation of net income (loss) per common share (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Numerator:	**2024**	**2023**	**2024**	**2023**
Net income (loss)	$ (809)	$ 6,629	$ (43,781)	$ (37,265)
Denominator:				
Weighted average common shares outstanding - basic	235,911	222,782	234,516	214,977
Weighted average common shares outstanding - diluted	235,911	227,894	234,516	214,977
Net income (loss) per share of common stock - basic and diluted	$ (0.00)	$ 0.03	$ (0.19)	$ (0.17)

For the periods presented, the total numbers of securities that could potentially dilute net income per share in the future that were not considered in the diluted net loss per share calculations because the effect would have been anti-dilutive were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Options to purchase common stock	28,296	14,718	27,584	20,561
Restricted stock units	8,257	268	7,753	2,982
ESPP shares issuable	224	197	231	247
Total	36,777	15,183	35,568	23,790

NOTE 14. CONTINGENCIES

On July 30 and August 12, 2021, two putative securities class action lawsuits were commenced in the U.S. District Court for the Northern District of California naming as defendants Ardelyx and two current officers captioned *Strezsak v. Ardelyx, Inc., et al.*, Case No. 4:21-cv-05868-HSG, and *Siegel v. Ardelyx, Inc., et al.*, Case No. 5:21-cv-06228-HSG (together, the "Securities Class Actions"). The complaints allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, and Rule 10b-5 thereunder, by making false and misleading statements and omissions of material fact related to tenapanor. The plaintiffs seek damages and interest, and an award of costs, including attorneys' fees. On July 19, 2022, the court consolidated the two putative class actions and appointed a lead plaintiff and lead counsel. The lead plaintiff filed a second amended complaint under which the plaintiffs seek to represent all persons who purchased or otherwise acquired Ardelyx securities between March 6, 2020 and July 19, 2021. Defendants filed a motion to dismiss the amended complaint on June 2, 2023. On March 22, 2024, the court granted defendants' motion to dismiss. The court provided plaintiffs a third opportunity to amend and plaintiffs filed a third amended complaint on April 19, 2024. Defendants filed a motion to dismiss the third amended complaint on June 3, 2024. The case was dismissed with prejudice on September 12, 2024. On October 9, 2024, plaintiff appealed the District Court's dismissal of the case to the Ninth Circuit. We believe the plaintiffs' claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

On December 7, 2021 and March 29, 2022, two verified shareholders derivative lawsuits were filed in the U.S. District Court for the Northern District of California purportedly on behalf of Ardelyx against certain of Ardelyx's executive officers and members of our board of directors, captioned *Go v. Raab*, et al., Case No. 4:21-cv-09455-HSG, and *Morris v. Raab*, et al., Case No. 4:22-cv-01988-JSC. The complaints allege that the defendants' violations of Section 14(a) of the Securities Exchange Act of 1934, as amended, breaches of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets for personally making and/or causing Ardelyx to make materially false and misleading statements regarding the Company's business, operations and prospects. The complaint seeks contribution under Sections 10(b) and 21D of the Securities Exchange Act of 1934 from two executive officers. On January 19, and April 27, 2022, the court granted the parties' stipulation to stay the Go and Morris actions, respectively, until resolution of the anticipated motion(s) to dismiss in the Securities Class Actions. On October 25, 2022, the parties filed a stipulation to consolidate and stay the Go and Morris actions, and on October 27, 2022, the court consolidated the Go and Morris action and stayed the consolidated action pending resolution of the anticipated motion(s) to dismiss in the Securities Class Action. The consolidated case remains stayed pending resolution of the appeal in the Securities Class Action. We believe the plaintiffs' claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

On July 17, 2024, the Company, in partnership with the American Association of Kidney Patients (AAKP) and the National Minority Quality Forum (NMQF), filed a lawsuit in the U.S. District Court for the District of Columbia against the Centers for Medicare & Medicaid Services (CMS), claiming that CMS has violated its statutory and regulatory authority under the Medicare Improvements for Patients and Providers Act (MIPPA), which established the ESRD PPS bundled payment system for dialysis services in 2008. Specifically, the lawsuit claims that CMS's plan to move XPHOZAH, along with all oral-only drugs, into the ESRD PPS is inconsistent with MIPPA's statutory provision, and contradicts CMS's own regulations. XPHOZAH and other oral-only drugs, which are currently available to patients under Medicare Part D, are not administered by dialysis providers and cannot be taken during the delivery of maintenance dialysis. The Company, AAKP and NMQF are seeking relief under the Administrative Procedure Act to enjoin CMS from proceeding with its plan to include XPHOZAH in the ESRD PPS and eliminate coverage under Medicare Part D beginning on January 1, 2025. On September 17, 2024, defendants filed a Motion to Dismiss, the case, and on September 19, 2024, plaintiffs filed a Motion for Preliminary Injunction or, in the Alternative, for Expedited Summary Judgment.

On August 16, 2024, a complaint was filed against the Company in the U.S. District Court of Massachusetts, captioned *Yarborough v. Ardelyx, Inc., et al.,* No. 24-cv-12119 (D. Mass.). The complaint names the Company, Mike Raab, and Justin Renz as defendants and alleges violations of Sections 10(b) and 20(a) the Exchange Act and Rule 10b-5 promulgated thereunder, related to the Company's announcement on July 2, 2024 that it had chosen not to file an application for Transitional Drug Add-on Payment Adjustment (TDAPA) for XPHOZAH (the "Yarborough Action"). The plaintiffs seek damages and interest, and an award of costs, including attorneys' fees. Two shareholders filed motions to be appointed lead plaintiff in the Yarborough Action on October 15, 2024. The court has not yet appointed a lead plaintiff. We believe the plaintiff's claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

On September 6 and 13, 2024, certain Ardelyx shareholders filed two verified derivative complaints purportedly on behalf of the Company in the United States District Court for the District of Massachusetts alleging violations of Sections 10(b) and/or 14(a) of the Exchange Act, breaches of fiduciary duty, unjust enrichment, waste, and aiding and abetting breaches of fiduciary duty against certain members of our board of directors and management based on substantially the same factual allegations in the Yarborough Action. The complaints seek unspecified damages and corporate governance reforms, as well as costs and attorneys' fees. On September 25, 2024, the Court consolidated the two derivative actions into the case *In re Ardelyx, Inc. Stockholder Derivative Litigation*, Case No. 1:24-cv-12302-LTS (D. Mass.). We believe the plaintiffs' claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. As of September 30, 2024, there is no litigation pending that would reasonably be expected to have a material adverse effect on our results of operations and financial condition, and no contingent liabilities were accrued as of September 30, 2024.

NOTE 15. SUBSEQUENT EVENTS

On October 3, 2024, we and BMR-Pacific Research Center LP (Landlord) entered into a Lease Agreement (New Fremont Lease) whereby we agreed to lease approximately 15,000 square feet on the first floor of the building located at 7999 Gateway Boulevard, Newark, California (New Fremont Premises). The initial term of the New Fremont Lease will be thirty-nine (39) months and we will have one (1) option to extend the term by sixty (60) months. The Landlord has agreed to conduct certain tenant improvements at Landlord's expense. The initial term of the New Fremont Lease commences once the tenant improvements are completed, which is estimated to be February 10, 2025. The initial monthly base rent will equal three and 15/100 dollars ($3.15) per square foot of rentable area of the New Fremont Premises and will be subject to an annual upward adjustment of three and a half percent (3.5%) of the then-current base rent. In connection with entering into the New Fremont Lease, we and the Landlord entered into a sixth amendment (the Sixth Amendment) to our existing lease (the Existing Fremont Lease) whereby we lease certain premises at 34175 Ardenwood Boulevard in Fremont, California, which amends the expiration date of the Existing Fremont Lease to be the date that is the later of (a) March 10, 2025, and (b) the date that is the actual "Term Commencement Date" under the New Fremont Lease.

On October 25, 2024, we entered into a Commercial Supply Agreement (the CSA) with Hovione Farmaciência, S.A. (Hovione Portugal) and Hovione, LLC (Hovione NJ and, together with Hovione Portugal, Hovione). The CSA contemplates that Hovione will perform spray-drying services for the Company at commercial scale, in the manner developed and validated under the existing Master Services Agreement between the parties. The CSA provides that Hovione will manufacture, and the Company will purchase, certain minimum quantities of tenapanor API beginning in 2024 from its Portugal facility and continuing through the end of the term of the CSA. The parties have agreed that Hovione will purchase, install, validate and qualify equipment at its New Jersey site so that, beginning in 2027, additional product can be supplied by Hovione NJ. The initial term of the CSA is until December 31, 2030, unless terminated earlier by one of the parties by its terms. Thereafter, the CSA will automatically renew for successive terms of two years until terminated by one of the parties.

On October 29, 2024, we entered into a Fourth Amendment to Loan and Security Agreement (the Fourth Amendment), by and among Ardelyx, as borrower, SLR, as collateral agent and the lenders party thereto, which amends the SLR Loan Agreement. The Fourth Amendment, among other things, (1) provided for the immediate draw of the Term D loan in a principal amount of $50.0 million on the closing date of the Fourth Amendment and (2) provides us with the option to draw an additional $50.0 million of committed senior secured term loans by June 30, 2025 (the Term E Loan); (3) extends the Maturity Date for all term loans under the SLR Loan Agreement from March 1, 2027 to July 1, 2028; and (4) extends the interest-only period for all term loans under the SLR Agreement until the Maturity Date.

The interest rate for the Term D Loan and the Term E Loan is 4.00% plus a rate equal to 0.022% plus the 1-month SOFR reference rate, subject to a SOFR floor of 4.70%.

We paid a fee of $0.3 million in connection with the funding of the Term D Loan. We are also obligated to pay an additional $0.3 million on the earliest of (1) the funding date of the Term E Loan, (2) June 30, 2025, and (3) the prepayment, refinancing, substitution, or replacement of any term loan under the SLR Loan Agreement on or prior to the date immediately preceding June 30, 2025. (See *Note 8. Borrowing* for additional information related to borrowing).

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 in conjunction with the condensed financial statements and notes thereto included elsewhere in this report and with the audited financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2023. This discussion and analysis and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk Factors." These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason. Unless the context requires otherwise, the terms "Ardelyx", "Company", "we", "us", and "our" refer to Ardelyx, Inc.

Overview

We are a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative first-in-class medicines that meet significant unmet medical needs. We developed a unique and innovative platform that enabled the discovery of new biological mechanisms and pathways to develop potent, and efficacious therapies that minimize the side effects and drug-drug interactions frequently encountered with traditional, systemically absorbed medicines. The first molecule we discovered and developed was tenapanor, a minimally absorbed, first-in-class, oral, small molecule therapy. Tenapanor, branded as IBSRELA®, is approved in the U.S. for the treatment of adults with irritable bowel syndrome with constipation (IBS-C). Tenapanor, branded as XPHOZAH®, is approved in the U.S. to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

Since commencing operations in October 2007, substantially all our efforts have been dedicated to our research and development (R&D) activities, including developing tenapanor and developing our proprietary drug discovery and design platform, as well as commercialization activities, including the marketing and sales of IBSRELA and XPHOZAH. We recognized our first product sales of IBSRELA in March 2022 and recognized our first product sales of XPHOZAH in November 2023. As of September 30, 2024, we had an accumulated deficit of $890.0 million.

We expect to continue to incur operating losses for the foreseeable future as we invest in the commercialization of IBSRELA and XPHOZAH, incur manufacturing and development costs for tenapanor, and incur additional expenses related to our ongoing operations and our pursuit of future business opportunities. To date, we have funded our operations from the sale of common stock and convertible preferred stock, funds from our collaboration partnerships (including license fees, milestones and product supply revenue), funds from our loan agreement with SLR Investment Corp. (SLR), as amended on August 1, 2022, February 9, 2023, October 17, 2023, and October 29, 2024 (collectively, the 2022 Loan Agreement), as well as from sales of IBSRELA and XPHOZAH.

Our Commercial Products

IBSRELA for IBS-C

IBSRELA is a first-in-class sodium hydrogen exchange 3 (NHE3) inhibitor U.S. FDA approved for the treatment of IBS-C in adults. IBSRELA acts locally in the gut and is minimally absorbed. IBS-C is a gastrointestinal (GI) disorder characterized by both abdominal pain and altered bowel habits. IBS-C is associated with significantly impaired quality of life, reduced productivity and substantial economic burden.

We recognized our first sales of IBSRELA in the U.S. in March 2022. We deploy a market-responsive commercial strategy for IBSRELA and have a commercial organization highly experienced in launching and commercializing novel therapies into specialty areas. The dynamics of the IBS-C market reflect an established patient base, limited number of competitors all confined to a single mechanism of action (secretagogues), concentrated number of prescribers, and recognized unmet need. In addition, market research indicated a favorable response to the IBSRELA product profile as a novel mechanism therapy. These dynamics enabled a targeted promotional focus on IBS-C patients currently being managed by high-writing healthcare providers. Central to our go to market strategy for IBSRELA has been our highly experienced specialty sales force, composed of many with existing relationships across their GI target base, and omnichannel digital initiatives.

We believe competition for IBSRELA comes largely from the three prescription products indicated for IBS-C: Linzess (linaclotide), Amitiza (lubiprostone) and Trulance (plecanatide). Generic lubiprostone is also available in the U.S. Additionally, over-the-counter products and prescription therapies, not indicated for IBS-C, are commonly used to treat the constipation component of IBS-C, alone and in combination with the IBS-C-indicated prescription therapies.

We have established commercial agreements with Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (Fosun Pharma) in China and Knight Therapeutics, Inc. (Knight) in Canada for IBSRELA. Knight is currently marketing IBSRELA in Canada. In October 2023, we announced that Fosun Pharma received approval from the Hong Kong Department of Health for the marketing application for tenapanor for the treatment of IBS-C.

XPHOZAH to Reduce Serum Phosphorus in Adults with CKD on dialysis as Add-on Therapy in Patients who have an Inadequate Response to Phosphate Binders or who are Intolerant of any Dose of Phosphate Binder Therapy

On October 17, 2023, we received approval from the U.S. FDA to market XPHOZAH, a first-in-class phosphate absorption inhibitor, in the U.S. to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. XPHOZAH has a differentiated mechanism of action and acts locally in the gut to inhibit NHE3. This results in the tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption. It is estimated that there are more than 550,000 adult patients with CKD on dialysis in the U.S. and approximately 80% of those patients are being treated with phosphate lowering therapies. In addition, approximately 70% of patients treated with phosphate binders to treat hyperphosphatemia were unable to consistently maintain phosphorous levels <=5.5 mg/dL over a six-month period. XPHOZAH is the first therapy for phosphate management that blocks phosphate absorption at the primary site of uptake.

We recognized our first sales of XPHOZAH in the U.S. in November 2023. For our commercial launch of XPHOZAH, we designed a market-responsive commercial strategy and built a commercial organization highly experienced and knowledgeable of the nephrology market. The dynamics of the hyperphosphatemia market reflect an established patient base, limited number of competitors all confined to a single mechanism of action (phosphate binders), concentrated number of prescribers, and recognized unmet need. In addition, market research indicated a high level of awareness, interest and intent to adopt XPHOZAH upon approval and favorable response to the XPHOZAH product profile as a novel mechanism therapy. These dynamics enabled a targeted promotional focus on patients currently being managed for hyperphosphatemia by the approximately 8,000 nephrology healthcare providers who write approximately 80% of phosphate lowering therapy prescriptions in the U.S. Central to our go to market strategy for XPHOZAH has been our highly experienced specialty sales force, many with existing relationships across their nephrology target base, and innovative omnichannel digital initiatives.

XPHOZAH is indicated to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. The various types of phosphate binders commercialized in the U.S. include the following: Calcium acetate (several prescription brands including PhosLo and Phoslyra); Lanthanum carbonate (Fosrenol); Sevelamer hydrochloride (Renagel); Sevelamer carbonate (Renvela); Sucroferric oxyhydroxide (Velphoro); and Ferric citrate (Auryxia). All of the listed phosphate binders are available as generics in the U.S., with the exception of Velphoro and Auryxia. Additionally, over-the-counter calcium carbonate, such as Tums and Caltrate, is also used to bind phosphorus.

In addition to the currently available phosphate binders, we are aware of at least four other binders in development, including fermagate (Alpharen), an iron-based binder in Phase 3 being developed by Opko Health, Inc.; PT20, an iron-based binder in Phase 3 being developed by Shield Therapeutics, AP-301 in Phase 2 being developed by Alebund Pharmaceutical (Hong Kong) Limited; and Oxylanthanum Carbonate (OLC), which has demonstrated pharmacodynamic bioequivalence to Fosrenol. OLC is being developed by Unicycive Therapeutics, which has announced its plans to seek U.S. FDA approval via the 505(b)(2) pathway. Additionally, Chugai and Alebund are developing EOS789, an inhibitor of phosphate transporters NaPi-2b, PiT-1, and PiT-2, thus far studied in a phase 1 clinical trial.

In November 2023, XPHOZAH was granted orphan drug designation by the U.S. FDA for the treatment of pediatric hyperphosphatemia.

On July 2, 2024, the Company announced that it had chosen not to apply to include XPHOZAH in the Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Transitional Drug Add-on Payment Adjustment (TDAPA) following an analysis of the CMS policy to include oral-only medicines in the PPS and the Calendar Year 2025 ESRD PPS Proposed Rule released on June 27, 2024, which revealed that the policy and the manner in which CMS intends to implement it are likely to cause significant restrictions on the use of XPHOZAH for all patients, irrespective of insurance coverage, because it interferes with the essential and appropriate shared decision-making between healthcare professionals and their patients.

On July 17, 2024, the Company, in partnership with the American Association of Kidney Patients (AAKP) and the National Minority Quality Forum (NMQF), filed a lawsuit in the U.S. District Court for the District of Columbia against CMS, claiming that CMS has violated its statutory and regulatory authority under the Medicare Improvements for Patients and Providers Act (MIPPA), which established the ESRD PPS bundled payment system for dialysis services in 2008. Specifically, the lawsuit claims that CMS's plan to move XPHOZAH, along with all oral-only drugs, into the ESRD PPS is inconsistent with MIPPA's statutory provision, and contradicts CMS's own regulations. XPHOZAH and other oral-only drugs, which are currently available to patients under Medicare Part D, are not administered by dialysis providers and cannot be taken during the delivery of maintenance dialysis. The Company, AAKP and NMQF are seeking relief under the Administrative Procedure Act to enjoin CMS from proceeding with its plan to include XPHOZAH in the ESRD PPS and eliminate coverage under Medicare Part D beginning on January 1, 2025.

We have established commercial agreements with Kyowa Kirin, Co. Ltd. (Kyowa Kirin) in Japan, Fosun Pharma in China and Knight in Canada for tenapanor for hyperphosphatemia. In July 2023, we announced that a New Drug Application (NDA) for tenapanor had been accepted for review by China's Center for Drug Evaluation of the NMPA for the control of serum phosphorus in adult patients with CKD on hemodialysis. In September 2023, we announced that Kyowa Kirin received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis. In February 2024, Kyowa Kirin announced the launch of tenapanor, marketed as PHOZEVEL®, for patients in Japan.

Collaboration Partners

We have exclusive rights to tenapanor in the U.S. and we have established agreements with Kyowa Kirin in Japan, Fosun Pharma in China and Knight in Canada for the development and commercialization of tenapanor for certain indications in their respective territories.

In March 2018, we entered into an exclusive license agreement with Knight (Knight Agreement) for the development, commercialization and distribution of tenapanor in Canada for hyperphosphatemia and IBS-C. In March 2021, Knight announced the commercial availability of IBSRELA in Canada, following its approval by Health Canada in April 2020. Under the terms of the Knight Agreement, Knight paid us a $2.3 million non-refundable, one-time payment in March 2018. We may also be eligible to receive approximately CAD 22.2 million for development and commercialization milestones, or approximately $16.4 million at the currency exchange rate on September 30, 2024, of which $0.7 million has been received and recognized as revenue as of September 30, 2024. We are also eligible to receive royalties throughout the term of the agreement, and a transfer price for manufacturing services.

In November 2017, we entered into an exclusive license agreement with Kyowa Kirin (2017 Kyowa Kirin Agreement) for the development, commercialization and distribution of tenapanor in Japan for cardiorenal indications. Under the terms of the 2017 Kyowa Kirin Agreement, we received a $30.0 million upfront payment from Kyowa Kirin, and we may be entitled to receive up to $55.0 million in total development and regulatory milestones, of which $35.0 million has been received and recognized as revenue as of September 30, 2024. We may also be eligible to receive approximately ¥8.5 billion for commercialization milestones, or approximately $59.8 million at the currency exchange rate on September 30, 2024, as well as reimbursement of costs plus a reasonable overhead for the supply of product and royalties on net sales throughout the term of the agreement. As discussed in *Note 7. Deferred Royalty Obligation Related to the Sale of Future Royalties*, the future royalties and commercial milestone payments we may receive under the 2017 Kyowa Kirin Agreement are remitted to HealthCare Royalty Partners IV, L.P. (HCR) upon receipt pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement (HCR Agreement).

On April 11, 2022, we entered into an amendment to the 2017 Kyowa Kirin Agreement (2022 Amendment). Under the terms of the 2022 Amendment, we and Kyowa Kirin agreed to a reduction in the royalty rate payable to us by Kyowa Kirin upon net sales of tenapanor in Japan. The royalty rate was reduced from the high teens to low double digits for a two-year period of time following the first commercial sale in Japan, and then to mid-single digits for the remainder of the royalty term. As discussed in *Note 7. Deferred Royalty Obligation Related to the Sale of Future Royalties*, the future royalties we may receive under the 2017 Kyowa Kirin Agreement will be remitted to HCR pursuant to the HCR Agreement. As consideration for the reduction in the royalty rate, Kyowa Kirin agreed to pay us up to an additional $40.0 million, which was received and recognized as revenue as of September 2023 as described below.

In October 2022, we announced that Kyowa Kirin submitted an NDA to the Japanese MHLW for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $35.0 million for milestone payments and payments under the 2022 Amendment.

In September 2023, we announced that Kyowa Kirin received approval from the Japanese MHLW for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with chronic kidney disease on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $30.0 million for milestone payments and payments under the 2022 Amendment. In February 2024, Kyowa Kirin announced the launch of tenapanor, marketed as PHOZEVEL®, for patients in Japan and during the first quarter of 2024, we began to recognize non-cash royalty revenue related to the sale of future royalties, which is remitted to HCR in accordance with the HCR Agreement.

In December 2017, we entered into an exclusive license agreement with Fosun Pharma (Fosun Agreement) for the development and commercialization of tenapanor in China for both hyperphosphatemia and IBS-C. Under the terms of the Fosun Agreement, Fosun paid us a $12.0 million upfront license fee. In July 2023, we announced that an NDA for tenapanor had been accepted for review by China's Center for Drug Evaluation of the NMPA for the control of serum phosphorus in adult patients with chronic kidney disease on hemodialysis. This acceptance triggered a $2.0 million milestone payment to us under the terms of the Fosun Agreement, which we received in the third quarter of 2023.

In October 2023, the U.S. FDA approved XPHOZAH to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. This triggered an additional $3.0 million milestone payment to us under the terms of the Fosun Agreement, which we received during the first quarter of 2024. Also, in October 2023, we announced that Fosun Pharma received approval from the Hong Kong Department of Health for the marketing application for tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C). We may be entitled to receive development and commercialization milestones of up to $113.0 million, of which $8.0 million has been received and recognized as revenue as of September 30, 2024, as well as reimbursement of cost plus a reasonable overhead for the supply of product and tiered royalties on net sales ranging from the mid-teens to 20%.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States.

Critical accounting policies are those that require significant judgment and/or estimates by management at the time that financial statements are prepared such that materially different results might have been reported if other assumptions had been made. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates.

The critical accounting policies that we believe impact significant judgments and estimates used in the preparation of our condensed financial statements presented in this report are described in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, in our Annual Report on Form 10-K filed with the SEC on February 22, 2024.

During the nine months ended September 30, 2024, we did not adopt any new critical accounting policies and significant judgements and estimates.

Recent Accounting Pronouncements

A summary of recent accounting pronouncements that we have adopted or may expect to adopt is included in *Note 1 – Organization and Basis of Presentation* to our condensed financial statements (see Part I, Item 1, *Notes to Condensed Financial Statements*, of this Quarterly Report on Form 10-Q).

Financial Operations Overview

Revenue

Our revenue to date has been generated primarily through a combination of product sales and payments in connection with license, research and development collaborative agreements with our various collaboration partners. We realized our first commercial product sales of IBSRELA in March 2022 and our first commercial product sales of XPHOZAH in November 2023. In the future, we may generate revenue from a combination of our own product sales and payments in connection with our current or future collaborative partnerships, including license fees, other upfront payments, milestone payments, royalties and payments for drug product and/or drug substance. We expect that any revenue we generate will fluctuate in future periods as a result of, among other factors: the extent to which we are successful in our commercialization of IBSRELA and XPHOZAH; our ability to obtain and sustain an adequate level of coverage and reimbursement for IBSRELA and XPHOZAH by third-party payors; whether and the extent to which we are successful in our commercialization of XPHOZAH; any legislative, regulatory or judicial action is taken to further delay or prevent the inclusion of XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, in the ESRD PPS; the adequacy of reimbursement and coverage of XPHOZAH beginning January 1, 2025 for all patients, regardless of insurance coverage, in the event that legislative, regulatory or judicial action to further delay or prevent the inclusion of oral only drugs in the ESRD PPS is not taken; the timing and progress of goods and services provided pursuant to our current or future collaborative partnerships; our collaborators' achievement of clinical, regulatory or commercialization milestones, to the extent achieved; the timing and amount of any payments to us relating to the aforementioned milestones; addressing any competing technological and market developments; maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how, and our ability to develop, manufacture and commercialize our product candidates and products without infringing intellectual property rights of others; attracting, hiring, and retaining qualified personnel; and the extent to which tenapanor or other licensed products are approved and successfully commercialized by a collaboration partner. If our current collaboration partners or any future collaboration partners fail to obtain regulatory approval for tenapanor or other licensed products, our ability to generate future revenue from our collaborative arrangements, and our results of operations and financial position, would be materially and adversely affected. Our past revenue performance is not necessarily indicative of results to be expected in future periods.

Cost of Goods Sold

Cost of product sales consists of the cost of commercial goods sold to our Customers. Other cost of revenue consists of the cost of materials sold to our international partners under product supply agreements, certain costs related to capacity expansion at current and future contract manufacturing service providers, as well as payments due to AstraZeneca AB (AstraZeneca) based on sales of tenapanor. We capitalize as inventory costs associated with the production of our products after regulatory approval or when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Otherwise, such costs are expensed as research and development. A portion of the costs of IBSRELA and XPHOZAH units recognized as revenue during the three and nine months ended September 30, 2024 were expensed in periods prior to the commencement of capitalization of inventory costs for each respective product. We believe our cost of goods sold for the three and nine months ended September 30, 2024 would have been $2.2 million and $4.6 million higher, respectively, if we had not previously expensed certain material and production costs with respect to the units sold. We believe our cost of goods sold for the three and nine months ended September 30, 2023 would have been $1.0 million and $3.4 million higher, respectively, if we had not previously expensed certain material and production costs with respect to the units sold. As of September 30, 2024 and December 31, 2023, we had approximately $18.0 million and $21.8 million, respectively, of inventory on hand that was previously expensed as research and development expense and will not be reported as cost of goods sold in future periods when sales of IBSRELA and XPHOZAH are recognized as revenue.

Other cost of revenue includes payments due to AstraZeneca, which under the terms of a termination agreement entered into in 2015 (AstraZeneca Termination Agreement) is entitled to (i) future royalties at a rate of 10% of net sales of tenapanor or other NHE3 products by us or our licensees, and (ii) 20% of non-royalty revenue received from our collaboration partners in connection with the development and commercialization of tenapanor or other NHE3 products. We have agreed to pay AstraZeneca up to a maximum of $75.0 million in the aggregate for (i) and (ii). We recognize these expenses as other cost of revenue when we recognize the corresponding revenue that gives rise to payments due to AstraZeneca. To date, we have recognized an aggregate of $50.3 million as other cost of revenue under the AstraZeneca Termination Agreement. See details in *Note 6, Collaboration and Licensing Agreements*, under AstraZeneca, in the notes to our financial statements of this Quarterly Report on Form 10-Q.

Research and Development

We recognize all research and development expenses as they are incurred to support the discovery, research, development and manufacturing of our products and product candidates. R&D expenses include, but are not limited to, the following:

- external research and development expenses incurred under agreements with consultants, third-party contract research organizations (CROs) and investigative sites where a substantial portion of our clinical studies are conducted, and with contract manufacturing organizations where our clinical supplies are produced;
- expenses associated with supplies and materials consumed in connection with our research operations;
- expenses associated with producing XPHOZAH prior to U.S. FDA approval;
- expenses associated with producing discovery and developmental assets prior to U.S. FDA approval;
- other costs associated with research, clinical development and regulatory activities;
- employee-related expenses, which include salaries, bonuses, benefits, travel and stock-based compensation; and
- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expense, information technology expense and other supplies.

Selling, General and Administrative

Selling, general and administrative expenses relate to sales and marketing, finance, human resources, legal and other administrative activities, including information technology investments. Selling, general and administrative expenses consist primarily of personnel costs, outside professional services, marketing, advertising and legal expenses, facilities costs not otherwise allocated to research and development and other general and administrative costs.

Interest Expense

Interest expense represents the interest associated with our 2022 Loan Agreement.

Non-cash interest expense related to the sale of future royalties

Non-cash interest expense related to the sale of future royalties represents the imputed interest expense on our deferred royalty obligation related to the sale of future royalties using the effective interest method. As further described in *Note 7. Deferred Royalty Obligation Related to the Sale of Future Royalties*, in June 2022, we and HCR entered into the HCR Agreement. Under the terms of the HCR Agreement, HCR agreed to pay us up to $20.0 million in exchange for the royalty payments and commercial milestone payments (collectively the Royalty Interest Payments) that we may receive under our 2017 License Agreement with Kyowa Kirin based upon Kyowa Kirin's net sales of tenapanor in Japan for hyperphosphatemia. As part of the HCR Agreement, we have received a $10.0 million upfront payment and a $5.0 million milestone payment from HCR, which we recorded as a deferred royalty obligation on our balance sheet. Non-cash interest expense is recognized over the life of the HCR Agreement using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of future royalty payments to be received from Kyowa Kirin.

Other Income, net

Other income, net consists of interest income earned on our cash, cash equivalents and available-for-sale investments, the periodic revaluation of the exit fee related to our 2022 Loan Agreement and currency exchange gains and losses.

RESULTS OF OPERATIONS

The results of operations as of September 30, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024, for any other interim period, or for any other future year.

Comparison of the three and nine months ended September 30, 2024 and 2023

Revenue

Below is a summary of our total revenue (dollars in thousands):

	Three Months Ended September 30,		Change 2024 vs. 2023		Nine Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	$	%	2024	2023	$	%
Product sales, net	$ 92,090	$ 22,285	$ 69,805	313 %	$ 208,193	$ 51,949	$ 156,244	301 %
Product supply revenue	5,322	2,092	3,230	154 %	7,461	5,354	2,107	39 %
Licensing revenue	20	32,014	(31,994)	(100)%	56	32,790	(32,734)	(100)%
Non-cash royalty revenue related to the sale of future royalties	809	—	809	(a)	1,776	—	1,776	(a)
Total revenues	$ 98,241	$ 56,391	$ 41,850	74 %	$ 217,486	$ 90,093	$ 127,393	141 %

(a) Percent change is not meaningful.

Below is a summary of our net product sales by product (dollars in thousands):

	Three Months Ended September 30,		Change 2024 vs. 2023		Nine Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	$	%	2024	2023	$	%
Product sales, net:								
IBSRELA	$ 40,638	$ 22,285	$ 18,353	82 %	$ 104,444	$ 51,949	$ 52,495	101 %
XPHOZAH	51,452	—	51,452	(a)	103,749	—	103,749	(a)
Total product sales, net	$ 92,090	$ 22,285	$ 69,805	313 %	$ 208,193	$ 51,949	$ 156,244	301 %

(a) Percent change is not meaningful.

The increase in product sales, net during the three and nine months ended September 30, 2024 as compared to the same periods in 2023 is attributable to increased net product sales for IBSRELA, which is primarily driven by increased demand, as well as sales from XPHOZAH following the launch of the product in the fourth quarter of 2023.

The increase in product supply revenue during the three and nine months ended September 30, 2024 as compared to the same periods in 2023 is attributable to the timing of product supply shipments to Kyowa Kirin.

The decrease in licensing revenue during the three and nine months ended September 30, 2024 as compared to the same periods in 2023 is primarily attributable to earning an aggregate of $30.0 million for milestones under the 2017 Kyowa Kirin Agreement and payments under the 2022 Amendment upon approval from the Japanese MHLW for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with CKD on dialysis during the three months ended September 30, 2023. We also earned a $2.0 million milestone under the terms of the Fosun Agreement upon acceptance of the NDA for tenapanor by China's Center for Drug Evaluation of the NMPA for the control of serum phosphorus in adult patients with CKD on hemodialysis and a one-time upfront payment we received from METiS Therapeutics Inc. during the prior year.

Non-cash royalty revenue during the three and nine months ended September 30, 2024 is attributable to royalties from Kyowa Kirin for sales of PHOZEVEL in Japan, which we remit to HCR upon receipt in accordance with the HCR Agreement.

Cost of Goods Sold

Below is a summary of our cost of goods sold (dollars in thousands):

	Three Months Ended September 30,		Change 2024 vs. 2023		Nine Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	$	%	2024	2023	$	%
Cost of product sales	$ 1,715	$ 644	$ 1,071	166 %	$ 4,133	$ 1,508	$ 2,625	174 %
Other cost of revenue	14,013	7,048	6,965	99 %	28,159	11,210	16,949	151 %
Total cost of goods sold	$ 15,728	$ 7,692	$ 8,036	104 %	$ 32,292	$ 12,718	$ 19,574	154 %

The increase to cost of product sales during the three and nine months ended September 30, 2024 as compared to the same periods in 2023 is primarily attributable to cost of goods sold for increased net product sales of IBSRELA and XPHOZAH.

The increase to other cost of revenue during the three and nine months ended September 30, 2024 as compared to the same periods in 2023 is primarily attributable to an increase in payments due to AstraZeneca under the AstraZeneca Termination Agreement, driven by increases in our product sales, as well as cost of goods sold for increased product supply sold to our collaboration partners.

Operating Expenses

Below is a summary of our operating expenses (dollars in thousands):

	Three Months Ended September 30,		Change 2024 vs. 2023		Nine Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	$	%	2024	2023	$	%
Research and development	$ 15,310	$ 8,637	$ 6,673	77 %	$ 38,651	$ 26,012	$ 12,639	49 %
Selling, general and administrative	64,970	32,664	32,306	99 %	182,618	86,653	95,965	111 %
Total operating expenses	$ 80,280	$ 41,301	$ 38,979	94 %	$ 221,269	$ 112,665	$ 108,604	96 %

Research and Development

Below is a summary of our research and development expenses (dollars in thousands):

	Three Months Ended September 30,		Change 2024 vs. 2023		Nine Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	$	%	2024	2023	$	%
External R&D expenses	$ 4,087	$ 3,089	$ 998	32 %	$ 11,342	$ 10,295	$ 1,047	10 %
Employee-related expenses	7,100	4,454	2,646	59 %	19,751	12,549	7,202	57 %
Facilities, equipment and depreciation expenses	1,072	763	309	40 %	2,908	2,120	788	37 %
Other	3,051	331	2,720	822 %	4,650	1,048	3,602	344 %
Total research and development expenses	$ 15,310	$ 8,637	$ 6,673	77 %	$ 38,651	$ 26,012	$ 12,639	49 %

The increase in our R&D expenses, including other R&D expenses, during the three and nine months ended September 30, 2024 as compared to the same periods in 2023 is primarily the result of increased medical engagement with scientific communities in the areas of gastroenterology and nephrology, as well as pediatric clinical trial activities. The increase in employee-related R&D expenses is the result of increases in headcount and related personnel costs, including stock-based compensation expense which increased by $2.0 million and $4.6 million, respectively, during the three and nine months ended September 30, 2024 as compared to the same periods in 2023.

Selling, General and Administrative

The increase in selling, general and administrative expenses during the three and nine months ended September 30, 2024 as compared to the same periods in 2023 is primarily due to increased costs associated with the commercialization of IBSRELA and XPHOZAH and increases in expenses associated with administrative support functions as our company has grown in headcount and activity level. The increases consisted of external spending for disease awareness initiatives, commercial infrastructure, and strategy, as well as headcount and related personnel costs, including stock-based compensation expense which increased by $3.6 million and $13.3 million, respectively, during the three and nine months ended September 30, 2024 as compared to the same periods in 2023.

Interest Expense

Below is a summary of our interest expense (dollars in thousands):

	Three Months Ended September 30,		Change 2024 vs. 2023		Nine Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	$	%	2024	2023	$	%
Interest expense	$ (3,357)	$ (1,107)	$ (2,250)	203 %	$ (9,039)	$ (3,210)	$ (5,829)	182 %

The increase in interest expense during the three and nine months ended September 30, 2024 as compared to the same periods in 2023 is due to a larger loan balance outstanding following the draw of an additional $22.5 million for the Term B Loan in October 2023 and $50.0 million for the Term C Loan in March 2024, as well as a higher variable interest rate applied to our loan balance primarily resulting from market fluctuations.

Non-Cash Interest Expense Related to the Sale of Future Royalties

Below is a summary of our non-cash interest expense (dollars in thousands):

	Three Months Ended September 30,		Change 2024 vs. 2023		Nine Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	$	%	2024	2023	$	%
Non-cash interest expense related to the sale of future royalties	$ (1,924)	$ (922)	$ (1,002)	109 %	$ (5,202)	$ (2,859)	$ (2,343)	82 %

The increase in non-cash interest expense related to the sales of future royalties during the three and nine months ended September 30, 2024 as compared to the same periods in 2023 is due to a higher full year liability balance following the receipt a $5.0 million payment in October 2023 as a result of Kyowa Kirin's receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan, as well as prospective adjustments to the imputed interest rate and the related amortization of the deferred royalty obligation.

Other Income, net

Below is a summary of our other income, net (dollars in thousands):

	Three Months Ended September 30,		Change 2024 vs. 2023		Nine Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	$	%	2024	2023	$	%
Other income, net	$ 2,282	$ 1,460	$ 822	56 %	$ 6,766	$ 4,308	$ 2,458	57 %

The increase in other income, net during the three and nine months ended September 30, 2024 as compared to the same periods in 2023 is primarily due to increased income on our investments resulting from both higher interest rates and larger investment balances throughout the period.

Liquidity and Capital Resources

Below is a summary of our cash, cash equivalents and short-term investments (dollars in thousands):

	September 30, 2024	December 31, 2023	Change $	Change %
Cash and cash equivalents	$ 47,429	$ 21,470	$ 25,959	121 %
Short-term investments	142,973	162,829	(19,856)	(12)%
Total liquid funds	$ 190,402	$ 184,299	$ 6,103	3 %

As of September 30, 2024, we had cash, cash equivalents and short-term investments of approximately $190.4 million.

In January 2023, we filed a registration statement on Form S-3, which became effective in January 2023 (2023 Registration Statement), containing (i) a base prospectus for the offering, issuance and sale by us of up to a maximum aggregate offering price of $250.0 million of our common stock, preferred stock, debt securities, warrants and/or units, from time to time in one or more offerings; and (ii) a prospectus supplement for the offering, issuance and sale by us of up to a maximum aggregate offering price of $150.0 million of our common stock that may be issued and sold, from time to time, under a sales agreement with Jefferies, deemed to be “at-the-market offerings” (2023 Open Market Sales Agreement). Pursuant to the 2023 Open Market Sales Agreement, Jefferies, as sales agent, may receive a commission of up to 3.0% of the gross sales price for shares of common stock sold under the 2023 Open Market Sales Agreement. During the three months ended September 30, 2024 and 2023, we completed no sales pursuant to the 2023 Open Market Sales Agreement. As of September 30, 2024, we have sold 16.8 million shares of our common stock and received gross proceeds of $70.0 million at a weighted average sales price of approximately $4.17 per share under the 2023 Open Market Sales Agreement.

In February 2022, we entered into a loan and security agreement (2022 Loan Agreement) with SLR Investment Corp (SLR). The 2022 Loan Agreement was subsequently amended on August 1, 2022 and February 9, 2023. The 2022 Loan Agreement as amended through February 9, 2023 provides for a senior secured term loan facility, with $27.5 million funded at closing (the Term A Loan) and an additional $22.5 million that we could borrow on or prior to December 20, 2023; provided that (i) we received approval by the U.S. FDA for our NDA for XPHOZAH by November 30, 2023 and (ii) we achieved certain product revenue milestone targets described in the 2022 Loan Agreement (the Term B Loan). During the three months ending June 30, 2024, we achieved the Revenue Milestone and, in October 2024, we paid the $1.0 million 2022 Exit Fee to the Agent.

The initial funding of $27.5 million was used to repay the 2018 Loan and is funding our ongoing operations. We had $25.0 million principal from the 2018 Loan outstanding as of the closing date, as well as the 2018 Exit Fee in the amount of $1.5 million. We paid the 2018 Exit Fee in October 2023 following approval from the U.S. FDA for XPHOZAH to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

In October 2023, we entered into a Third Amendment (the Third Amendment) to the 2022 Loan Agreement by and between us and the 2022 Lenders. As discussed in *Note 8. Borrowing*, the Third Amendment, among other things, (1) provided us with the option to draw an additional $50.0 million of committed capital by March 15, 2024 (the Term C Loan) provided we have drawn the Term B Loan; and (2) provided us with the option to draw up to an additional $50.0 million of uncommitted capital by December 31, 2026, subject to approval by the Agent's investment committee (the Term D Loan). In February 2024, we provided the Agent with notice of our decision to draw the Term C Loan to support the commercial launch of XPHOZAH and received the proceeds of the Term C Loan in March 2024.

On October 29, 2024, we entered into a Fourth Amendment (the Fourth Amendment) to the 2022 Loan Agreement by and between us and the 2022 Lenders. The Fourth Amendment, among other things, (1) provides for the immediate draw of the Term D Loan on the closing date of the Fourth Amendment and (2) provides us with the option to draw an additional $50.0 million of committed capital by June 30, 2025 (the Term E Loan).

Under the Fourth Amendment, the maturity date for the Five 2022 Loans is extended from March 1, 2027 to July 1, 2028 (the Maturity Date). The interest rate for each of the Term A Loan and the Term B Loan is 7.95% plus a SOFR value equal to 0.022% plus the 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website, subject to a SOFR floor of one percent. The interest rate for the Term C Loan is 4.25% plus a SOFR value equal to 0.022% plus the 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website, subject to a SOFR floor of 4.7%. The interest rate for each of the Term D Loan and the Term E Loan is 4.00% plus a SOFR value equal to 0.022% plus the 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website, subject to a SOFR floor of 4.7%.

In September 2023, we announced that Kyowa Kirin received approval from the Japanese MHLW for the NDA for tenapanor for the improvement of hyperphosphatemia in adult patients with chronic kidney disease on dialysis, which resulted in payment to us from Kyowa Kirin for an aggregate of $30.0 million for milestone payments and payments under the 2022 Amendment and entitled us to a $5.0 million payment under the terms of the HCR Agreement. We received these payments in October 2023.

We have incurred operating losses since inception in 2007 and our accumulated deficit as of September 30, 2024 is $890.0 million. Our primary sources of cash have been from the sale of common stock (in both public offerings and private placements), private placements of convertible preferred stock, funds from our collaboration partnerships, funds from our 2018 Loan Agreement, as amended, and 2022 Loan Agreement, as amended, as well as from product sales. Our primary uses of cash have been to fund operating expenses, primarily research and development expenditures, as well as pre-commercial and commercial expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We addressed our operating cash flow requirements through cash generated from product sales of IBSRELA and XPHOZAH, proceeds from the sale of shares of our common stock under our at-the-market offering, from the receipt of milestones payments from our collaboration partners and payments from Kyowa Kirin under the 2022 Amendment to our License Agreement, which were received in October 2023, and from proceeds of the Term B and Term C Loans. We believe our available cash, cash equivalents and short-term investments as of September 30, 2024 will be sufficient to fund our planned operations for at least a period of one year from the issuance of these financial statements. 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. In particular, our operating plan may change and we may require significant additional capital to fund our operations. There are no assurances that our efforts to meet our operating cash flow requirements will be successful. If our current cash, cash equivalents and short-term investments as well as our plans to meet our operating cash flow requirements are not sufficient to fund necessary expenditures and meet our obligations following the issuance of these financial statements, our liquidity, financial condition and business prospects will be materially affected.

Our future funding requirements will depend on many factors, including, but not limited to:

- the extent to which we are able to generate product revenue from sales of IBSRELA and XPHOZAH;
- whether any legislative, regulatory or judicial action is taken to further delay or prevent the inclusion of XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, in the ESRD PPS, which would otherwise occur on January 1, 2025;
- the adequacy of reimbursement and coverage of XPHOZAH beginning January 1, 2025 for all patients, regardless of insurance coverage, in the event that legislative, regulatory or judicial action to further delay or prevent the inclusion of oral only drugs in the ESRD PPS is not taken;

- the availability of adequate third-party reimbursement for IBSRELA and XPHOZAH;
- the manufacturing, selling and marketing costs associated with IBSRELA and XPHOZAH;
- our ability to maintain our existing collaboration partnerships and to establish additional collaboration partnerships, in-license/out-license, joint ventures or other similar arrangements and the financial terms of such agreements;
- the timing, receipt and amount of any milestones that may be received from our collaboration partners in connection with tenapanor, if any;
- the timing, receipt and amount of royalties we may receive as a result of sales of tenapanor by our collaboration partners in China, and Canada, if any;
- the cash requirements for the discovery and/or development of other potential product candidates;
- the time and cost necessary to respond to technological and market developments;
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, and costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of tenapanor or any of our product candidates; and
- the payment of interest and principal related to our loan and security agreement entered into with SLR Investment Corp., as amended to date.

Please see the risk factors set forth in Part II, Item 1A, Risk Factors, in this Quarterly Report on Form 10-Q for additional risks associated with our capital requirements.

CASH FLOW ACTIVITIES

The following table summarizes our cash flows (dollars in thousands):

	Nine Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	$	%
Net cash used in operating activities	$ (54,619)	$ (80,999)	$ 26,380	(33)%
Net cash provided by (used in) investing activities	23,302	(101,681)	124,983	(123)%
Net cash provided by financing activities	57,276	120,307	(63,031)	(52)%
Net increase (decrease) in cash and cash equivalents	$ 25,959	$ (62,373)	$ 88,332	(142)%

Cash Flows from Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2024 decreased by $26.4 million as compared to the same period in 2023 primarily due to higher product sales, net, as well as net changes in our operating assets and liabilities, including decreased accounts receivable and increased accounts payable and accrued and other liabilities, which were partially offset by increased inventory expenditures.

Cash Flows from Investing Activities

Net cash provided investing activities during the nine months ended September 30, 2024 increased by $125.0 million as compared to the same period in 2023 primarily due to the timing of our investment maturities and purchases.

Cash Flows from Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2024 decreased by $63.0 million as compared to the same period in 2023 primarily due to the receipt of $119.2 million from the issuance of common stock under the 2021 Open Market Sales Agreement in 2023. We have not received any proceeds under the 2021 Open Market Sales Agreement in 2024. Largely offsetting the decrease were $49.8 million net of proceeds from the Term C Loan received in March 2024, as well as from the issuance of common stock under our equity incentive and stock purchase plans.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk. We are subject to market risks, including interest rate fluctuation exposure through our investments, in the ordinary course of our business. However, the goals of our investment policy are the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market

risk, we maintain our excess cash and cash equivalents in money market funds and short-term debt securities. Because of the short-term maturities of our cash equivalents, we do not believe that a decrease in interest rates would have any material negative impact on the fair value of our cash equivalents.

As of September 30, 2024, we had cash, cash equivalents and short-term investments of $190.4 million, which consisted of bank deposits and money market funds, as well as high quality fixed income instruments including commercial paper, U.S. government-sponsored agency bonds, corporate bonds, Yankee bonds and asset-backed securities. The credit rating of our short-term investments must be rated A-1/P-1, or better by Standard and Poor's and Moody's Investors Service. Asset-backed securities must be rated AAA/Aaa. Money Market funds must be rated AAA/Aaa. Such interest-earning instruments carry a degree of interest rate risk. However, because our investments are high quality and short-term in duration, we believe that our exposure to interest rate risk is not significant and that a 10% movement in market interest rates would not have a significant impact on the total value of our portfolio, as noted above. We do not enter into investments for trading or speculative purposes.

We are subject to interest rate fluctuation exposure through our borrowings under the Loan Agreement and our investment in money market accounts which bear a variable interest rate. Borrowings under the 2022 Loan Agreement as amended bear interest at a floating per annum interest rate with 7.95% plus the greater of (a) one percent (1.00%) per annum and (b)(i) 0.022% plus (ii) 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website. A hypothetical increase in one-month CME Term SOFR of 100 basis points above the current one-month CME Term SOFR rate would have increased our interest expense by approximately $0.7 million for the nine months ended September 30, 2024. As of September 30, 2024, we had an aggregate principal amount of $100.0 million outstanding pursuant to our 2022 Loan Agreement.

Foreign Currency Risk. The majority of our transactions are denominated in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar, primarily Swiss francs and the euro, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against other currencies affects the reported amounts of expenses, non-cash royalty revenue related to the sale of future royalties, assets and liabilities associated with a limited number of manufacturing activities.

We do not use derivative financial instruments for speculative trading purposes, nor do we hedge foreign currency exchange rate exposure in a manner that entirely offsets the earnings effects of changes in foreign currency exchange rates. The counterparties to our forward foreign currency exchange contracts are creditworthy commercial banks, which minimizes the risk of counterparty nonperformance.

As of September 30, 2024, we had no open forward foreign currency exchange contracts.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (Exchange Act), our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2024. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2024, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the nine months ended September 30, 2024, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal

control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On July 30 and August 12, 2021, two putative securities class action lawsuits were commenced in the U.S. District Court for the Northern District of California naming as defendants Ardelyx and two current officers captioned *Strezsak v. Ardelyx, Inc., et al.*, Case No. 4:21-cv-05868-HSG, and *Siegel v. Ardelyx, Inc., et al.*, Case No. 5:21-cv-06228-HSG (together, the Securities Class Actions). The complaints allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder, by making false and misleading statements and omissions of material fact related to tenapanor. The plaintiffs seek damages and interest, and an award of costs, including attorneys' fees. On July 19, 2022, the court consolidated the two putative class actions and appointed a lead plaintiff and lead counsel. The lead plaintiff filed a second amended complaint under which the plaintiffs seek to represent all persons who purchased or otherwise acquired Ardelyx securities between March 6, 2020 and July 19, 2021. Defendants filed a motion to dismiss the amended complaint on June 2, 2023. On March 22, 2024, the court granted defendants' motion to dismiss. The court provided plaintiffs a third opportunity to amend and plaintiffs filed a third amended complaint on April 19, 2024. Defendants filed a motion to dismiss the third amended complaint on June 3, 2024. The case was dismissed with prejudice on September 12, 2024. On October 9, 2024, plaintiff appealed the District Court's dismissal of the case to the Ninth Circuit. We believe the plaintiffs' claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

On December 7, 2021 and March 29, 2022, two verified shareholders derivative lawsuits were filed in the U.S. District Court for the Northern District of California purportedly on behalf of Ardelyx against certain of Ardelyx's executive officers and members of our board of directors, captioned Go v. Raab, et al., Case No. 4:21-cv-09455-HSG, and Morris v. Raab, et al., Case No. 4:22-cv-01988-JSC. The complaints allege that the defendants' violations of Section 14(a) of the Securities Exchange Act of 1934, as amended, breaches of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets for personally making and/or causing Ardelyx to make materially false and misleading statements regarding the Company's business, operations and prospects. The complaint seeks contribution under Sections 10(b) and 21D of the Securities Exchange Act of 1934 from two executive officers. On January 19, and April 27, 2022, the court granted the parties' stipulation to stay the Go and Morris actions, respectively, until resolution of the anticipated motion(s) to dismiss in the Securities Class Actions. On October 25, 2022, the parties filed a stipulation to consolidate and stay the Go and Morris actions, and on October 27, 2022, the court consolidated the Go and Morris action and stayed the consolidated action pending resolution of the anticipated motion(s) to dismiss in the Securities Class Action. The consolidated case remains stayed pending resolution of the appeal in the Securities Class Action. We believe the plaintiffs' claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

On July 17, 2024, the Company, in partnership with the American Association of Kidney Patients (AAKP) and the National Minority Quality Forum (NMQF), filed a lawsuit in the U.S. District Court for the District of Columbia against the Centers for Medicare & Medicaid Services (CMS), claiming that CMS has violated its statutory and regulatory authority under the Medicare Improvements for Patients and Providers Act (MIPPA), which established the ESRD PPS bundled payment system for dialysis services in 2008. Specifically, the lawsuit claims that CMS's plan to move XPHOZAH, along with all oral-only drugs, into the ESRD PPS is inconsistent with MIPPA's statutory provision, and contradicts CMS's own regulations. XPHOZAH and other oral-only drugs, which are currently available to patients under Medicare Part D, are not administered by dialysis providers and cannot be taken during the delivery of maintenance dialysis. The Company, AAKP and NMQF are seeking relief under the Administrative Procedure Act to enjoin CMS from proceeding with its plan to include XPHOZAH in the ESRD PPS and eliminate coverage under Medicare Part D beginning on January 1, 2025. On September 17, 2024, defendants filed a Motion to Dismiss, the case, and on September 19, 2024, plaintiffs filed a Motion for Preliminary Injunction or, in the Alternative, for Expedited Summary Judgment.

On August 16, 2024, a complaint was filed against the Company in the U.S. District Court of Massachusetts, captioned *Yarborough v. Ardelyx, Inc., et al*., No. 24-cv-12119 (D. Mass.). The complaint names the Company, Mike Raab, and Justin Renz as defendants and alleges violations of Sections 10(b) and 20(a) the Exchange Act and Rule 10b-5 promulgated thereunder, related to the Company's announcement on July 2, 2024 that it had chosen not to file an application for Transitional Drug Add-on Payment Adjustment (TDAPA) for XPHOZAH (the "Yarborough Action"). The plaintiffs seek damages and interest, and an award of costs, including attorneys' fees. Two shareholders filed motions to be appointed lead plaintiff in the Yarborough Action on October 15, 2024. The court has not yet appointed a lead plaintiff. We believe the plaintiff's claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

On September 6 and 13, 2024, certain Ardelyx shareholders filed two verified derivative complaints purportedly on behalf of the Company in the United States District Court for the District of Massachusetts alleging violations of Sections 10(b) and/or 14(a) of the Exchange Act, breaches of fiduciary duty, unjust enrichment, waste, and aiding and abetting breaches of fiduciary duty against certain members of our board of directors and management based on substantially the same factual allegations in the Yarborough Action. The complaints seek unspecified damages and corporate governance reforms, as well as costs and attorneys' fees. On September 25, 2024, the Court consolidated the two derivative actions into the case *In re Ardelyx, Inc. Stockholder Derivative Litigation*, Case No. 1:24-cv-12302-LTS (D. Mass.). We believe the plaintiffs' claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. As of September 30, 2024, there is no litigation pending that would reasonably be expected to have a material adverse effect on our results of operations and financial condition, and no contingent liabilities were accrued as of September 30, 2024.

ITEM 1A. RISK FACTORS

Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as other information in this Quarterly Report on Form 10-Q, including our financial statements and the notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, cash flows, the trading price of our common stock and our growth prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to our Financial Condition and Capital Requirements

We have incurred losses in each year since our inception, and we expect to continue to incur operating losses in the future as we commercialize IBSRELA® and XPHOZAH®, incur manufacturing and development costs for tenapanor, and incur additional expenses related to our ongoing operations and our pursuit of future business opportunities.

In March 2022, we commenced the commercialization of our first product, IBSRELA® (tenapanor) for the treatment of irritable bowel syndrome with constipation (IBS-C) in adult patients. In November 2023, we commenced the commercialization of XPHOZAH® (tenapanor) for the reduction of serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

We have incurred losses in each year since our inception in October 2007, and we do not know whether or when we will become profitable. We continue to incur significant commercialization, development and additional expenses related to our ongoing operations. As of September 30, 2024, we had an accumulated deficit of $890.0 million.

We expect to continue to incur operating losses for the foreseeable future as we commercialize IBSRELA and XPHOZAH, incur manufacturing and development costs for tenapanor, and incur additional expenses related to our ongoing operations and our pursuit of future business opportunities.

There are no assurances that our efforts to meet our operating cash flow requirements will be successful. If our current cash, cash equivalents and short-term investments as well as our plans to meet our operating cash flow requirements are not sufficient to fund necessary expenditures and meet our obligations, our liquidity, financial condition, and business prospects will be materially affected.

Our prior losses, combined with any future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Further, the net losses 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.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have substantial net operating loss and tax credit carryforwards for Federal and California income tax purposes. Such net operating losses and tax credits carryforwards may be reduced as a result of certain intercompany restructuring transactions. In addition, the future utilization of such net operating loss and tax credit carryforwards and credits may be subject to limitations, pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code). In general, if a

corporation undergoes an "ownership change," generally defined as a cumulative change of more than 50 percentage points (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss (NOL) carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and may experience additional ownership changes in the future, as a result of subsequent changes in our stock ownership, some of which are outside our control. Accordingly, we may not be able to utilize a material portion of our NOL carryforwards, even if we achieve profitability.

We will require additional financing for the foreseeable future as we invest in the commercialization of IBSRELA and XPHOZAH in the U.S. and incur additional expenses related to our ongoing operations. The inability to access necessary capital when needed on acceptable terms, or at all, could force us to reduce our efforts to commercialize IBSRELA or XPHOZAH, or to delay or limit our pursuit of other future business opportunities.

We believe that we will continue to expend substantial resources for the foreseeable future, including costs associated with our efforts to commercialize IBSRELA and XPHOZAH; conducting pediatric clinical trials for IBSRELA; manufacturing for IBSRELA and XPHOZAH and research and development related to potential new product candidates. The inability to access necessary capital when needed on acceptable terms, or at all, could force us to reduce our efforts to commercialize IBSRELA or XPHOZAH, or to otherwise limit aspects of our business. Our future funding requirements will depend on many factors, including, but not limited to:

- the extent to which we are able to generate product revenue from sales of IBSRELA and XPHOZAH;
- whether any legislative, regulatory or judicial action is taken to further delay or prevent the inclusion of XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, in the ESRD PPS, which would otherwise occur on January 1, 2025;
- the adequacy of reimbursement and coverage of XPHOZAH beginning January 1, 2025 for all patients, regardless of insurance coverage, in the event that legislative, regulatory or judicial action to further delay or prevent the inclusion of oral only drugs in the ESRD PPS is not taken;
- the availability of adequate third-party reimbursement for IBSRELA and XPHOZAH;
- the manufacturing, selling and marketing costs associated with IBSRELA and XPHOZAH;
- our ability to maintain our existing collaboration partnerships and to establish additional collaboration partnerships, in-license/out-license, joint ventures or other similar arrangements and the financial terms of such agreements;
- the timing, receipt and amount of any milestones that may be received from our collaboration partners in connection with tenapanor, if any;
- the timing, receipt, and amount of royalties we may receive as a result of sales of tenapanor by our collaboration partners in China, and Canada, if any;
- the cash requirements for the discovery and/or development of other potential product candidates;
- the time and cost necessary to respond to technological and market developments;
- the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights, including litigation costs and the outcome of such litigation, and costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of tenapanor or any of our product candidates; and
- the payment of interest and principal related to our loan and security agreement entered into with SLR Investment Corp., as amended to date.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to limit or reduce our commercialization of IBSRELA or XPOHZAH, delay or limit additional clinical trials for tenapanor, or delay or limit our pursuit of other future business opportunities. Additionally, our inability to access capital on a timely basis and on terms that are acceptable to us may force us to restructure certain aspects of our business or identify and complete one or more strategic collaborations or other transactions in order to fund the commercialization of IBSRELA or XPHOZAH through the use of alternative structures.

We have generated limited revenue from product sales and may never be profitable for a full fiscal year.

We have generated limited revenue from product sales and have incurred significant net losses in each year since inception. We began selling IBSRELA in the U.S. in March 2022 and we began selling XPHOZAH in the U.S. in November 2023. We have no other products approved for sale.

There can be no assurances that we will generate sufficient product revenue from sales of IBSRELA and XPHOZAH to cover our expenses. Our ability to generate product revenue from sales or pursuant to milestone or royalty payments depends heavily on many factors, including but not limited to:

- our ability to successfully commercialize ISBRELA and XPHOZAH and to increase market share for both products;
- maintaining sufficient market acceptance of IBSRELA as a viable treatment option for IBS-C;
- obtaining market acceptance of XPHOZAH;
- our ability to obtain and sustain an adequate level of coverage and reimbursement for IBSRELA and XPHOZAH by third-party payors;
- whether any legislative or judicial action is taken to further delay or prevent the inclusion of XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, in the ESRD PPS, which would otherwise occur on January 1, 2025;
- the adequacy of reimbursement and coverage of XPHOZAH beginning January 1, 2025 for all patients, regardless of insurance coverage, in the event that legislative, regulatory or judicial action to further delay or prevent the inclusion of oral only drugs in the ESRD PPS is not taken;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide an adequate (in amount and quality) supply of product to support the market demand for IBSRELA and XPHOZAH;
- addressing any competing technological and market developments;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how, and our ability to develop, manufacture and commercialize our product candidates and products without infringing intellectual property rights of others; and
- attracting, hiring, and retaining qualified personnel.

With respect to our commercialization of IBSRELA and XPHOZAH, our revenue will be dependent, in part, upon the size of the markets in the U.S., the label for which approval was granted, accepted price for the product, and the ability to secure and maintain adequate reimbursement. While there is significant uncertainty related to the insurance coverage and reimbursement of newly approved products in general in the U.S., there is additional uncertainty related to insurance coverage and reimbursement for drugs, like XPHOZAH, which is being marketed for the reduction of serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. Our ability to generate and sustain future revenues from sales of XPHOZAH, will be significantly dependent upon whether and when XPHOZAH, along with other oral drugs without an injectable or intravenous equivalent, are bundled into the ESRD PPS. See "*—Third-party payor coverage and reimbursement status of newly commercialized products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for IBSRELA and XPHOZAH could limit our ability to market those products and decrease our ability to generate revenue*" and "*—In the event that legislative, regulatory or judicial action to further delay or prevent the inclusion of oral only drugs in the ESRD PPS is not taken, XPHOZAH will become part of the ESRD PPS on January 1, 2025, and will no longer be covered under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted*" below.

Additionally, if the number of adult patients for IBSRELA and/or XPHOZAH is not as significant as we estimate, coverage and reimbursement for either IBSRELA or XPHOZAH are not available in the manner and to the extent we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from the sale of IBSRELA or XPHOZAH. Even if we achieve profitability on a quarterly basis in the future, we may not be able to sustain profitability for a full fiscal year. Our failure to generate adequate revenue from product sales would likely depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations. A decline in the value of our common stock could cause our stockholders to lose all or part of their investment.

Principal Risks Related to Our Business

We are substantially dependent on the successful commercialization of IBSRELA, and there is no guarantee that we will maintain sufficient market acceptance for IBSRELA, grow market share for IBSRELA, secure and maintain adequate coverage and reimbursement for IBSRELA, or generate sufficient revenue from product sales of IBSRELA.

We began selling IBSRELA in the U.S. in March 2022. The overall commercial success of IBSRELA will depend on a number of factors, including the following:

- the ability of the third-party manufacturers we contract with to provide an adequate (in amount and quality) supply of product to support the market demand for IBSRELA;
- our ability to obtain and sustain an adequate level of coverage and reimbursement for IBSRELA by third-party payors;
- the effectiveness of IBSRELA as a treatment for adult patients with IBS-C;
- the size of the treatable patient population;
- our ability to continue to increase the market share of IBSRELA;
- the effectiveness of our sales, market access and marketing efforts;
- whether physicians view IBSRELA as a safe and effective treatment for adult patients with IBS-C, which will impact the adoption of IBSRELA by physicians for the treatment of IBS-C;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of IBSRELA compared to alternative and competing treatments;
- the prevalence and severity of adverse side effects of IBSRELA;
- our potential involvement in lawsuits in connection with enforcing intellectual property rights in and to IBSRELA;
- our potential involvement in third-party interference, opposition, derivation or similar proceedings with respect to our patent rights directed to IBSRELA, and avoiding other challenges to our patent rights and patent infringement claims; and
- a continued acceptable safety and tolerability profile of IBSRELA following approval.

The amount of potential revenue we may achieve from the commercialization of IBSRELA is subject to these and other factors, and may be unpredictable from quarter-to-quarter. If the number of patients in the market for IBSRELA or the price that the market can bear is not as significant as we estimate, or if we are not able to continue to secure and maintain physician and patient acceptance of IBSRELA or adequate coverage and reimbursement for IBSRELA, we may not generate sufficient revenue from sales of IBSRELA. Any failure of IBSRELA to maintain market acceptance, continue to increase market share, obtain and maintain sufficient third-party coverage or reimbursement, or achieve commercial success would adversely affect our results of operations.

There is no guarantee that we will achieve sufficient market acceptance for XPHOZAH, secure and maintain adequate coverage and reimbursement for XPHOZAH, or generate sufficient revenue from product sales of XPHOZAH.

Our ability to maintain adequate coverage and reimbursement for XPHOZAH significantly depends upon whether and when XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, are bundled into the ESRD PPS. Absent legislative, regulatory or judicial action, XPHOZAH will enter the ESRD PPS on January 1, 2025, and separate reimbursement under Medicare Part D will no longer be available, which will negatively and materially impact our sales of XPHOZAH. See "*—Third-party payor coverage and reimbursement status of newly commercialized products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for IBSRELA and XPHOZAH could limit our ability to market those products and decrease our ability to generate revenue*" and "*—In the event that legislative, regulatory or judicial action to further delay or prevent the inclusion of oral only drugs in the ESRD PPS is not taken, XPHOZAH will become part of the ESRD PPS on January 1, 2025, and will no longer be covered under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted*" below.

Even if legislative, regulatory or judicial action is taken to delay or prevent the inclusion of oral only drugs in the ESRD PPS, the commercial success of XPHOZAH will depend on a number of factors, including the following:

- the length of any such legislative, regulatory or judicial delay in the inclusion of oral only drugs in the ESRD PPS;
- the extent to which access to XPHOZAH is restricted, regardless of insurance coverage, during and/or following any applicable TDAPA period, which may depend largely on the manner in which, XPHOZAH and other oral ESRD-related

drugs without an injectable or intravenous equivalent are bundled into the ESRD PPS, including, but not limited to, whether or not we file for TDAPA at a future date, whether or not TDAPA is granted, the length of any applicable TDAPA period, the amount of any applicable TDAPA payment, and the extent to which, the ESRD PPS base rate is adjusted following any applicable TDAPA period;

- the ability of the third-party manufacturers we contract with to provide an adequate (in amount and quality) supply of product to support the market demand for both IBSRELA and XPHOZAH;
- whether or not the content and breadth of the label that has been approved by the U.S. FDA for XPHOZAH will materially and adversely impact our ability to commercialize the product for the approved indication;
- the prevalence and severity of adverse side effects of XPHOZAH;
- acceptance of XPHOZAH as safe, effective and well-tolerated by patients and the medical community;
- our ability to manage the commercialization of IBSRELA and XPHOZAH and the complex pricing and reimbursement negotiations that may arise with marketing products containing the same active ingredient at different doses for separate indications;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of XPHOZAH compared to alternative and competing treatments;
- obtaining and sustaining an adequate level of coverage and reimbursement for XPHOZAH by third-party payors;
- our potential involvement in lawsuits in connection with enforcing intellectual property rights in and to XPHOZAH;
- our potential involvement in third-party interference, opposition, derivation or similar proceedings with respect to our patent rights, and avoiding other challenges to our patent rights and patent infringement claims; and
- a continued acceptable safety and tolerability profile of XPHOZAH following approval.

In the event that legislative, regulatory or judicial action to further delay or prevent the inclusion of oral only drugs in the ESRD PPS is not taken, XPHOZAH will become part of the ESRD PPS on January 1, 2025, after which time, coverage for XPHOZAH for Medicare beneficiaries will no longer be available under Medicate Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted.

In January 2011, the Centers for Medicare & Medicaid Services (CMS), an agency within the United States Department of Health and Human Services responsible for administering the Medicare program, implemented the ESRD PPS, a new prospective payment system for dialysis treatment. Under the ESRD PPS, CMS generally makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at their home, including the cost of certain drugs defined by CMS to be part of the renal dialysis service. The inclusion of oral medications without injectable or intravenous equivalents in the bundled payment was initially delayed by CMS until January 1, 2014, and through several subsequent legislative actions has been delayed until January 1, 2025.

On June 27, 2024, CMS released the proposed Calendar Year 2025 ESRD PPS rule (CY 2025 Proposed Rule) in which CMS confirmed its intention to bring XPHOZAH along with other oral ESRD-related drugs without and injectable or intravenous equivalent into the ESRD PPS beginning January 1, 2025, and to cease separate payment for XPHOZAH and other such drugs under Medicare Part D on such date. CMS also provided specific guidance as to how it intends to bundle XPHOZAH into the ESRD PPS indicating that it does not intend to introduce XPHOZAH into the ESRD PPS in the same manner that it intends to introduce all other phosphate lowering medications. Rather, CMS has determined that the Transitional Drug Add on Payment Adjustment (TDAPA) for new renal dialysis drugs applies to XPHOZAH. Under the CMS guidance for new renal dialysis drugs, in order to ensure TDAPA availability on January 1, 2025, a TDAPA application should be filed in the application period ending on July 1, 2024. Additionally, CMS's determination to introduce XPHOZAH into the ESRD PPS through a different pathway than that through which phosphate binders will be introduced suggests CMS' current intention to limit the utilization data considered in determining the amount of a permanent base rate adjustment after the TDAPA period to the utilization data collected for the phosphate binders, excluding XPHOZAH utilization from such permanent base rate adjustment analysis.

With review and analysis of the CY 2025 Proposed Rule, we determined that filing for TDAPA at this time is not in the best interest of patients and would materially and adversely impact sales of XPHOZAH, and on July 2, 2024, we announced that we did not file an application for TDAPA on or prior to July 1, 2024. CMS's determination to bring XPHOZAH into the ESRD PPS will materially and adversely impact our XPHOZAH product sales, our profitability, results of operations, financial condition and prospects will be materially and adversely impacted.

The extent to which the inclusion of XPHOZAH in the ESRD PPS will materially and adversely impact our XPHOZAH business is dependent on the following:

- the extent to which access to XPHOZAH is restricted by the dialysis providers and the extent to which such restrictions will interfere with the shared decision-making between healthcare professionals and their patients, regardless of insurance coverage; and
- the extent to which the elimination of separate payment for XPHOZAH for Medicare beneficiaries under Medicare Part D will influence the payment decisions of other payors and the extent to which payment for XPHOZAH will continue to be made as a pharmacy benefit for non-Medicare patients.

IBSRELA and/or XPHOZAH may cause undesirable side effects or have other properties that could limit the commercial success of the product.

Undesirable side effects caused by IBSRELA and/or XPHOZAH could cause us or regulatory authorities to interrupt, delay or halt the commercialization of the product. Despite marketing approval for IBSRELA and XPHOZAH, the prevalence and/or severity of side effects caused by IBSRELA and/or XPHOZAH could result in a number of potentially significant negative consequences, including:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we or a collaboration partner may be required to recall the product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof, including the imposition of a Risk Evaluation and Mitigation Strategy (REMS) which could require creation of a Medication Guide or patient package insert outlining the risks of such side effects for distribution to patients, a communication plan to educate healthcare providers of the drugs' risks, as well as other elements to assure safe use of the product, such as a patient registry and training and certification of prescribers;
- we or a collaboration partner may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of new labeling statements, such as a "black box" warning or a contraindication;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us, or a collaboration partner, from achieving or maintaining market acceptance of IBSRELA and/or XPHOZAH, and could result in the loss of significant revenue to us, which would materially and adversely affect our results of operations and business.

Third-party payor coverage and reimbursement status of newly commercialized products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for IBSRELA and XPHOZAH could limit our ability to market those products and decrease our ability to generate revenue.

The pricing, coverage and reimbursement of IBSRELA and XPHOZAH must be adequate to support a commercial infrastructure. The availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford treatments. Sales of IBSRELA and XPHOZAH, will depend substantially, both domestically and abroad, on the extent to which the costs of the product will be paid for by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government authorities, private health insurers, and other third-party payors. If coverage and reimbursement are not available, or are available only to limited levels, we, or our collaboration partners, may not be able to successfully commercialize IBSRELA, or XPHOZAH. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment.

In the U.S., the principal decisions about coverage and reimbursement for new drugs are typically made by CMS, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree.

On June 27, 2024, CMS released the CY 2025 Proposed Rule in which CMS confirmed its intention to bring XPHOZAH and all oral only drugs in the ESRD PPS beginning January 1, 2025, and to cease separate payment for XPHOZAH and all oral only drugs under Medicare Part D on such date. In the event no legislative, regulatory or judicial action is taken, XPHOZAH, along with other oral ESRD related drugs without injectable or intravenous equivalents, will be included in the ESRD PPS beginning on January 1, 2025. See "*—In the event that legislative, regulatory or judicial action to further delay or prevent the inclusion of oral only drugs in the ESRD PPS is not taken, XPHOZAH will become part of the ESRD PPS on January 1, 2025, and will no longer be covered under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted*" above for a more detailed discussion related to the risks that may occur if XPHOZAH is brought into the ESRD PPS bundle.

Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, Japan, China and other countries has and will continue to put pressure on the pricing and usage of IBSRELA and XPHOZAH, even if regulatory approval is received in such countries. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medicinal products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, these caps may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of IBSRELA and XPHOZAH, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We rely completely on third parties, including certain single-source suppliers, to manufacture IBSRELA and XPHOZAH. If they are unable to comply with applicable regulatory requirements, unable to source sufficient raw materials, experience manufacturing or distribution difficulties or are otherwise unable to manufacture sufficient quantities to meet demand, our commercialization of IBSRELA and XPHOZAH may be materially harmed.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture IBSRELA or XPHOZAH on a commercial scale, or to manufacture our drug supplies for use in the conduct of our nonclinical and clinical studies. Our success depends upon our ability to enter into new supplier agreements and maintain our relationships with suppliers who are critical and necessary to the production of our drug supply.

The facilities used by our contract manufacturing organizations (CMOs) to manufacture our drug supply are subject to inspection by the U.S. FDA. Our ability to control the manufacturing process of our product candidates is limited to the contractual requirements and obligations we impose on our CMOs. Although they are contractually required to do so, we are completely dependent on our CMOs for compliance with the regulatory requirements, known as current Good Manufacturing Practice requirements (cGMPs), for manufacture of both active drug substances and finished drug products.

The manufacture of pharmaceutical products requires significant expertise and capital investment. Manufacturers of pharmaceutical products often encounter difficulties in commercial production. These problems may include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, and shortages of qualified personnel, as well as compliance with federal, state and foreign regulations and the challenges associated with complex supply chain management. Even if our CMOs do not experience problems and commercial manufacturing is achieved, their maximum or available manufacturing capacities may be insufficient to meet commercial demand. Finding alternative manufacturers or adding additional manufacturers requires a significant amount of time and involves significant expense. New manufacturers would need to develop and implement the necessary production techniques and processes, which along with their facilities, would need to be inspected and approved by the regulatory authorities in each applicable territory. In addition, the raw materials necessary to make API for our products are acquired from a limited number of sources. Any delay or disruption in the availability of these raw materials could result in production disruptions, delays or higher costs with consequent adverse effects on us.

If our CMOs fail to adhere to applicable GMP or other regulatory requirements, experience delays or disruptions in the availability of raw materials or experience manufacturing or distribution problems, we may suffer significant consequences, including the inability to meet our product requirements for our clinical development programs, and such events could result in product seizures or recalls, loss of product approval, fines and sanctions, reputational damage, shipment delays, inventory shortages, inventory write-offs and other product-related charges and increased manufacturing costs. As a result, or if maximum or available manufacturing capacities are insufficient to meet demand, our development or our commercialization efforts for IBSRELA and/or XPHOZAH may be materially harmed.

Our future results depend on CMOs, many of whom are our single source manufacturers.

Many of our CMOs are currently single source manufacturers. While we try to obtain multiple sources whenever possible, similar to other commercial pharmaceutical companies, three stages of our manufacturing process are currently completed by a single source, which exposes us to a number of risks related to our supply chain, including delivery failure and drug shortages. To date, we have no qualified alternative sources for these single source CMOs.

Our manufacturing and commercial supply agreements with our CMOs, including our single source CMOs, contain or are likely to contain pricing provisions that are subject to adjustment based on factors outside of our control, including changes in market prices. Substantial increases in the prices for necessary materials and equipment, whether due to supply chain or logistics issues or due to inflation, would increase our operating costs and could reduce our margins. Any attempts to increase the announced or expected prices of IBSRELA and/or XPHOZAH in response to increased costs could be viewed negatively by the public and could adversely affect our business, prospects, financial condition, and results of operations.

An inability to continue to source product from any of these CMOs, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a CMO, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our products, which could adversely and materially affect our product sales and operating results, which could significantly harm our business. Furthermore, qualifying alternate suppliers or developing our own manufacturing capability for certain highly customized stages of our manufacturing process may be time consuming and costly. There can be no assurance that our business, financial condition, and results of operations will not be materially and adversely affected by supply chain disruptions. Any disruption in the supply chain, whether or not from a single source CMO, could temporarily disrupt production of our drug supply until an alternative supplier is fully qualified by us or until such CMO is able to perform. There can be no assurance that we would be able to successfully retain an alternative CMO on a timely basis, on acceptable terms, or at all. Changes in business conditions, force majeure, governmental changes, and other factors beyond our control or which we do not presently anticipate, could also affect our CMOs' ability to deliver components to us on a timely basis. Any of the foregoing could materially and adversely affect our results of operations, financial condition, and prospects.

Our operating activities may be restricted as a result of covenants related to the indebtedness under our loan and security agreement with SLR, as amended, and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

On February 23, 2022, we entered into a loan and security agreement (2022 Loan Agreement) with SLR Investment Corp. as collateral agent (Agent or SLR), and the lenders listed in the 2022 Loan Agreement (collectively, the 2022 Lenders). The 2022 Loan Agreement was subsequently amended in August 2022 (the First Amendment), February 2023 (the Second Amendment), October 2023 (the Third Amendment) and October 2024 (Fourth Amendment). The loan was funded in the amount of $27.5 million on February 23, 2022 and additional amounts of $22.5 million, $50.0 million and $50.0 million were drawn on October 19, 2023, March 1, 2024, and October 29, 2024, respectively. In addition, we may be able to draw up to an additional $50.0 million by June 30, 2025. Until we have repaid all funded indebtedness, the 2022 Loan Agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock, to redeem capital stock, to enter into licensing agreements, to engage in transactions with affiliates, and to encumber our intellectual property. Our business may be adversely affected by these restrictions on our ability to operate our business.

Under the Fourth Amendment, the maturity date for the term loans is extended to July 1, 2028 (Maturity Date). We are permitted to make interest only payments on the loan facility through the Maturity Date. In addition, we may be required to repay the outstanding indebtedness under the loan facility if an event of default occurs under the 2022 Loan Agreement. An event of default will occur if, among other things, we fail to make payments under the 2022 Loan Agreement; we breach any of our covenants under the 2022 Loan Agreement, subject to specified cure periods with respect to certain breaches; the Lender determines that a material adverse change has occurred; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; we are unable to pay our debts as they become due; or we default on contracts with third parties which would permit the Lender to accelerate the maturity of such indebtedness or that could have a material adverse change on us. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to limit or reduce our activities necessary to commercialize IBSRELA and/or XPHOZAH, or delay or limit clinical trials for tenapanor or other product candidates. The Lender could also exercise its rights as collateral agent to take possession of and to dispose of the collateral securing the term loans, which collateral includes substantially all of our property (excluding intellectual property, which is subject to a negative pledge). Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

Additional Risks Related to Our Business and Industry

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain.

In the conduct of additional clinical trials, we could encounter delays in our development if any clinical trials are suspended or terminated by us, by the institutional review boards of the institutions in which the trial is being conducted, or by the U.S. FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the U.S. FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

In addition, identifying and qualifying patients to participate in any clinical trials is critical to the success of the clinical trials. The timing of any future clinical trials that we may determine to conduct, will depend, in part, on the speed at which we can recruit patients to participate in testing our product candidates. Patients may be unwilling to participate in our clinical studies because of concerns about adverse events observed with the current standard of care, competitor products and/or other investigational agents, in each case for the same indications and/or similar patient populations. In addition, patients currently receiving treatment with the current standard of care or a competitor product may be reluctant to participate in a clinical trial with an investigational drug, or our inclusion and exclusion criteria for our clinical trials may present challenges in identifying acceptable patients. As a result, the timeline for recruiting patients and conducting clinical trials may be delayed. These delays could result in increased costs, delays in advancing our development of the program, or termination of the clinical studies altogether. Any of these occurrences may significantly harm our business, financial condition and prospects.

We will rely on third parties to conduct all of our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for additional products or commercialize our product candidates.

We do not have the ability to independently conduct nonclinical studies or clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as Contract Research Organizations (CROs), to conduct clinical trials on our product candidates. The third parties with whom we contract for execution of the clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we control only certain aspects of their activities and have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely, and will continue to rely, on these third parties to conduct our nonclinical studies and our clinical trials, we remain responsible for ensuring that each of our studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We, and these third parties are required to comply with current GLPs for nonclinical studies, and good clinical practices (GCPs) for clinical studies. GLPs and GCPs are regulations and guidelines enforced by the U.S. FDA, the Competent Authorities of the Member States of the European Economic Area (EEA) and comparable foreign regulatory authorities for all of our products in nonclinical and

clinical development, respectively. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third-party contractors fail to comply with applicable regulatory requirements, including GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the U.S. FDA, the European Medicines Agency (EMA), or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which could add additional costs and could delay the regulatory approval process.

We face substantial competition, and our competitors may discover, develop or commercialize products faster or more successfully than us.

The biotechnology and pharmaceutical industries are highly competitive, and we face significant competition from companies in the biotechnology, pharmaceutical and other related markets that are researching and marketing products designed to address diseases that we are currently developing products to treat.

Competition for IBSRELA largely comes from three prescription products marketed for certain patients with IBS-C that we are aware of, including Linzess (linaclotide), Amitiza (lubiprostone) and Trulance (plecanatide). Generic lubiprostone is also available in the U.S. Additionally, over-the-counter products not indicated for IBS-C are commonly used to treat the constipation component of IBS-C, alone and in combination with the IBS-C-indicated prescription therapies.

XPHOZAH is indicated to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. The various types of phosphate binders commercialized in the U.S. include the following: Calcium acetate (several prescription brands including PhosLo and Phoslyra); Lanthanum carbonate (Fosrenol); Sevelamer hydrochloride (Renagel); Sevelamer carbonate (Renvela); Sucroferric oxyhydroxide (Velphoro); and Ferric citrate (Auryxia). All of the listed phosphate binders are available as generics in the U.S., with the exception of Velphoro and Auryxia. Additionally, over-the-counter calcium carbonate, such as Tums and Caltrate, is also used to bind phosphorus.

In addition to the currently available phosphate binders, we are aware of at least four phosphate binders in development, including fermagate (Alpharen), an iron-based binder in Phase 3 being developed by Opko Health, Inc., PT20, an iron-based binder in Phase 3 being developed by Shield Therapeutics, AP-301, a binder in Phase 3 being developed by Alebund Pharmaceutical (Hong Kong) Limited, and Oxylanthanum Carbonate (OLC), which has demonstrated pharmacodynamic bioequivalence to Fosrenol. OLC is being developed by Unicycive Therapeutics, which has announced its plans to seek U.S. FDA approval via the 505(b)(2) pathway. Additionally, Chugai and Alebund are developing EOS789/AP-306, an inhibitor of phosphate transporters NaPi-2b, PiT-1, and PiT-2, thus far studied in a Phase 2 clinical trial.

It is possible that our competitors' drugs may be less expensive and more effective than our product candidates, or may render our product candidates obsolete. It is also possible that our competitors will commercialize competing drugs or treatments before we or our collaboration partners can launch any products developed from our product candidates. We also may face increased competition in the future as new companies enter into our target markets.

Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaboration partnerships or licensing relationships with our competitors.

We may experience difficulties in managing our current activities and growth given our level of managerial, operational, financial and other resources.

While we have continued to work to optimize our management composition, personnel and systems to support our current activities for future growth, these resources may not be adequate for this purpose. Our need to effectively execute our business strategy requires that we:

- manage any commercialization activities in which we may engage effectively;
- manage our clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors, collaborators, government agencies and other third parties;
- continue to improve our operational, financial and management controls, reporting systems and procedures; and
- retain and motivate our remaining employees and potentially identify, recruit, and integrate additional employees.

If we are unable to maintain or expand our managerial, operational, financial and other resources to the extent required to manage our development and commercialization activities, our business will be materially adversely affected.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of IBSRELA and/or XPHOZAH.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and our commercialization of IBSRELA and XPOHZAH. For example, we may be sued if any product we develop and/or commercialize allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for the product;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize or co-promote IBSRELA and/or XPHOZAH.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

If we fail to attract, retain and motivate our executives, senior management and key personnel, our business will suffer.

Recruiting and retaining qualified scientific, clinical, medical, manufacturing, and sales and marketing personnel is critical to our success. We are highly dependent on our executives, senior management and certain other key employees. The loss of the services of our executives, senior management or other key employees could impede the achievement of our development and commercial objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executives, senior management and other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. We may be unable to hire, train or motivate these key personnel on acceptable terms given the intense competition among numerous biopharmaceutical companies for similar personnel, particularly in our geographic regions. If we are unable to continue to attract and retain high quality personnel, our ability to grow and pursue our business strategy will be limited.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect in connection with clinical trials in the U.S. and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business; affect our ability to operate in certain jurisdictions, or to collect, store, transfer use and share personal information; necessitate the acceptance of more onerous obligations in our contracts; result in liability; or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., the Health Insurance Portability and Accountability Act of 1996, as amended, and regulations promulgated thereunder (collectively HIPAA) imposes, among other things, certain standards relating to the privacy, security, transmission, and breach reporting of individually identifiable health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act (CCPA) went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risk associated with data breach litigation. Further, the California Privacy Rights Act (CPRA) generally went into effect on January 1, 2023 and significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required. Similar laws have passed in other states and are continuing to be at the state and federal level, reflecting a trend toward more stringent privacy legislation in the U.S. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Furthermore, the Federal Trade Commission (FTC) also has authority to initiate enforcement actions against entities that mislead customers about HIPAA compliance, make deceptive statements about privacy and data sharing in privacy policies, fail to limit third-party use of personal health information, fail to implement policies to protect personal health information or engage in other unfair practices that harm customers or that may violate Section 5(a) of the FTC Act. According to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive, including on websites, to regulate the presentation of website content. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, in Europe, the European Union General Data Protection Regulation (GDPR) went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area (EEA). Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the U.S. and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union (CJEU) states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework (DPF), rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As a result, we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.

Relatedly, following the United Kingdom's withdrawal from the EEA and the European Union, and the expiry of the transition period, companies have had to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the United Kingdom to U.S. entities self-certified under the DPF. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

We and our collaborators, CROs and other contractors and consultants depend on information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

We and our collaborators, CROs, and other contractors and consultants collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we and our collaborators, CROs and other contractors and consultants collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, clinical trial data and personal information (collectively, Confidential Information). It is critical that we and our collaborators, CROs and other contractors and consultants do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information. We have established physical, electronic and organizational measures designed to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of Confidential Information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our Confidential Information.

Our information technology systems and infrastructure, and those of our current and any future collaborators, CROs, contractors and consultants and other third parties on which we rely, are vulnerable to attack, damage and interruption from computer viruses, malware (*e.g.,* ransomware), natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, phishing attacks and other social engineering schemes, attachments to emails, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access Confidential Information increases the risk of data security breaches, which could lead to the loss of Confidential Information or other intellectual property. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. There can also be no assurance that our and our collaborators', CROs', CMOs, contractors', consultants' and other service providers' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. We do not believe that we have experienced any significant system failure, accident or security breach to date, but if such an event were to occur and cause interruptions in our operations, it could result in a material disruption to our business. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable. Moreover, if a computer security breach affects our systems or those of our collaborators, CROs or other contractors, or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. Any adverse impact to the availability, integrity or confidentiality of our or third-party systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs, which could materially adversely affect our business, results of operations and financial condition.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us and could have a material adverse effect on the price of our common stock.

Our failure to implement and maintain effective internal controls over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements and cause us to fail to meet our reporting obligations. If we cannot in the future favorably assess the effectiveness of our internal controls over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on the trading price of our common stock.

We have formed in the past, and may form in the future, collaboration partnerships, joint ventures and/or licensing arrangements, and we may not realize the benefits of such collaborations.

We have current collaboration partnerships for the commercialization of tenapanor in certain foreign countries, and we may form additional collaboration partnerships, create joint ventures or enter into additional licensing arrangements with third parties in the U.S. and abroad that we believe will complement or augment our existing business. In particular, we have formed collaboration partnerships with Kyowa Kirin for commercialization of tenapanor for hyperphosphatemia in Japan; with Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (Fosun Pharma) for commercialization of tenapanor for hyperphosphatemia and IBS-C in China and related territories; in Canada with Knight Therapeutics, Inc. (Knight) for commercialization of tenapanor for IBS-C and hyperphosphatemia; and with METiS Therapeutics, Inc. (METiS) for the development and commercialization of a portfolio of TGR5 agonist compounds for all therapeutic areas. We face significant competition in seeking appropriate collaboration partners, and the process to identify an appropriate partner and negotiate appropriate terms is time-consuming and complex. Any delays in identifying suitable additional collaboration partners and entering into agreements to develop our product candidates could also delay the commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. There is no guarantee that our current collaboration partnerships or any such arrangements we enter into in the future will be successful, or that any collaboration partner will commit sufficient resources to the development, regulatory approval, and commercialization effort for such products, or that such alliances will result in us achieving revenues that justify such transactions.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

We may consider strategic transactions, such as acquisitions of companies, asset purchases, and/or in-licensing of products, product candidates or technologies. In addition, if we are unable to access capital on a timely basis and on terms that are acceptable to us, we may be forced to further restructure certain aspects of our business or identify and complete one or more strategic collaborations or other transactions in order to fund the commercialization of IBSRELA and XPHOZAH, and/or the development of discovery and developmental assets through the use of alternative structures. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, spin outs, collaboration partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- up-front, milestone and royalty payments, equity investments and financial support of new research and development candidates including increase of personnel, all of which may be substantial;
- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities;
- higher-than-expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and

- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our CMOs manufacture tenapanor API outside of the U.S., our collaboration partners outside of the U.S. have sought and obtained and may continue to seek and obtain approval to commercialize tenapanor outside of the U.S., and as a result a variety of risks associated with international operations could materially adversely affect our business.

Our collaboration partners have sought and obtained and may continue to seek and obtain marketing approval for tenapanor outside the U.S. Furthermore, we may seek and obtain marketing approval for IBSRELA or XPHOZAH in other territories outside of the U.S. Additionally, we have contractual agreements with CMOs involving the manufacture of tenapanor API outside of the U.S., and may otherwise engage in business outside of the U.S., including entering into additional contractual agreements with third parties. We are subject to additional risks related to entering these international business markets and relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing U.S. and foreign drug import and export rules;
- reduced protection for intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems, and different competitive drugs;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- potential liability resulting from development work conducted by these distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

Our business involves the use of hazardous materials and we and third-parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

We and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of hazardous materials, including the components of our tenapanor and our product candidates. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, and business operations, and could result in environmental damage requiring costly clean-up and resulting in liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot guarantee that the safety procedures utilized by third-party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

We may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

We currently occupy a leased facility located in the San Francisco Bay Area, which in the past has experienced severe earthquakes. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our leased facilities, including our California facility, that damaged critical infrastructure supporting access to systems such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or time consuming to restore some business of our business functions. The disaster recovery and business continuity plans we have in place currently are not holistic in coverage and may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Risks Related to Government Regulation

Despite having received regulatory approval for IBSRELA and XPHOZAH, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, IBSRELA and XPHOZAH could be subject to other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Even after a drug is approved by the U.S. FDA or foreign regulatory authorities, the manufacturing processes, labeling, packaging, distribution, pharmacovigilance, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP regulations for any clinical trials that we conduct post-approval. As such, we and our third-party CMOs will be subject to continual review and periodic inspections to assess compliance with regulatory requirements. 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. Regulatory authorities may also impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing studies. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs to assure compliance.

We will also be required to report certain adverse reactions and production problems, if any, to the U.S. FDA, 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 U.S. FDA approval.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- warning or untitled letters or fines;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- injunctions or the imposition of civil or criminal penalties;
- suspension or revocation of existing regulatory approvals;
- suspension of any of our ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications submitted by us;
- restrictions on our or our CMOs' operations; or
- product seizure or detention, or refusal to permit the import or export of products.

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 IBSRELA and XPHOZAH. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

In addition, the U.S. FDA's policies may change, and additional government regulations may be enacted. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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 U.S. or abroad.

Disruptions at the U.S. FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise review and process regulatory submissions in a timely manner, which could negatively impact our business.

The ability of the U.S. FDA to review and process regulatory submissions can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, policy changes, and other events that may otherwise affect the U.S. FDA's ability to perform routine functions. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the U.S. FDA, have had to furlough critical U.S. FDA employees and stop critical activities.

Disruptions at the U.S. FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, or if global health concerns prevent the U.S. FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the U.S. FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We and our CMOs are subject to significant regulation with respect to manufacturing IBSRELA and XPHOZAH. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

All entities involved in the preparation of product for commercial sale, or product candidates for clinical trials, including our existing CMOs are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP regulations. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our products or product candidates that may not be detectable in final product testing. We or our CMOs must supply all necessary documentation in support of an NDA or comparable regulatory filing on a timely basis and must adhere to cGMP regulations enforced by the U.S. FDA and other regulatory agencies through their facilities inspection programs. The facilities and quality systems of some, or all, of our CMOs must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the manufacture of our product or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the CMOs, we cannot control the manufacturing process of, and are completely dependent on, our CMOs for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. In addition, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our CMOs. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent suspension of production or closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the U.S. FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA, a supplemental NDA or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed, or we could lose potential revenue.

If we fail to comply or are found to have failed to comply with U.S. FDA and other regulations related to the promotion of our products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the U.S. FDA and other government agencies. With respect to the commercialization of IBSRELA and/or XPHOZAH, we will be restricted from marketing the product outside of its approved labeling, also referred to as off-label promotion. However, physicians may nevertheless prescribe an approved product to their patients in a manner that is inconsistent with the approved label, which is an off-label use. We have implemented compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations regarding off-label promotion. Notwithstanding these programs, the U.S. FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our product candidates for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the U.S. FDA, the FTC and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug, and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the U.S. FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

IBSRELA and/or XPHOZAH may cause or contribute to adverse medical events that we are required to report to regulatory agencies and if we fail to do so we could be subject to sanctions that would materially harm our business.

We are required to report certain information about adverse medical events if our products may have caused or contributed to those adverse events. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the U.S. FDA or a foreign regulatory agency could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

Our employees, independent contractors, principal investigators, CROs, collaboration partners, consultants, CMOs and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, collaboration partners, consultants, CMOs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate any of the following: U.S. FDA regulations, including those laws that require the reporting of true, complete and accurate financial and other information to the U.S. FDA; manufacturing standards; or federal and state healthcare fraud and abuse laws and regulations. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These activities also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Failure to obtain regulatory approvals in foreign jurisdictions would prevent us from marketing our products internationally.

In order to market any product in the EEA (which is composed of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein), and many other foreign jurisdictions, separate regulatory approvals are required. In the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization (MA). Before the MA is granted, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain U.S. FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the U.S. FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the U.S. FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining U.S. FDA approval. We may not be able to file for regulatory approvals or to do so on a timely basis, and even if we do file, we may not receive necessary approvals to commercialize our products in any market.

We and our collaboration partners are subject to healthcare laws, regulation and enforcement; our failure or the failure of any such collaboration partners to comply with these laws could have a material adverse effect on our results of operations and financial conditions.

We and our collaboration partners are subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate as a commercial organization include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;
- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- the federal Physician Payments Sunshine Act requirements under the Affordable Care Act (ACA), which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians (as defined by the statute) and their immediate family members;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or pricing information and marketing expenditures; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to market our products and adversely impact our financial results.

Legislative or regulatory healthcare reforms in the U.S. may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, U.S. FDA regulations and guidance are often revised or reinterpreted by the U.S. FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recall, replacement, or discontinuance of one or more of our products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition and results of operations.

In addition, the full impact of recent healthcare reform and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model. In the U.S., the ACA was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Moreover, on June 27, 2024, CMS released the CY 2025 Proposed Rule in which CMS confirmed its intention to bring XPHOZAH and all oral only drugs in to the ESRD PPS beginning January 1, 2025, and to cease separate payment for XPHOZAH and all oral only drugs under Medicare Part D on such date. Our ability to maintain adequate coverage and reimbursement for XPHOZAH significantly depends upon whether and when XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, are bundled into the ESRD PPS. Absent legislative, regulatory or judicial action, XPHOZAH will enter the ESRD PPS on January 1, 2025, which means it will no longer be covered by Medicare Part D, which will negatively and materially impact our sales of XPHOZAH. See "*—In the event that legislative, regulatory or judicial action to further delay or prevent the inclusion of oral only drugs in the ESRD PPS is not taken, XPHOZAH will become part of the ESRD PPS on January 1, 2025, and will no longer be covered under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted*" above.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These new laws, among other things, included aggregate reductions of Medicare payments to providers that will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress, additional specific reductions in Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminated the statutory Medicaid drug rebate cap beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Recently, there has also been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. On August 16, 2022, the Inflation Reduction Act of 2022 (the IRA) was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). Under the IRA, small molecule drugs and biologics first become eligible for price negotiation seven and eleven years, respectively, after U.S. FDA approval. The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations. HHS has issued and will continue to issue guidance implementing the IRA, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. Additionally, individual states have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing.

We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, results of operations and financial condition.

With the commercial launch of IBSRELA, we participate in the Medicaid Drug Rebate Program (MDRP) and other federal and state government pricing programs in the U.S., and we may participate in additional government pricing programs in the future. These programs generally require manufacturers to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries of these programs. Medicaid drug rebates are based on pricing data that we will be obligated to report on a monthly and quarterly basis to CMS, the federal agency that administers the MDRP and Medicare programs. For the MDRP, these data include the average manufacturer price (AMP) and the best price (BP) for each drug. If we become aware that our MDRP price reporting submission for a prior period was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. In addition, there is increased focus by the Office of Inspector General within the U.S. Department of Health and Human Services on the methodologies used by manufacturers to calculate AMP, and BP, to assess manufacturer compliance with MDRP reporting requirements. If we fail to provide information timely or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP, which would result in payment not being available for our covered drugs under Medicaid. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the Federal False Claims Act and other laws and regulations.

Federal law requires that a manufacturer that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program (340B program) in order for federal funds to be available for the manufacturer's drugs under Medicaid. We participate in the 340B program, which is administered by the Health Resources and Services Administration (HRSA), and requires us to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We are obligated to report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs.

In order to be eligible to have drug products paid for with federal funds under Medicaid and purchased by certain federal agencies and grantees, we also participate in the U.S. Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. Under the VA/FSS program, we are obligated to report the Non-Federal Average Manufacturer Price (Non-FAM) for our covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non-FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and the U.S. Public Health Service (including the Indian Health Service). We are also required to pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If we fail to provide timely information or are found to have knowingly submitted false information, we may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for IBSRELA and, if launched, XPHOZAH, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations are complex, vary among products and programs, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. The terms, scope and complexity of these government pricing programs change frequently, as do interpretations of applicable requirements for pricing and rebate calculations. Responding to current and future changes may increase our costs and the complexity of compliance will be time consuming. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. Price recalculations under the MDRP also may affect the ceiling price at which we are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. In the event that CMS were to terminate our Medicaid rebate agreement, no federal payments would be available under Medicaid or Medicare for IBSRELA or, if launched, XPHOZAH. We cannot offer any assurances that our submissions will not be found to be incomplete or incorrect.

Risks Related to Intellectual Property

Our success will depend on our ability to obtain, maintain and protect our intellectual property rights.

Our success and ability to compete depend in part on our ability to obtain, maintain and enforce issued patents, trademarks and other intellectual property rights and proprietary technology in the U.S. and elsewhere. If we cannot adequately obtain, maintain and enforce our intellectual property rights and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have and our ability to compete, which could harm our business and ability to achieve profitability and/or cause us to incur significant expenses.

We rely on a combination of contractual provisions, confidentiality procedures and patent, trademark, copyright, trade secret and other intellectual property laws to protect the proprietary aspects of our products, product candidates, brands, technologies, trade secrets, know-how and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property rights and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining, maintaining and enforcing other intellectual property rights. We may not be able to obtain, maintain and/or enforce our intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

Failure to obtain, maintain and/or enforce intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the U.S. and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation, or misappropriation of our patents, trademarks, data, technology, and other intellectual property rights and products by others; and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated, or otherwise violated by others.

We rely in part on our portfolio of issued and pending patent applications in the U.S. and other countries to protect our intellectual property and competitive position. However, it is also possible that we may fail to identify patentable aspects of inventions made in the course of our development, manufacture and commercialization activities before it is too late to obtain patent protection on them. If we fail to timely file for patent protection in any jurisdiction, we may be precluded from doing so at a later date. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, should we become a licensee of a third party's patents or patent applications, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted, maintained and/or enforced in a manner consistent with the best interests of our business. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent positions of companies, including our patent position, may involve complex legal and factual questions that have been the subject of much litigation in recent years, and, therefore, the scope of any patent claims that we have or may obtain cannot be predicted with certainty. Accordingly, we cannot provide any assurances about which of our patent applications will issue, the breadth of any resulting patent, whether any of the issued patents will be found to be infringed, invalid or unenforceable or will be threatened or challenged by third parties, that any of our issued patents have, or that any of our currently pending or future patent applications that mature into issued patents will include, claims with a scope sufficient to protect our products and services. Our pending and future patent applications may not result in the issuance of patents or, if issued, may not issue in a form that will be advantageous to us. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We cannot offer any assurances that the breadth of our granted patents will be sufficient to stop a competitor from developing, manufacturing and commercializing a product or technologies in a non-infringing manner that would be competitive with one or more of our products or technologies, or otherwise provide us with any competitive advantage. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for our commercial success. Further, there can be no assurance that we will have adequate resources to enforce our patents.

Patents have a limited lifespan. In the U.S., the natural expiration of a utility patent is generally 20 years from the earliest effective non-provisional filing date. Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products or services. Patents, if issued, may be challenged, deemed unenforceable, invalidated, narrowed or circumvented. Proceedings challenging our patents or patent applications could result in either loss of the patent, or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Any successful challenge to our patents and patent applications could deprive us of exclusive rights necessary for our commercial success. In addition, defending such challenges in such proceedings may be costly. Thus, any patents that we may own may not provide the anticipated level of, or any, protection against competitors. Furthermore, an adverse decision may result in a third party receiving a patent right sought by us, which in turn could affect our ability to develop, manufacture or commercialize our products or technologies.

Some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products, services and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- Any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products or product candidates;
- Any of our pending patent applications will issue as patents;
- We were the first to make the inventions covered by each of our patents and pending patent applications;
- We were the first to file patent applications for these inventions;
- Others will not develop, manufacture and/or commercialize similar or alternative products or technologies that do not infringe our patents;
- Any of our challenged patents will ultimately be found to be valid and enforceable;
- Any patents issued to us will provide a basis for an exclusive market for our commercially viable products or technologies will provide us with any competitive advantages or will not be challenged by third parties;
- We will develop additional proprietary technologies or products that are separately patentable; or
- Our commercial activities or products will not infringe upon the patents of others.

We may become subject to third-party claims alleging infringement, misappropriation or violation of such third parties' patents or other intellectual property rights and/or third-party claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development, manufacture or commercialization of our products or product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture or commercialize our products and product candidates without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There have been many lawsuits and other proceedings asserting infringement or misappropriation of patents and other intellectual property rights in the pharmaceutical and biotechnology industries, and companies in the industry have used intellectual property litigation to gain a competitive advantage. While we take steps to ensure that we do not infringe upon, misappropriate or otherwise violate the intellectual property rights of others, there can be no assurances that we will not be subject to claims alleging that the manufacture, use or sale of IBSRELA or XPHOZAH or of any other product candidates infringes existing or future third-party patents, or that such claims, if any, will not be successful. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of IBSRELA or XPHOZAH or other product candidates. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. We may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of IBSRELA or XPHOZAH or our other product candidates.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights. These proceedings could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents. We may be required to indemnify future collaboration partners against such claims. We are not aware of any threatened or pending claims related to these matters, but in the future, litigation may be necessary to defend against such claims. If a patent infringement suit were brought against us, we could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit. As a result of patent infringement claims, or in order to avoid potential claims, we may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, we may be unable to maintain such licenses and the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms, or unable to maintain such licenses when granted. Even if we are successful in defending against such claims, such litigation can be expensive and time consuming to litigate and would divert management's attention from our core business. Any of these events could harm our business significantly.

We also could be ordered to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents or other intellectual property right. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third party patents are valid and enforceable, and infringed by the use of our products and/or technologies, which could have a negative impact on the commercial success of our current and any future products or technologies. If we were to challenge the validity of any such third party U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. We will have similar burdens to overcome in foreign courts in order to successfully challenge a third party claim of patent infringement. Even if we are successful in defending against such claims, such litigation can be expensive and time consuming to litigate and would divert management's attention from our core business. Any of these events could harm our business significantly.

In addition to infringement claims against us, third parties may also raise similar claims before administrative bodies in the U.S. or abroad. Such mechanisms include reexamination, post grant review, inter parties review, derivation or opposition proceedings before the United States Patent and Trademark Office (USPTO) or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. If third parties prepare and file patent applications in the U.S. that also claim technology similar or identical to ours, we may have to participate in interference or derivation proceedings in the USPTO to determine which party is entitled to a patent on the disputed invention. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Such administrative proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our products or product candidates. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our products or technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

If we are not able to successfully enforce our intellectual property rights, the commercial value of IBSRELA and XPHOZAH or other product candidates may be adversely affected and we may not be able to compete effectively in our market.

The enforceability of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions, the answers to which can be uncertain. The patent applications that we own or license may fail to result in issued patents in the U.S. or in foreign countries. Additionally, our research and development efforts may result in product candidates for which patent protection is limited or not available. Even if patents do issue, third parties may challenge the validity, enforceability, scope or infringement thereof, which may result in such patents being narrowed, invalidated, held unenforceable or not infringed. For example, U.S. patents can be challenged by any person before the new USPTO Patent Trial and Appeals Board at any time before one year after that person is served an infringement complaint based on the patents. Patents granted by the European Patent Office may be similarly opposed by any person within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in the U.S., Europe and other jurisdictions third parties can raise questions of validity with a patent office even before a patent has granted. Furthermore, even if unchallenged, our patents and patent applications may not prevent others from designing around our patent claims. For example, a third party may develop a

competitive product that provides therapeutic benefits similar to one or more of our product candidates but has a sufficiently different composition to fall outside the scope of our patent protection. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to IBSRELA and XPHOZAH or any future product candidates is successfully challenged, then our ability to commercialize such product could be negatively affected, and we may face unexpected competition that could have a material adverse impact on our business.

Even where laws provide intellectual property and/or regulatory protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or one of our collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering a product or product candidate, the defendant could counterclaim that our patent is invalid, unenforceable and/or not infringed. In patent litigation in the U.S. and other jurisdictions, defendant counterclaims alleging invalidity, unenforceability and/or noninfringement are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, nonobviousness and enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity, unenforceability and noninfringment is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity, unenforceability or non-infringement of our intellectual property related to a product or a product candidate, we could lose part, and possibly all, of the patent protection on such product or product candidate. Such a loss of patent protection could have a material adverse impact on our business. Moreover, our competitors could counterclaim that we infringe their intellectual property and may attempt to prevent us from commercializing a product.

Although the composition and use of IBSRELA are currently claimed by four (4) issued patents that are listed in the U.S. FDA's Orange Book, we cannot assure that we will be successful in defending against third parties asserting that any of our patents are invalid, unenforceable or not infringed by the third parties' products, or in competing against third parties seeking to introduce generic versions of IBSRELA or any of our future products.

In the U.S., the Hatch-Waxman Act provides non-patent regulatory exclusivity for five years from the date of the first U.S. FDA approval of a drug containing a new chemical entity (NCE). The U.S. FDA is prohibited during those five years from approving an Abbreviated New Drug Application (ANDA) that references the NDA that has been granted NCE exclusivity. However, if any patents are listed in the U.S. FDA Orange Book for such NCE-containing drug, a generic manufacturer may file an ANDA that references a NDA product with granted NCE exclusivity after four years from the first NDA approval date provided it is accompanied by a Paragraph IV certification asserting that each Orange Book listed patent is invalid, unenforceable, or that the generic product does not infringe the Orange Book listed patents. The Hatch-Waxman Act does not prevent a third party from filing, or the U.S. FDA from approving, another full NDA (i.e. not an ANDA) for an already-approved drug where the third party has conducted its own pre-clinical and clinical trials to independently demonstrate safety and effectiveness without reliance on the original NDA data.

In cases where NCE exclusivity has been granted for an NDA, as in the case of IBSRELA, if an ANDA sponsor has provided a Paragraph IV certification to the U.S. FDA when filing an ANDA, the ANDA sponsor must also send a notice thereof to the NCE NDA owner. The NCE NDA owner may then initiate a patent infringement lawsuit in response to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the NCE NDA owner's receipt of a notice of the Paragraph IV certification automatically prevents the U.S. FDA from approving the ANDA until the earlier of 30 months after the NCE NDA owner's receipt of the Paragraph IV certification notice or a final decision in the infringement case in favor of the ANDA sponsor. There can be no assurances that an ANDA that references our IBSRELA NDA and includes a Paragraph IV certification will not be filed, or that we will be successful in enforcing our Orange Book listed patents against such ANDA sponsor.

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain and/or enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, to assign their inventions to us, and endeavor to execute confidentiality agreements with all such parties, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or who had access to our proprietary information, nor can we be certain that our agreements will not be breached by such consultants, advisors or third parties, or by our former employees. The breach of such agreements by individuals or entities who were actively involved in the discovery and design of our products or potential drug candidates, or in the development of our discovery and design platform could require us to pursue legal action to protect our trade secrets and confidential information, which could be expensive, and the outcome of which would be unpredictable. If we are not successful in prohibiting the continued breach of such agreements, our business could be negatively impacted. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Although we have obtained patent term extension in the U.S. under the Hatch-Waxman Act, extending the term of exclusivity for tenapanor, if we do not obtain patent term extension in foreign countries under similar legislation, our business may be materially harmed. Furthermore, we have obtained patent term adjustment in the U.S. under the American Inventors Protection Act extending the patent term for certain patents covering tenapanor.

U.S. Patent No. 8,541,448 covering tenapanor was subject to patent term adjustment (PTA) under the American Inventors Protection Act for delays by the United States Patent and Trademark Office in granting the patent. Additionally, following the approval by the U.S. FDA for our NDA to market tenapanor for IBS-C, this patent was granted patent term extension (PTE) under the Hatch-Waxman Act and together with PTA provides us with exclusivity for tenapanor and uses thereof until August 1, 2033. The Hatch-Waxman Act allows a maximum of one patent to be extended per U.S. FDA approved product. Extension and/or adjustment of patent term (collectively Patent Restoration) also may be available in certain foreign countries upon regulatory approval of our product candidates. Despite seeking Patent Restoration for tenapanor in all countries where it is available, it may not be granted in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of patent protection subject to Patent Restoration, as well as the scope of patent protection during any such Patent Restoration, afforded by the governmental authority could be less than we request or could change due to changes to applicable Patent Restoration laws or regulations or interpretations thereof.

If we are unable to obtain Patent Term Restoration in any particular country, or the term of any such extension is less than we request, or is changed due to changes in applicable laws or regulations or interpretations thereof, the period during which we will have exclusive rights to our product in such country could be shortened and our competitors may obtain approval of competing products following our non-extended/adjusted patent expiration, and our revenue could be reduced, possibly materially.

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. Noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties.

Europe's new Unified Patent Court may, in particular, present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. In 2012, the European Patent Package (EU Patent Package) regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (UPC), for litigation involving European patents. Implementation of the EU Patent Package entered into force on June 1, 2023. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package as currently proposed, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

In addition, geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the U.S. and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

We may be subject to claims that we or our employees have misappropriated the intellectual property, including know-how or trade secrets, of a third party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at or engaged by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property and other proprietary information or know-how or trade secrets of others in their work for us, and do not perform work for us that is in conflict with their obligations to another employer or any other entity, we may be subject to claims that we or these employees, consultants and contractors have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information. In addition, an employee, advisor or consultant who performs work for us may have obligations to a third party that are in conflict with their obligations to us, and as a result such third party may claim an ownership interest in the intellectual property arising out of work performed for us. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Risks Related to Our Common Stock

Our stock price may continue to be volatile and our stockholders may not be able to resell shares of our common stock at or above the price they paid.

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this "Risk Factors" section and others such as:

- the success or lack of success with regards to our commercialization of IBSRELA and XPHOZAH;
- results of regulatory inspections of our facilities or those of our CMOs, or specific label restrictions or patient populations for XPHOZAH's use, or changes or delays in the regulatory review process;
- announcements regarding whether XPHOZAH alone or with other oral only medications, will be included in the ESRD PPS, and the time and manner in which such transition is achieved;
- announcements relating to our current or future collaboration partnerships;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our product label, our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our approved products or our product candidates;
- the success of our testing and clinical trials;
- failure to meet any of our projected timelines or goals with regard to the commercialization of IBSRELA and XPOHZAH, or the clinical development and commercialization of any of our product candidates;
- the success of our efforts to acquire or license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- the success of our efforts to obtain adequate intellectual property protection for our product candidates;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- U.S. FDA or other U.S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the U.S.;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- sales of debt securities and sales or licensing of assets;
- general economic and market conditions and overall fluctuations in the U.S. equity markets; and
- the loss of any of our key scientific or management personnel.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could seriously harm our financial position. Any adverse determination in litigation could also subject us to significant liabilities.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders will experience additional dilution and, as a result, our stock price may decline.

We are no longer a "smaller reporting company" and as a result we are or will be subject to certain enhanced disclosure requirements which will require us to incur significant expenses and expend time and resources.

We are no longer a "smaller reporting company," and, as a result, we are or will be required to comply with various disclosure and compliance requirements that did not previously apply to us. Compliance with these additional requirements increases our legal and financial compliance costs and causes management and other personnel to divert attention from operational and other business matters to these additional public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to delisting proceedings by the Nasdaq Global Market, or sanctions or investigations by the Securities and Exchange Commission (SEC) or other regulatory authorities, which would require additional financial and management resources.

General Risk Factors

We incur significant costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended (Exchange Act) and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 (Section 404) and the related rules of the SEC which generally require, among other things, our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Our compliance with Section 404 requires that we incur substantial expense and expend significant management efforts.

During the course of our review and testing of our internal controls, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm our business.

We may be adversely affected by the global economic environment.

Our ability to attract and retain collaboration partners or customers, invest in and grow our business and meet our financial obligations depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the U.S., presidential elections, other political influences and inflationary pressures. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including the current inflationary environment and rising interest rates. Adverse developments that affect financial institutions, transactional counterparties, or other third parties, or concerns or rumors about these events, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the U.S. Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, other institutions have been and may continue to be swept into receivership. We currently have no borrowing or deposit exposure to directly impacted institutions and have not experienced an adverse impact to our liquidity or to our business operations, financial condition, or results of operations as a result of these recent events. However, uncertainty may remain over liquidity concerns in the broader financial services industry, and there may be unpredictable impacts to our business and our industry. We cannot anticipate all the ways in which the global economic climate and global financial market conditions could adversely impact our business in the future.

We are exposed to risks associated with reduced profitability and the potential financial instability of our collaboration partners or customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and pharmaceuticals. If fewer patients are seeking medical care because they do not have insurance coverage, our collaboration partners or customers may experience reductions in revenues, profitability and/or cash flow that could lead them to reduce their support of our programs or financing activities. If collaboration partners or customers are not successful in generating sufficient revenue or are precluded from securing financing, they may not be able to pay, or may delay payment of, accounts receivable that are owed to us. In addition, volatility in the financial markets could cause significant fluctuations in the interest rate and currency markets. We currently do not hedge for these risks. The foregoing events, in turn, could adversely affect our financial condition and liquidity. In addition, if economic challenges in the U.S. result in widespread and prolonged unemployment, either regionally or on a national basis, or if certain provisions of the Patient Protection and ACA, as amended by the Health Care and Education Reconciliation Act, collectively known as the ACA, are repealed, a substantial number of people may become uninsured or underinsured. To the extent economic challenges result in fewer individuals pursuing or being able to afford our product candidates once commercialized, our business, results of operations, financial condition and cash flows could be adversely affected.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquirer or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least two-thirds of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such a person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnities, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Additionally, the terms of our 2022 Loan Agreement could restrict our ability to pay dividends. Therefore, our stockholders are not likely to receive any dividends on our common stock for the foreseeable future. Since we do not intend to pay dividends, our stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

None.

Use of Proceeds

Not applicable.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Trading Plans

During the three months ended September 30, 2024, our Section 16 officers and directors adopted or terminated contracts, instructions or written plans for the purchase or sale of our securities as noted below:

Name and Title of Director or Officer	Action	Date	Trading Arrangement		Total Shares Available to be Sold	Expiration Date
			Rule 10b5-1*	Non-Rule 10b5-1**		
Michael Raab, President and Chief Executive Officer	Adoption	September 4, 2024	X		500,000	January 2, 2026
*Intended to satisfy the affirmative defense conditions of Rule 10b5-1(c)						
**Not intended to satisfy the affirmative defense conditions of Rule 10b5-1(c)						

ITEM 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	June 24, 2024	3.1	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	8-K	June 20, 2023	3.1	
3.3	Amended and Restated Bylaws.	8-K	June 24, 2014	3.2	
10.1†	Commercial Supply Agreement, dated August 7, 2024 and effective as of July 23, 2024, by and between Ardelyx, Inc. and Catalent.	8-K	August 12, 2024	10.1	
10.2†	Commercial Supply Agreement, dated October 25, 2024, by and among Ardelyx, Inc., Hovione Farmaciência, S.A. and Hovione, LLC.				X
10.3	Lease Agreement, dated October 3, 2024, by and between Ardelyx, Inc. and BMR-Pacific Research Center LP.	8-K	October 9, 2024	10.1	
10.4	Sixth Amendment to Lease, dated May 25, 2021, by and between Ardelyx, Inc. and 34175 Ardenwood Venture, LLC.	8-K	October 9, 2024	10.2	
10.5	Fourth Amendment to the Loan and Security Agreement dated October 29, 2024, by and between Ardelyx, Inc. and SLR Investment Corp.				X
10.6#	Offer Letter, dated July 25, 2024 by and between Alderyx, Inc. and Eric Foster.				X
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following financial statements, formatted in Inline Extensible Business Reporting Language (XBRL): (i) Condensed Balance Sheets as of September 30, 2024 and December 31, 2023, (ii) Condensed Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2024 and 2023, (iii) Condensed Statements of Changes in Stockholders Equity for the three and nine months ended September 30, 2024 and 2023, (iv) Condensed Statements of Cash Flows for the nine months ended September 30, 2024 and 2023, and (v) Notes to Unaudited Condensed Financial Statements.				X
104	Cover Page Interactive Data File, formatted in Inline XBRL and contained in Exhibit 101.				X

† Portions of the exhibit, marked by brackets, have been omitted because the omitted information (i) is not material and (ii) is the type that the Company treats as private or confidential.

# Indicates management contract or compensatory plan.

*The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q, is deemed furnished and not filed with the Securities and Exchange Commission is not to be incorporated by reference into any filing of Ardelyx, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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.

Ardelyx, Inc.

Date: October 31, 2024

By: /s/ Robert Felsch

Robert Felsch
Senior Vice President and Chief Accounting Officer
(Principal Accounting Officer)

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE COMPANY TREATS AS PRIVATE OR CONFIDENTIAL

Commercial Supply Agreement

THIS COMMERCIAL SUPPLY AGREEMENT (this "Agreement") is made as of October 21, 2024 (the "Effective Date") by and between Hovione Farmaciência, S.A., having a principal place of business at Sete Casas 2674-506 Loures, Portugal ("Hovione Portugal"), Hovione, LLC., having its registered office at 202 Carnegia Center, CN-5226, Princeton, New Jersey, 08543-5226, U.S.A. ("Hovione NJ"), each on behalf of itself and its Affiliates (and together, "Hovione"), and Ardelyx, Inc., a Delaware corporation having a principal place of business at 400 5th Ave., Suite 210, Waltham, MA 02451 USA ("Ardelyx"). Each of Hovione and Ardelyx may be referred to herein as a "Party", and collectively as the "Parties".

WHEREAS, Ardelyx and Hovione are parties to a Master Services Agreement dated December 22, 2015 governing Hovione's performance of spray-drying and development services for Ardelyx in respect of its tenapanor products (as amended, and including all attachments and work orders thereunder, the "Development Agreement");

WHEREAS, the Parties desire to enter into a commercial supply agreement pursuant to which the Original Manufacturing Site (and potentially one or more of its Affiliates) shall perform spray-drying services for Ardelyx at commercial scale, in the manner developed and validated under the Development Agreement;

THEREFORE, in consideration of the foregoing and the covenants contained herein, the Parties hereto agree that the following provisions shall govern the performance of Services hereunder:

1. Definitions. The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

1.1. "Adverse Supply Event" means one or more of the following: (i) Hovione is unable to [***] that is required by [***], or (ii) [***] orders a halt to any further performance of the Manufacturing Services for a Product.

1.2. "Affiliate" means a business entity which, directly or indirectly, owns a controlling interest in a Party, is controlled by a Party, or is under common control with Party; where "control" means the lawful right to determine (by ownership of shares or otherwise) the election of the majority of directors (or equivalent managers) of a business entity;

1.3. "Additional Services" has the meaning specified in Section 3.1;

1.4. "Annual Commitment" has the meaning specified in Section 2.2;

1.5. "API" means the active pharmaceutical ingredient tenapanor in free base form;

1.6. "API Reimbursement Price" means the reimbursement price per kilo of API as set forth in Appendix 3.

1.7. "Applicable Laws" means (i) with respect to Hovione, all Laws applicable at the jurisdiction where the Manufacturing Site is located; and (ii) with respect to Ardelyx and Ardelyx's use of the Product, the applicable Laws of all jurisdictions in the Territory;

1.8. "Ardelyx Background IP" means Intellectual Property that is owned or controlled by or on behalf of Ardelyx and developed or obtained independently of this Agreement, whether before or after the Effective Date. Ardelyx Background IP specifically [***];

1.9. "Ardelyx Inventions" has the meaning specified in Section 13.3;

1.10. "Ardelyx Property" has the meaning specified in Section 8.3.2;

1.11. "Authority" means any governmental or regulatory authority, department, securities exchange, body or agency or any court, tribunal, bureau, commission or other similar body, whether foreign, federal, state, provincial, county or municipal, with competent jurisdiction over a party, the Manufacturing Services, or within the Territory of the Product (or its use);

1.12. "Banking System" has the meaning specified in Section 3.3(d)(ii);

1.13. "Batch" means the Product Manufactured from a single run of a Manufacturing campaign hereunder. For clarity, any given Manufacturing campaign may contain a single Batch or several Batches.

1.14. "Binding Forecast" has the meaning specified in Section 5.1;

1.15. "Business Day" means a day other than a Saturday, Sunday or a day that is a statutory holiday in Hovione's resident jurisdiction, Ardelyx's resident jurisdiction, or the jurisdiction where the applicable Manufacturing Site is located;

1.16. "Business Need" means a decision by Ardelyx to reduce or cease Manufacture of Product in connection with major changes to its business strategy or Product markets, substantively unrelated to any breaches or failures of Hovione as otherwise regulated herein. Business Need may include, by way of example and not limitation, significant changes to Licensee arrangements or Licensee demand, or a significant reduction in the market for the Product in a jurisdiction of the Territory.

1.17. "cGMPs" means the principles described in ICH Q7 Good Manufacturing Guidance for Active Pharmaceutical Ingredients, as promulgated (i) in the United States under Parts 210 and 211 of Title 21 of the United States Code of Federal Regulations, and (ii) under the corresponding pharmaceutical manufacturing Laws and guidances issued by any other Regulatory Authority in the Territory;

1.18. "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by either Party with respect to any objective, such commercially reasonable, diligent efforts as such Party would normally use to accomplish a similar objective under similar commercial circumstances as expeditiously as possible, which will take into consideration such Party's existing prior and conflicting obligations to third parties;

1.19. "Components" means, collectively, all raw materials, ingredients, reference standards, impurity markers and other materials required to manufacture Product in accordance with the Processing Instructions, other than the API;

1.20. "Confidential Information" has the meaning specified in Section 12;

1.21. "Contract Year" means the twelve (12) month period commencing on the Effective Date and ending on the day before the first anniversary thereof and each consecutive twelve (12) month period thereafter during the Term;

1.22. "[***]" has the meaning specified in Section 6.4;

1.23. "Deficient Product" has the meaning specified in Section 6.2;

1.24. "Deficiency" has the meaning specified in Section 7.6.2;

1.25. "Delivery Date" means in relation to each Batch of Product, the scheduled date of the Hovione Release (by confirmation or certification, as agreed in the Quality Agreement) and made available for shipment [***], as confirmed by Hovione upon receipt of a Firm Order;

1.26. "Development Services" means any pharmaceutical research or development services for the Product, including without limitation the manufacture of Product validation batches, performed by Hovione for Ardelyx under the Development Agreement, whether before or after the Effective Date and throughout the Term;

1.27. "Discloser" has the meaning specified in Section 12;

1.28. "Equipment" has the meaning specified in Section 2.5;

1.29. "Equipment Agreement" has the meaning specified in Section 2.5;

1.30. "Fault" means a Party's (a) [***], (b) [***] or (c) [***].

1.31. "FDA" means the United States Food and Drug Administration;

1.32. "FFDCA" means the United States Federal Food, Drug, and Cosmetic Act, 21 USC §§ 301 et seq.;

1.33. "Final Invoice" has the meaning specified in Section 8.3.2;

1.34. "Firm Order" has the meaning specified in Section 5.3;

1.35. "Forecast" has the meaning specified in Section 5.1;

1.36. "Hovione Background IP" means Intellectual Property owned or controlled by Hovione and developed or obtained independently of this Agreement, whether before or after the Effective Date; for clarity, Hovione Background IP specifically [***]

1.37. "Hovione Inventions" has the meaning specified in Section 13.4;

1.38. "Hovione Release" has the meaning specified in Section 5.5;

1.39. "Indemnitee" has the meaning specified in Section 11.3;

1.40. "Indemnitor" has the meaning specified in Section 11.3;

1.41. "Initial Term" has the meaning specified in Section 8.1;

1.42. "Intellectual Property" means any rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

1.43. "Invention" means any innovation, improvement, development, discovery, computer program, device, trade secret, method, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

1.44. "Inventory" means, at a point in time, all inventories under Hovione's care or control of Product, API, Components, intermediates used for the manufacture of Product and work-in-process;

1.45. "[***]" has the meaning specified in Section 6.2;

1.46. "Laws" means all laws (including common law), statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Regulatory Authority;

1.47. "Licensees" means any person to whom Ardelyx has entered into a license agreement for the marketing, sale or distribution of the Product in any form;

1.48. "Losses" has the meaning specified in Section 11.1;

1.49. "Manufacturing Records" means, for a shipment of Product, the Batch records, certificate of analysis, certificate of conformity, BSE/TSE certificate and any other documents Specified in Appendix D of the Quality Agreement;

1.50. "Manufacture" means performance of any Manufacturing Services.

1.51. "Manufacturing Services" means the spray-drying and quality control, quality assurance, stability testing, packaging, and related services for the manufacture of Product;

1.52. "Manufacturing Site" means the facilities located in Loures, Portugal (the "Original Manufacturing Site"), and East Windsor, New Jersey, U.S.A. (the "New Jersey Site"), and any other Hovione site where the Parties agree that Manufacturing Services will be performed;

1.53. "[***]" has the meaning specified in Section 3.3(d);

1.54. "Notice of Termination" has the meaning specified in Section 8.1;

1.55. "Price" means, as applicable, (a) the price per kilogram of Manufactured Product delivered to Ardelyx as set out in Appendix 1; and (b) the separate costs and fees for services requested by Ardelyx and specifically excluded from the cost of the Product, as may be subject to an additional written work order or written agreement that is expressly made subject to the terms and conditions of this Agreement;

1.56. "Process" means the process for Manufacture of the Product as reflected in the Processing Instructions, Specifications and Manufacturing Records.

1.57. "Processing Instructions" means the documented parameters maintained by Hovione for the Manufacturing Services for the Product, each as updated from time to time in accordance with Section 3.2, which includes:

(a) quality control testing methods for API and Components;

(b) master Batch, production and control records, manufacturing instructions, directions, and processes;

(c) any storage requirements for the API, Components, or Product; and

(d) the Product quality control testing methods, packaging instructions and shipping requirements for the Product;

1.58. "Product" means the spray-dried form of API manufactured pursuant to this Agreement;

1.59. "Product Change Control Request" has the meaning specified in Section 3.2;

1.60. "Product Rejection" has the meaning specified in Section 6.2;

1.61. "Product Yield" has the meaning specified in Section 3.3(d);

1.62. "Purchase Order" has the meaning specified in Section 5.2;

1.63. "Quality Agreement" means the Quality Agreement between Ardelyx and Hovione Portugal, dated November 16, 2018, as amended from time to time;

1.64. "Recall" has the meaning specified in Section 6.7;

1.65. "Recipient" has the meaning specified in Section 12.1;

1.66. "Regulatory Approval" has the meaning specified in Section 7.6.1;

1.67. "Regulatory Authority" means the FDA and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical or biopharmaceutical products, including the Products, in the Territory;

1.68. "Representative" means a Party's director, officer, employee, advisor, agent, consultant, subcontractor or service partner;

1.69. "Scale-Up" has the meaning specified in Section 2.5;

1.70. "Specifications" means the requirements and standards for the Product as set forth in Appendix B to the Quality Agreement;

1.71. "Supply Failure" means (a) Hovione's Manufacture of [***] Batches of Deficient Product, or (b) with respect to Product scheduled for Delivery pursuant to Firm Orders during [***], a failure by Hovione to deliver to Ardelyx or its designee at least [***] within [***] of the applicable scheduled Delivery Dates, absent [***], *provided, however*, that in the case of [***]. A Supply Failure may result from [***]. The Parties acknowledge that [***].

1.72. "Term" means the Initial Term and any and all renewal terms applicable under Section 8.1;

1.73. "Territory" means [***];

1.74. "Third Party Claim" has the meaning specified in Section 11.1;

1.75. "Third Party Subcontractors" has the meaning specified in Section 2.8;

1.76. "Third Party Rights" means the Intellectual Property of any third party;

1.77. "Work Order" has the meaning set forth in Section 3.1 and

1.78. "Year" means in the first year of this Agreement, the time from the Effective Date up to and including December 31 of the same calendar year, and after that will mean a calendar year, except for in the case of the calendar year in which this Agreement is terminated or expires, in which case the Year will be the date beginning on January 1 of that Year and ending on the date of the effective termination of this Agreement.

2. Manufacturing Services

2.1. Performance Standard. Hovione shall perform the Manufacturing Services in accordance with the Processing Instructions and supply Product manufactured in accordance with the Specifications, for the Price, in accordance with the material provisions of the Quality Agreement, Applicable Law, cGMP and the prevailing industry standards and practices for the performance of similar services. Subject to the preceding sentence, Hovione will convert API and Components into Product, and provide supportive Manufacturing Services such as quality assurance (for example quality controls, analytical testing, and stability programs). From time to time during the Term and by mutual agreement between the Parties, Ardelyx may request any other related Manufacturing Services, excluding any Development Services which shall be subject to the Development Agreement, and such additional Manufacturing Services shall be charged separately as may be agreed by and between the Parties.

2.2. Annual Commitment.

(a) Conditional upon Ardelyx's timely payments as required in accordance with the Equipment Agreement and beginning in Year 2024, subject to Sections 6.3 and 6.5 and the other terms of this Agreement, Ardelyx will place Purchase Orders (as defined below) in accordance with Section 5.2 for, and Hovione will manufacture for Ardelyx, Product for delivery by the scheduled Delivery Dates specified in the accepted Purchase Order in accordance with this Agreement, in the following minimum quantities (the "Annual Commitment"):

2024	[***]
2025	[***]
2026	[***]
2027	[***]
2028 to end of the Term	[***]

For the avoidance of doubt, the Delivery Dates set out in the relevant Purchase Orders shall be the applicable dates for determination of Ardelyx's satisfaction of the Annual Commitment.

(b) The Annual Commitment may be adjusted by mutual agreement of the Parties pursuant to Section 2.6 below. For clarity, in the event of failure to order the Annual Commitment absent Supply Failure, Adverse Supply Events (subject to the applicable limitations of Section 6.5.3), or mutually agreed Manufacturing reductions, Hovione may on December 31st of the relevant Year charge Ardelyx the respective shortfall between the Annual Commitment for such Year and the orders for Product actually placed by Ardelyx and with the Delivery Dates (set out in the relevant Purchase Orders) in such Year.

(c) Subject to the terms of the Equipment Agreement, until the Scale-Up (defined below) is completed, and notwithstanding anything to the contrary herein, the Parties' Annual Commitment obligation shall remain at [***] until completion of Scale-Up, at which time [***].

2.3. Existing Orders. For the Year 2024, the Parties acknowledge that all orders for Product Manufacturing have been placed and accepted pursuant to the Development Agreement. The Development Agreement shall govern the Manufacture of all Product delivered prior to the Effective Date, provided that following Hovione release pursuant to the Quality Agreement, the terms of this Agreement shall govern the use, integrity and remedies associated with of the Product itself, including without limitation the Product Warranties set forth in Section 9.2.3. Thereafter, this Agreement shall govern any such order for Product Manufacturing placed and not yet delivered for the Year 2024.

2.4. [***]. So long as Ardelyx is otherwise in substantial compliance with the terms of this Agreement, including without limitation, the Annual Commitment obligations hereunder, Hovione will not at any time during the Term [***], without the express written consent of Ardelyx. Hovione acknowledges and agrees that Ardelyx may grant or withhold its consent [***].

2.5. Scale-Up. The Parties acknowledge that, beginning in Year 2027, the Annual Commitment will exceed [***]. Therefore parties have entered into an [***] pursuant to which Hovione shall purchase, install, validate and qualify certain [***] equipment for [***] (the "Equipment") [***] ("Equipment Agreement"), and reference is made to relevant terms thereunder whereby Ardelyx's agrees to deliver upfront payments and success fees to Hovione totaling up to [***] dollars (US $[***]) in consideration of timely validation and qualification of commercial Product [***] (the "Scale Up"). For clarity, any validation or qualifications batches (including any such batches required for Scale Up) shall be subject to the Development Agreement (or other service agreement as may be agreed between the Parties) and do not count towards Supply Failures.

2.6. Continuity of Supply. After Scale Up, [***]. Notwithstanding the foregoing, at the request of Ardelyx, Hovione shall continue to supply (i) [***] of the Annual Commitment (unless otherwise agreed by the Parties) from Hovione Portugal until Ardelyx's Licensees have received regulatory approval for Hovione NJ, and thereafter (ii) mutually agreed volumes of Product from Hovione Portugal, at least sufficient to retain the Hovione Portugal facility as an alternative supplier's site in the applicable regulatory filing for Product. Ardelyx shall use Commercially Reasonable Efforts to [***]. Ardelyx and Hovione shall cooperate to facilitate delivery of information required for such licensee Regulatory Approvals. For clarity, following Regulatory Approval of Hovione NJ by all Ardelyx licensees, clause (i) above shall expire and only clause (ii) shall apply.

2.7. No Sole Source. Subject to Section 2.2, nothing in this Agreement will prohibit Ardelyx from purchasing tenapanor products and services from a third party,

entering into any contract with any third party for the supply of such products and services, manufacturing its own products, or qualifying additional facilities for supply of products.

2.8. Subcontracting. Subject to compliance with the Quality Agreement, Hovione may engage third parties to perform services ancillary to the Manufacturing Services with the written consent of Ardelyx (except for the subcontracting of analytical testing or stability storage services, which will require no written consent) ("Third Party Subcontractors"), provided that each such Third Party Subcontractor complies with all applicable obligations of this Agreement and, if applicable, the Quality Agreement. Hovione will be liable to Ardelyx for the breach of this Agreement (or, if applicable, the Quality Agreement) by any Third Party Subcontractor, or failure of any Third Party Subcontractor to perform any part of the subcontracted services, as if Hovione had breached, performed or failed to perform the subcontracted services directly.

2.9. Facilities. Hovione, at no cost to Ardelyx, will qualify (and thereafter will maintain qualification of) each Manufacturing Site as required under Applicable Laws and cGMP. Hovione will not change the Manufacturing Site without first obtaining Ardelyx's written consent. Except for [***], if any changes to the Manufacturing Site are proposed by Hovione and agreed by Ardelyx regarding the Manufacturing Site at which the Manufacturing Services are to be performed, (a) if such changes are specific to Ardelyx or its Product Processing, then Parties shall negotiate in good faith the costs of any validation activities required for this change and the respective allocation of benefits arising therefrom, to the extent the proposed changes improve the cost and/or efficiency of Manufacturing Services and (b) [***]. Hovione will not undertake or permit any modifications to the Manufacturing Site that materially affect the Product or implement any changes in the Process, including, without limitation, the Processing Instructions or equipment used to manufacture the Product without Ardelyx's prior written consent, not to be unreasonably withheld.

2.10. Inventory Reporting. Hovione will provide to Ardelyx, on a monthly basis (at a minimum) and otherwise upon receipt of a written request and within a reasonable timeframe, a written report of Inventory, in each case in the form generated by Hovione's electronic inventory management platform, and/or a written cycle count report. In addition, once annually at mutually agreed times, Hovione shall give Ardelyx reasonable access to the locations where all Inventory and related records are kept, and to the personnel that regularly manage such Inventory and records, to permit Ardelyx to conduct a physical count of all Inventory in Hovione's possession or control. Hovione will use Commercially Reasonable Efforts to ensure that its Third Party Contractors permit Ardelyx similar access. Hovione will promptly advise Ardelyx if it encounters Component supply problems, including delays or delivery of non-conforming Components. In the event that any Component becomes subject to purchase lead time beyond the Binding Forecast time frame, or Hovione is otherwise unable to obtain, in a timely manner, a particular Component necessary for Manufacturing, the Parties will negotiate in good faith an appropriate amendment to this Agreement and will cooperate to reduce or eliminate any supply problems from the suppliers.

2.11. Packaging. Hovione will make arrangements for and implement the imprinting of lot numbers and expiration dates on the packaging drums of each Product shipped. These lot numbers and expiration dates will be affixed on the shipping container of each Product as is required by Applicable Laws, cGMP (if applicable) and consistent with the Specifications. If applicable, electronic on-line verification of lot number/expiration date and serialization will be performed by Hovione. If Hovione places an internal lot number on a shipping container that is different from the Ardelyx lot number referenced in any Purchase Order for that Batch of Product, Hovione will provide a cross-reference for the Ardelyx lot number on all documents associated with that Batch of Product.

3. Ardelyx's Obligations

3.1. Payment. As full consideration for the Manufacturing Services, Ardelyx will pay Hovione the applicable Price in accordance with Section 4. From time to time during the Term and by mutual agreement between the Parties, Ardelyx may request that Hovione provide additional services which are not included in Price to support the Manufacture of Product, excluding any Development Services which shall be subject to the Development Agreement ("Additional Services"), as specified in a written work order signed by duly authorized representatives from both Parties and detailing the specific services to be performed and any deliverables to be provided by Hovione (each, a "Work Order"). Hovione will perform the Additional Services in accordance with the terms of this Agreement (including any deviations of applicable terms and conditions as may be contained on any such Work Order) and such Additional Services shall be charged separately as may be agreed by and between the Parties on such Work Order.

3.2. Change Control Requests. Ardelyx and Hovione will cooperate on any requested changes to the Processing Instructions, Specifications or accompanying documents (a "Product Change Control Request") in accordance with the change control process set forth in the Quality Agreement. Upon acceptance of the Product Change Control Request by the relevant persons identified in the Quality Agreement, Hovione will give Ardelyx a signed and dated receipt indicating Hovione's acceptance. At Hovione's request, Ardelyx will provide evidence of the executed original documents submitted by or on behalf of Ardelyx to the Regulatory Authority. Hovione will respond promptly to any Product Change Control Request and use commercially reasonable, good faith efforts to agree to the terms of the requested changes in a timely manner (including any changes in Price), and the Parties will execute a change order reflecting such changes in Manufacturing Services and Price (a "Change Order"). Hovione agrees that any changes mandated by a Regulatory Authority will be considered and acted upon expeditiously and with due diligence.

3.3. API Supply.

(a) Lead Time. Ardelyx will at its sole cost and expense deliver the API to the Manufacturing Site [***]. [***]'s obligation will include obtaining the release of the API from the applicable customs agency and Regulatory Authority. Unless otherwise agreed in

writing, Ardelyx or Ardelyx's designated broker will be the "Importer" or "Importer of Record" (or equivalent, as understood under Applicable Laws to Ardelyx) for API imported to the Manufacturing Site, and Ardelyx is responsible for compliance with Applicable Laws to Ardelyx (and the cost of compliance) relating to that role. Ardelyx shall deliver the API to the Manufacturing Site at least [***] before the scheduled manufacture date for Product covered by a Firm Order, in sufficient quantity to enable Hovione to manufacture the agreed quantities of Product for that Firm Order. If delays in performance of the Manufacturing Services are caused by Ardelyx's failure to supply Hovione with API with the lead time as set forth in the preceding sentence ("API Delay"), then Hovione will be entitled, after conferring in good faith with Ardelyx to ensure minimal disruption to both Parties' operations, to either: (a) (i) reallocate resources otherwise reserved for the performance of such Manufacturing and reschedule such Manufacturing based on available capacity planning at the applicable Manufacturing Site and (ii) use Commercially Reasonable Efforts to fill any idle capacity resulting from such API Delay, and (iii) with respect to any remaining idle capacity caused by such API Delay, charge Ardelyx the amount due for any such rescheduled Manufacturing as compensation for such idle capacity at the applicable Manufacturing Site, or (b) extend the timelines for delivery of Product, provided that Parties agree on adequate compensation (if applicable) for any idle time in the allocated resources in the applicable Manufacturing Site. If any such delay lasts for [***] or more, the Parties will meet to discuss how to resolve the situation including, if appropriate, the impact of cost and timeline.

(b) Storage. Hovione will handle, store and Manufacture the API in accordance with all environmental, health and safety information for the Product included within the material safety data sheets. Hovione will control the unloading of API arriving at the Manufacturing Site and will store such API at the Manufacturing Site or other mutually agreed storage facility (subject to any qualification of such facility required by Ardelyx) for up to [***] free of charge. The API will be held by Hovione on behalf of Ardelyx in accordance with this Agreement and any written instructions provided in connection with the API including as applicable any safety data sheets, safe handling instructions and health and environmental information associated therewith. The API will at all times remain the property of Ardelyx. Any API received by Hovione will only be used by Hovione to perform the Manufacturing Services for Ardelyx. Hovione will collect samples of API and deliver them to a third party designated by Ardelyx for testing in accordance with the Processing Instructions.

(c) Risk of Loss. Risk of loss of the API will at all times remain with Ardelyx while not in Hovione's custody. [***]. Notwithstanding the foregoing:

(i) Hovione will use Commercially Reasonable Efforts to keep secure and account for all API, Components and Product;

(ii) Risk of loss to Product will transfer to Ardelyx as set forth in Section 5.5.

(iii) Hovione's liability for API wasted as a result of Deficient Product Manufacturing shall be as set forth in Section 6;

(iv) API loss resulting from [***] shall be mitigated in accordance with the Banking System described in Section 3.3(d);

(v) Except as provided in clauses (iii) and (iv) above relating to Deficient Product and low Product Yields, respectively, and subject to the terms of Section 10 and any adjustments resulting from the application of 3.3(d), Hovione agrees to reimburse Ardelyx in accordance with the API Reimbursement Price for any other quantities of API lost or destroyed while in the custody of Hovione if [***]; and

(vi) If requested, Ardelyx will provide Hovione's insurer with reasonable support for the cost of the lost or destroyed API.

(d) Yield Bank

(i) With respect to each Manufacturing Site, after the first ten (10) Batches of Product have been manufactured and released to Ardelyx in accordance with the Quality Agreement, the Parties shall agree in good faith on the actual Product per API ratio ("Product Yield") achieved from such ten (10) Batches. Thereafter, Hovione shall ensure that, on an annual basis, the Product Yield complies with [***] (the "[***]"). Parties acknowledge and agree that the [***] shall contain an allowed statistical deviation, as agreed by the Parties, which may change during the Term as more Batches of Product are manufactured and additional data are gathered from such manufacturing. The parties agree that as of the Effective Date, the Product Yield for Hovione Portugal is [***]% and the [***] for Hovione Portugal is [***]%. The [***] shall be revised yearly concurrently with updated annual Pricing pursuant to Section 4.2 to incorporate data from additional Batches of Product Manufactured and released to Ardelyx under this Agreement. For clarity, the Parties agree that the [***] and annual revision calculation shall be based only on Batches of Product released to Ardelyx in accordance with the Quality Agreement and shall not include Batches containing Deficient Product, whether or not the Deficient Product was released to Ardelyx.

(ii) Hovione shall have the right to credit yields in excess of the [***] to offset yields below the [***] or to offset losses due to Deficient Product prior to any compensation to Ardelyx (the "Banking System"). If the [***] is not met with respect to a Batch, Hovione shall apply losses to the Banking System.

(iii) Within ninety (90) days after the end of each calendar year, Hovione will prepare an annual reconciliation of actual annual Product Yield against the [***], considering the credits and debits applied to the Banking System. Should the annual Product Yield for such calendar year be less than [***], then Hovione will [***]. Should the actual Product Yield be higher than the [***], such excess shall be carried forward as a

credit in the Banking System for the following year to be used to offset a future shortfall of Product Yield or losses due to Deficient Product during the Term.

3.5. Information. Upon reasonable request Ardelyx will provide information to Hovione as reasonably requested by Hovione in connection with its performance of Manufacturing of Product and its other obligations under this Agreement in compliance with Applicable Law.

4. Price and Price Adjustments

4.1. Pricing. The Pricing for manufacture and release of Product from the Original Manufacturing Site shall be as set forth on Appendix 1, subject to adjustment in accordance with this Section 4. All payments hereunder to be made in US Dollars. With respect to Fees for Manufacturing performed at Hovione Portugal, if the exchange rate between USD and Euro varies by [***]% or more beyond the Reference Exchange Rate (as defined in Appendix 2), then Parties agree to redefine the value of the Fees in accordance with the terms and conditions of Appendix 2.

4.2. Annual Price Adjustments. Hovione may adjust the Price effective January 1st of each Year following the first full Year, in an amount reflecting the greater of (a) [***] or (b) [***]. For all Price adjustments under this Section 4.2, Hovione will deliver to Ardelyx [***] a letter stating the adjusted Pricing to be effective for Product ordered on or after January 1 of the next Year together with [***].

4.3. Changes. If Ardelyx requests any change to the scope of the Manufacturing Services as set forth in Section 3.2, the corresponding Change Order will set forth any adjustments to the Prices that are necessitated by the changes, which shall become effective upon execution of such Change Order.

4.4. Taxes. Any use, sales, excise, or value added tax, duty, custom, inspection or testing fee, or any other tax, fee or charge of any nature whatsoever imposed by any governmental authority on or measured by the transactions contemplated hereunder between Hovione and Ardelyx (other than Hovione's income tax), will be paid by Ardelyx in addition to the Price. In the event Hovione is required to pay any such tax, fee, or charge: (a) Hovione will make such payment timely and in accordance with Applicable Laws, (b) Hovione will invoice Ardelyx for such payment including a copy of the applicable evidence of payment, and (c) Ardelyx will reimburse Hovione for such payment. In lieu of such payment, Ardelyx may provide Hovione at the time an order is submitted an exemption certificate or other document acceptable to the authority imposing the tax, fee or charge.

4.5. Efforts to Achieve Price Reductions. During the Term, Hovione and Ardelyx agree to use Commercially Reasonable Efforts to jointly develop a program aimed at [***] but this program will not involve capital or other extraordinary costs being incurred by any party without the prior written consent of the other party. To the extent successful, the

parties shall discuss and negotiate in good faith the allocation of costs savings resulting from this cost reduction program.

5. Purchasing Product

5.1. Forecasts. Within thirty (30) days after the Effective Date, Ardelyx will deliver to Hovione a written forecast of the volume of Product that Ardelyx expects to order from Hovione in each of the next [***] (the "Forecast"). The first [***] of each Forecast will be binding on the Parties (the "Binding Forecast") and the remaining [***] will be [***], good faith estimates that may be increased or decreased by no more than [***] percent ([***]%) during the entire period from such month's first appearance on the Forecast until such month becomes part of the Binding Forecast or as otherwise agreed by the Parties (the "Non-binding Forecast"). Ardelyx will provide an updated Forecast at least quarterly. To the extent that any updated portion of a Forecast exceeds the Annual Commitment, Hovione will consider in good faith and make all reasonable efforts to accommodate such excess, subject to Hovione's then binding capacity commitments to other customers. Within [***] after receipt of each Forecast, Hovione shall accept or reject such Forecast in writing, provided that [***]. If Hovione rejects a Forecast, it shall deliver written notice to Ardelyx of [***]. In the absence of such notice, [***].

5.2. Capacity; Order Placement. In respect of Year 2025, and each Year throughout the remainder of the Term, Ardelyx shall deliver purchase orders quarterly that specify the order quantities and requested delivery dates for the Product in accordance with this Agreement (each a "Purchase Order"). Ardelyx shall purchase Product in an amount at least equal to the Annual Commitment for each Year and otherwise consistent with the Binding Forecast. Hovione shall use Commercially Reasonable Efforts to accommodate any Ardelyx requests to manufacture and deliver volumes of Product which exceed the Binding Forecast ("Excess Product"), but Hovione expressly reserves the right to accept or reject any requests to supply Excess Product. Unless otherwise expressly agreed between the Parties, Ardelyx agrees that it has no right of reservation over the Equipment or any other equipment of Hovione. Each Purchase Order shall (i) specify order quantities consistent with the then current Forecast, (ii) meet the Annual Commitment, and (iii) specify the Purchase Order number and requested Delivery Dates for the Product (not less than [***] from the date of the relevant Purchase Order, and otherwise in accordance with the minimum number of Batches per Hovione Release as set forth in Section 5.5). All Purchase Orders for Product submitted by Ardelyx during the Term will be subject to and will comply with the terms of this Agreement even if the Purchase Order does not expressly make reference to this Agreement.

5.3. Acceptance of Purchase Orders. Hovione shall accept any Purchase Order which does not exceed the Binding Forecast and is properly submitted by Ardelyx in accordance with this Agreement, including in respect of the Delivery Dates stipulated in the relevant Purchase Order, and otherwise in compliance with Section 5.1 and Section 5.2 herein. Hovione may not reject a Purchase Order unless for reasons constituting Force Majeure or [***]. A Purchase Order submitted by Ardelyx and not properly rejected by

Hovione within [***] will be binding on the parties (a "Firm Order"). Promptly following acceptance of each Firm Order, Hovione will deliver to Ardelyx a copy of its campaign production schedule, after which either party may request a change to the Delivery Date in the Firm Order, and the parties will negotiate in good faith to agree on an alternative Delivery Date. If the parties cannot agree, the original Delivery Date set out in the relevant Firm Order will apply. The original Delivery Date shall in any event be the relevant date for purposes of KPI calculation described in Section 7.1.

5.4. Inventory Management. Hovione will handle and store the Inventory in accordance with this Agreement, any safety data sheets, safe handling instructions and health and environmental information associated therewith and customary industry standards. If any Components have a shelf life or other expiry dating, Hovione will use the Components in manufacturing Product on a first-in, first-out basis to retain shelf life.

5.5. Delivery, Shipping and Storage. Hovione shall release Product together with its issuance of a Certificate of Analysis (as defined in the Quality Agreement) and the Manufacturing Records for the applicable Batch in writing. If Ardelyx identifies any deficiency with the Manufacturing Records it should provide prompt notice to Hovione which shall occur no later than [***] after receipt of the complete Certificate of Analysis and the completed Manufacturing Records. The [***] period set forth in the preceding sentence shall be tolled until Hovione has delivered the complete Manufacturing Records (*i.e.* the time between the notice from Ardelyx of a deficient Manufacturing Batch and the date of reissuance of the complete Manufacturing Records to Ardelyx will not be included in calculating the [***] period set forth above). Hovione shall retain copies of the Manufacturing Records for such period set forth in the Quality Agreement. Upon Ardelyx's approval of the Manufacturing Records of at least [***] Batches, Hovione shall make available for Delivery the respective Batches of Product to Ardelyx or its designee in accordance with the Quality Agreement ("Hovione Release"). For clarity Hovione Release shall only occur with multiple Batches with a minimum threshold of three (3) Batches as set forth above, unless Hovione in its absolute discretion decides to act otherwise. Delivery of Product and any other materials will be [***] from Hovione's Manufacturing Site on the relevant Delivery Date. [***] is responsible for taking delivery of Product at Hovione's Manufacturing Site with its carrier of choice. [***]. All shipping instructions of Ardelyx will be accompanied by the name and address of the recipient and the shipping date and any costs and insurance associated with shipping will be borne by Ardelyx. Ardelyx will arrange for insurance and will select the freight carrier used by Hovione to ship Product and may monitor Hovione's shipping and freight activity under this Agreement. Should Ardelyx require special handling, packaging or services not set forth in the Specifications or Processing Instructions (other than for confirmatory testing required by downstream manufacturers), then the cost of such special handling, packaging or services will be borne entirely by Ardelyx at Hovione's prevailing rates. Ardelyx will use Commercially Reasonable Efforts to take delivery of all Product within [***] after the Delivery Date. Thereafter, Hovione will store Product for up to [***], subject to storage fees at Hovione's prevailing rates.

5.6. Invoices and Payment. Hovione will issue and deliver its invoice for each delivery of Product upon the applicable Hovione Release as set forth in Section 5.5, by email to [***]. Hovione will also submit to Ardelyx, with each shipment of Product, a duplicate copy of the invoice covering the shipment. Each invoice will, to the extent applicable, identify the applicable Ardelyx Purchase Order number, Product name and quantity, unit price, freight charges, and the total amount to be paid by Ardelyx. Ardelyx will pay all undisputed invoices within thirty (30) days of the delivery of the invoice. If any portion of an invoice is disputed, Ardelyx will pay Hovione for the undisputed amount and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Hovione shall not suspend Manufacturing Services, withhold Product, or otherwise delay or stop providing services in connection with any such good faith dispute. In the event any undisputed payment is not made on time for three consecutive invoices, Hovione will be entitled, in addition to its other rights and remedies, to (a) charge interest on the unpaid amount at the rate of one and one half percent (1.5%) per month of the unpaid undisputed balance per month or the maximum amount allowed by law; and (b) if such non-payment persists for six consecutive undisputed invoices, to cease work and stop deliveries until such payment, including any interest, is made.

6. Product Rejection and Recalls

6.1. Acceptance. Within [***] following Ardelyx's receipt of the Product and approved Manufacturing Records, Ardelyx shall provide Hovione with written notice of its acceptance or rejection of the Product. If Ardelyx fails to provide Hovione with written notice within such [***] period, the Product will be deemed to be accepted by Ardelyx.

6.2. Rejection. Ardelyx may reject any Product (a "Product Rejection") for any portion of any Batch of Product for which Hovione did not [***] or where the Product otherwise fails to [***] ("Deficient Product"). Any rejection notice issued shall state in reasonably sufficient detail the [***]. Ardelyx shall have the right to, and Hovione may require that Ardelyx, return any rejected Product to Hovione at [***]'s cost. With respect to Product Rejection relating to Deficient Product that (i) [***] ("[***]"), Ardelyx will in all cases give written notice within [***] after the Delivery Date of the Product. For clarity, Hovione shall only be liable for Product Rejection as expressly set forth in Section 6.4.

6.3. Determination of Deficiency. The basis for a Product Rejection by Ardelyx shall be conclusive unless Hovione notifies Ardelyx via email or otherwise in writing within [***] of its receipt of the rejection notice that it disagrees with the basis for rejection. In the event Hovione and Ardelyx are unable to agree as to whether the Product has been appropriately rejected, [***]. The conclusion of such mutually [***] shall be binding for both Parties.

6.4. Replacement Product. In the event that any Product is appropriately rejected and unless Hovione can show with sufficient evidence that (i) [***] (collectively "[***]") or (ii) Deficient Product is otherwise due to Ardelyx's Fault, then Hovione shall promptly [***]. If the Parties determine that replacement can not be done through reprocessing or

reworking, Hovione shall promptly, at Ardelyx's election following good faith consultation with Hovione, either:

6.4.1. Use Commercially Reasonable Efforts to replace such Deficient Product, if [***], provided that the acceptance procedures described above shall be repeated for any replacement Product. Costs for such replacement Product shall be as follows:

6.4.1.1. Manufacturing Services Costs. Unless Hovione can show with sufficient evidence that (i) [***] or (ii) Deficient Product is otherwise due to Ardelyx's Fault, Hovione will [***];

6.4.1.2. API Costs. Unless Ardelyx can provide sufficient evidence that the failure in the Deficient Product is due to Hovione's Fault, Ardelyx shall pay [***]; or

6.4.2. Credit such amounts as follows:

6.4.2.1. Manufacturing Services Costs. Credit [***]% of [***] unless Hovione can show with sufficient evidence that the Deficient Product is due to [***]; and

6.4.2.2. API Costs. If Ardelyx can provide sufficient evidence that the failure in the Deficient Product is due to Hovione Fault, credit [***]% of [***] in respect of such Deficient Product Batch(es).

6.4.3. Subject to Section 10.3, the remedies set forth in Section 6.4.1 and Section 6.4.2 are Ardelyx's sole remedies under this Agreement with respect to Deficient Product.

6.5. Supply Failure.

6.5.1. Remedies for Supply Failure. Hovione shall work diligently to avoid Supply Failure during the Term. In the event of a Supply Failure, Ardelyx may in its sole discretion do one or more of the following: (a) [***], (b) [***]. To the extent such Supply Failure was due to [***], for clarity excluding any Supply Failure resulting from Deficient Product to the extent Hovione is not liable for such Deficient Product under Section 6.2, and notwithstanding Section 5.1, Ardelyx may (i) adjust its Forecast as reasonably required by Ardelyx to account for the Supply Failure and its impact on forecasted market demands and (ii) adjust any outstanding Binding Forecast not yet Manufactured, including any payment obligations associated therewith, without any further liability on Ardelyx's part, and (iii) [***].

6.5.2. Annual Commitment. In addition to the remedies set forth in Section 6.5.1, if Hovione fails to deliver at least [***] percent ([***]%) of the total aggregate quantity of Product placed under all Firm Orders in any given Year (provide such quantities are equal or above the Annual Commitment), within [***] after the last Delivery Date

scheduled for each respective Firm Order for [***] within the Term ("Firm Order Failure"), then Ardelyx shall [***] until such time as Hovione has delivered at least [***], without Firm Order Failure, after which the [***]. The remedies contained in this Section 6.5 for a Supply Failure will be in addition to the rights of indemnification contained in Section 11.1 and any other rights and remedies available under this Agreement to Ardelyx.

6.5.3. Adverse Supply Events. If there is an Adverse Supply Event that Hovione does not remediate so that it can perform the Manufacturing Services in accordance with the Processing Instructions and manufacture Product in accordance with this Agreement within [***], Ardelyx may [***]. To the extent such Adverse Supply Event was due to Hovione's Fault, Ardelyx may in its discretion do any of the following (i) [***] or (ii) [***]. In the event an Adverse Supply Event is due to Hovione being unable to comply with a change in the Processing Instructions or Specifications that is required by the FDA or other United States Regulatory Agency, (a) the Parties shall discuss in good faith [***], and (b) [***]. The existence of an Adverse Supply Event will not exonerate or otherwise relieve either Party of any liability for breach of any independent obligation contained in this Agreement.

6.6. Processing Holds and Cancellation Fees. Notwithstanding anything to the contrary herein, Ardelyx may at any time instruct Hovione to suspend Manufacture of the Product on [***] days' written notice following [***] (a "Processing Hold") so that the Parties can confer to discuss the underlying cause(s). Hovione shall not commence Processing during such notice period but may complete Batches that have already commenced Processing on the date such notice was delivered. Within [***] days after initiation of a Processing Hold, the Parties shall negotiate in good faith any changes or remedies appropriate under the circumstances in respect of the applicable Firm Order, impacted Forecast, Annual Commitment and/or Pricing. The Processing Hold shall expire upon execution of a written instrument reflecting the foregoing mutually agreed changes and/or remedies, provided that if the Parties fail to reach agreement within [***]) days after initiation of the Processing Hold, then:

6.6.1. To the extent that Ardelyx instructs Hovione to remain in a Processing Hold, Ardelyx shall pay for Facility idle time ("Idle Time"), including any Idle Time incurred within [***] after a Processing Hold, at an annualized rate of [***] during such period of Processing Hold;

6.6.2. Ardelyx shall have a right to terminate this Agreement in the event of a Processing Hold, effective on the [***] anniversary of the notice of termination issued in accordance with this Section, subject to payment, at Ardelyx's discretion, of one of the following: (A) Annual Commitment for the remainder of such truncated Term (or the reduced Annual Commitment in accordance with Section 6.5.1(iii) if applicable), *provided, however*, Hovione shall use Commercially Reasonable Efforts to reallocate any resources liberated in connection with such termination to other projects, and to the extent successful in reallocating the resources previously reserved for Ardelyx, reduce or waive any corresponding payment obligations of Ardelyx; or (B) non-refundable yearly fees for the

remainder of such truncated Term, but without further Annual Commitment obligations, as follows: (i) [***] percent ([***]%) of the Idle Time fees due for the period between the notice of termination and [***]; (ii) [***] percent ([***]%) of the Idle Time fees due for the period between [***] and [***]; and (iii) [***] percent ([***]%) of the Idle Time fees due for the period between [***] and [***]. Ardelyx shall determine in its notice of termination its choice between items (A) and (B) above; and

6.6.3. A Processing Hold may be lifted by mutual agreement following Ardelyx's written notice to Hovione accompanied by an updated Forecast and a new Firm Order, subject to delivery of any Idle Time payments due in respect of such Processing Hold. Hovione shall agree to any such lifting of a Processing Hold unless it reasonably determines that further Processing would be unlawful or technically impossible. Commencing on the first Hovione Release of non-Deficient Product under such new Firm Order, (a) the Annual Commitment shall be reinstated to the level set forth in Section 2.2, prorated for the remainder of the applicable Year and (b) Ardelyx's right of termination under Section 6.6.2 shall expire in respect of the lifted Processing Hold. For clarity, such termination right shall be available for any subsequent Processing Hold, subject to the terms of this Section 6.6.

6.6.4. In either option (A) or (B) as set forth in Section 6.6.2, starting from the receipt of a notice of termination following a Processing Hold in accordance with Section 6.6.2, Hovione shall have the right to reallocate resources liberated through any Processing Hold to other projects and in option (A) shall reduce or waive the respective fees as set forth in Section 6.6.2. Any credits or other payments due to Ardelyx under this Agreement shall be issued within [***].

6.7. Product Recalls and Returns.

6.7.1. Records and Notice. The parties will each maintain records, in accordance with cGMP and each Party's standard operating procedures, and otherwise as reasonably necessary to permit a Recall of any Product delivered to Ardelyx or customers of Ardelyx. Each party will promptly notify the other of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product in accordance with the Quality Agreement. The decision to initiate a Recall or to take some other corrective action, if any, will be [***]. "Recall" will mean any action: (i) by Ardelyx to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market); (ii) by any Regulatory Authority to detain or destroy any of the Product; or (iii) by either party to refrain from selling or shipping quantities of the Product to third parties which would be subject to a Recall if sold or shipped.

6.7.2. Recalls. If: (i) any Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled; or (ii) a court of competent jurisdiction orders a Recall; or (iii) Ardelyx determines that any Product should be Recalled, then Hovione will [***]. Ardelyx

will bear all expenses of any Recall and Hovione's assistance unless and to the extent such Recall directly results from Hovione's gross negligence or willful misconduct.

6.7.3. Recalled Product. To the extent that a Recall directly results from Hovione Hovione's gross negligence or willful misconduct , Hovione will, subject to the limitations set forth in Section 10, be [***]. Ardelyx may adjust its Forecast as reasonably required by Ardelyx to account for the Recall and its impact on forecasted market demands.

6.8. Disposition of Deficient Product. Ardelyx will not dispose of any damaged, returned, or Deficient Product for which it intends to assert a Product Rejection against Hovione without Hovione's prior written authorization to do so. Hovione may instruct Ardelyx to return the Product to Hovione. Hovione will [***].

7. Co-operation and Regulatory Affairs

7.1. Governance. Each Party will without delay upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the Parties. The relationship managers will meet on a frequency agreed between the Parties to review the current status of the business relationship, including, but not limited to, review of key performance indicators such as API delivery, on-time delivery of Product, right first time, and satisfaction of the Annual Commitment ("KPIs"), and manage any issues that have arisen.

7.2. Governmental Agencies. The Parties will consult each other in relation to regulatory communications directly relating to the Product in accordance with the Quality Agreement. To the fullest extent permitted under Applicable Laws (in relation to Ardelyx's use of the Product) and cGMP, Ardelyx shall have sole authority and responsibility for communicating with any Regulatory Authority responsible for granting Regulatory Approval for the Product and any other relevant Authority regarding the Product. Hovione will provide to Ardelyx, its Affiliates and Licensees with reasonable assistance as Ardelyx may request in order to assist with obtaining Regulatory Approval for Products, subject to reimbursement of Hovione's reasonable expenses incurred in connection therewith.

7.3. Governmental Inspections and Requests. Hovione will promptly advise Ardelyx if an authorized agent of any Regulatory Authority intends to inspect a Manufacturing Site, to the extent such inspection is directly related to the Product or could reasonably be expected to impact the Manufacture of the Product. Hovione will promptly furnish Ardelyx a copy of any report or notice issued by the Regulatory Authority (including, without limitation, any Form 483s or warning letters) (redacted to the extent containing information that is not relevant to the Manufacturing Services or the Product). To the extent the inspection is announced and is directly related to the Product, Hovione will promptly inform Ardelyx and, to the extent permitted by the applicable Regulatory Authority, Parties will discuss in good faith an appropriate scope for Ardelyx agents and representatives to be present at the Manufacturing Site on the date and time of such Regulatory Authority inspection. Hovione shall in any event [***].

7.4. Records. Hovione will keep complete and accurate books, records, test and laboratory data, reports and other information relating to the manufacture, testing, and shipping of the Product (including, without limitation, all manufacturing and packaging Batch records), and retain samples of the Product as are necessary to comply with manufacturing regulatory requirements applicable to Hovione, Applicable Laws and cGMP. Copies of the records and samples will be retained as and for the period specified in the Quality Agreement *provided, however*, that Hovione may exclude or redact from such Records any confidential or proprietary information of third parties or any Hovione Background IP that Hovione regards as trade secrets. The Parties acknowledge and agree that the Manufacturing Records constitute Confidential Information of Ardelyx.

7.5. Audits. In accordance with the frequency and parameters set forth in the Quality Agreement ([***]), Hovione will give Ardelyx and its Licensees (if so requested by Ardelyx, and who cannot be competitors of Hovione and who are subject to confidentiality obligations no less restrictive than those set forth in this Agreement) reasonable access at agreed times to the areas of the Manufacturing Site in which the Product is manufactured, stored, handled, or shipped and to the personnel that regularly perform these activities, to permit Ardelyx and its Licensees to verify that the Manufacturing Services are being performed in accordance with the Processing Instructions, the Specifications, this Agreement, cGMPs and Applicable Laws. Ardelyx's and its Licensees' employees and representatives will at all times comply with Hovione's rules, regulations and SOPs relating to inspections and visits to the Facility, and Ardelyx shall be responsible for compliance with this Agreement by its and its Licensees' representatives on Hovione's premises. Hovione will use Commercially Reasonable Efforts to enable that its Third Party Subcontractors permit Ardelyx and its Licensees similar audit rights to those set forth in this Section 7.5 and to the extent unsuccessful shall make its own audit reports for such Subcontractors available for review by Ardelyx and its Licensees in the course of an audit in accordance with this Section 7.5.

7.6. Regulatory Filings.

7.6.1. Regulatory Authority Documentation. Ardelyx will provide copies of all relevant documents relating to Regulatory Authority approval for the commercial manufacture of the Product ("Regulatory Approval") to Hovione on request. Hovione will review and verify the accuracy of these documents in accordance with the Quality Agreement. Ardelyx shall refrain from submitting Regulatory Approvals specifically referring to Hovione or its Affiliates or the Manufacturing Services until approved by Hovione (this approval not to be unreasonably withheld or delayed).

7.6.2. Deficiencies. If Hovione reasonably determines that any regulatory information pertaining to the Manufacturing Services or the Manufacturing Site given by Ardelyx is inaccurate or deficient in any manner whatsoever (the "Deficiencies"), Hovione will notify Ardelyx promptly in writing of the Deficiencies. The Parties will each use commercially reasonable efforts and act in good faith to have the Deficiencies resolved prior to the date of filing of the relevant application and in any event before any pre-

approval inspection or before the Product is placed on the market if a pre-approval inspection is not performed.

7.6.3. Pharmacovigilance. If requested by either Party, Hovione and Ardelyx will use Commercially Reasonable Efforts to negotiate in good faith a process and procedure for sharing adverse event information received by Hovione. Hovione will provide Ardelyx with any information received by it regarding any adverse events and/or quality complaints in connection with the use of the Product to Ardelyx Pharmacovigilance within [***].

7.7. Release. Nothing in this Agreement will remove or limit the authority of the relevant quality function (as specified by the Quality Agreement) to determine whether the Product will be released for sale or distribution.

8. Term and Termination

8.1. Initial Term. This Agreement will become effective as of the Effective Date and will continue until December 31, 2030 (the "Initial Term"), unless terminated earlier by one of the Parties in accordance with this Agreement. Thereafter, this Agreement will automatically renew for successive terms of two Years until terminated in accordance with this Agreement. The Initial Term together with all successive renewal terms shall together be referred to herein as the "Term". In the event that a Party elects to exercise a right of termination afforded it in accordance with the provisions of Section 8.2, such Party shall provide the other Party with a written notice (a "Notice of Termination").

8.2. Termination.

8.2.1. Termination due to Legitimate Business Needs.

8.2.1.1. Initial Term. No earlier than [***] years from Effective Date, Ardelyx may terminate this Agreement for Business Need effective during the Initial Term, provided that such notice shall not be effective until [***] months after delivery of the Notice of Termination and that Parties shall negotiate in good faith a winding down of Annual Commitment to release capacity from the Equipment.

8.2.1.2. Renewal Term. Either Party may terminate this Agreement for convenience effective after expiration of the Initial Term, provided that such termination shall be effective (i) [***] months after delivery of a Notice of Termination by Ardelyx, or (ii) [***] months after delivery of a Notice of Termination by Hovione.

8.2.2. Termination for Cause. Either Party may terminate this Agreement by providing a Notice of Termination for breach if the other Party has failed to remedy a material breach of this Agreement within [***] days (the "Remediation Period") following receipt of a written notice of the breach from the aggrieved Party that expressly states that it is a 'notice of breach' under this Section 8.2.2 (a "Breach Notice"). Each Party will ensure that any Breach Notice delivered by it to the other Party will not contain any reference to a

Notice of Termination, or otherwise express any intent to terminate this Agreement, until that Party may properly submit a Notice of Termination for breach in accordance with this Section 8.2.2. The aggrieved Party's right to terminate this Agreement under this Section 8.2.2 may only be exercised for [***] days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved Party will be considered to have waived the breach described in the Breach Notice.

8.2.3. Termination for Regulatory Action. Ardelyx may terminate this Agreement effective [***] days after delivery of a Notice of Termination for regulatory action if any Regulatory Authority takes any legal action or procedure that prevents Ardelyx from selling the Product in the United States and such market interruption is reasonably expected to last at least [***].

8.2.4. Termination for Product Issue. Ardelyx may terminate this Agreement effective [***] days after delivery of a Notice of Termination for Product issue if a [***] notifies Hovione or Ardelyx [***] that there is a significant regulatory deficiency of Hovione related to the performance of the Manufacturing Services at the Manufacturing Site therefore resulting in an Adverse Supply Event in accordance with Section 1.1(ii) and Hovione is not able to satisfy its obligations under this Agreement through Manufacture at an alternative approved Manufacturing Site, and the deficiency is not remedied to the satisfaction of the Regulatory Authority within [***] days of the notice.

8.2.5. Supply Failure. Ardelyx may terminate this Agreement effective [***] after the delivery of a Notice of Termination for Supply Failure arising due to Hovione's Fault if there have been more than [***] Supply Failures in [***] or more than [***] Supply Failures in [***].

8.2.6. Force Majeure. Either Party may terminate this Agreement under Section 14.5 (Force Majeure) in accordance with the terms thereof.

8.3. Obligations in Connection with Termination. If this Agreement is terminated for any reason, then:

8.3.1. Firm Orders and Outstanding Credit. Following the delivery of a Notice of Termination by either Party in accordance with the provisions of Section 8.2 of this Agreement (except in the case of a Notice of Termination delivered for cause by Hovione pursuant to Section 8.2.2 or 8.2.6), Hovione shall continue to supply Product in accordance with the Binding Forecast and any Firm Orders until the effective date of the termination set forth in the Notice of Termination unless unlawful. To the extent there is any outstanding credit or amounts due from Hovione to Ardelyx hereunder, including any credit due in accordance with Section 3.3(d) after termination of the Agreement and delivery of the final Batch of Product as set forth in this Section 8.2.1, Hovione shall reimburse such amounts to Ardelyx within [***] days after the effective date of termination.

8.3.2. Inventory; Payment. At least [***] days prior to the effective date of termination or expiration of this Agreement, Hovione will deliver to Ardelyx a written accounting of all Inventory and any other moveable property owned by Ardelyx that is in Hovione's possession or control ("Ardelyx Property"), including quantities, identification information, location, and such other relevant information as may be reasonably requested by Ardelyx. The Parties shall cooperate in good faith to finalize such accounting, whereupon Ardelyx shall be entitled to take delivery of any Components that it desires to receive, and Hovione shall deliver to Ardelyx an invoice for (i) all undelivered Product Manufactured under a Firm Order (subject to the acceptance provisions of Section 6), at the Price in effect at the time the Firm Order was placed, (ii) all Components identified by Ardelyx for delivery, which shall be invoiced at Hovione's cost plus a [***]% administration fee and without additional mark-up, and (iii) any Annual Commitment payment obligations due pursuant to Section 2.2(b) in respect of the Term, as truncated by such termination (the "Final Invoice"). Subject to resolution of any disputed portion of the Final Invoice, Ardelyx shall pay the Final Invoice and take delivery of the Ardelyx Property within [***] days after receipt of the Final Invoice. If Ardelyx asks Hovione to destroy any Ardelyx Property, Hovione will arrange for such destruction, at Ardelyx's cost, in accordance with Applicable Laws and cGMP. Hovione acknowledges and agrees that, following payment of the Final Invoice, Ardelyx shall have no further payment obligations under this Agreement.

8.4. Survival. Except as otherwise set forth herein, the termination or expiration of this Agreement will not affect any prior outstanding obligations or payments due, nor will it prejudice any other rights or remedies that the Parties may have under this Agreement. The obligations and responsibilities of the Parties under Sections 6, 7, 8.3-8.4 and 10-14 shall survive any termination or expiration of this Agreement, as well as any other provisions that are by implication or otherwise intended to survive. Where Hovione has agreed to provide stability services beyond the final supply of Product, the relevant provisions of this Agreement related to stability services will survive for the agreed duration of those stability services.

9. Representations, Warranties and Covenants

9.1. Mutual Representations.

9.1.1. Authority. Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations under this Agreement.

9.1.2. Sanctions. Neither Ardelyx nor Hovione, nor any of their respective Affiliates, nor to the best knowledge of each Party, any of its directors, officers or representatives, is an individual or entity that is, or is owned or controlled by an individual or entity that is the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control, the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority

in the Territory. Breach of this Section 9.1.2 shall be considered a material breach of this Agreement and, notwithstanding anything to the contrary herein, to the extent either Party reasonably determines the breach by the other Party of this Section 9.1.2, the non-breaching Party shall be able to terminate this Agreement for cause and with immediate effect.

9.2. Manufacturer Warranties. Hovione covenants, represents, and warrants to Ardelyx as follows:

9.2.1. Compliance. Hovione will perform the Manufacturing Services in accordance with this Agreement, the Processing Instructions, cGMPs and Applicable Laws.

9.2.2. Non-Infringement. To the best of Hovione's knowledge, the Hovione Intellectual Property used by Hovione to perform the Manufacturing Services (i) is Hovione's or its Affiliate's unencumbered property or is otherwise licensed to Hovione, (ii) may be lawfully used by Hovione, and (iii) does not infringe and will not infringe any Third Party Rights.

9.2.3. Product. Upon delivery to Ardelyx or its designee, the Product will: (i) have been manufactured in accordance with the Processing Instructions and all cGMPs, (ii) meet the Specifications and conform to the Manufacturing Records, and (iii) [***] (collectively, the "Product Warranties").

9.2.4. Custody. Hovione will at all times use commercially reasonable measures to protect all Inventory in its possession or control from theft, damage, loss or misuse.

9.2.5. No Debarment. Hovione will not in the performance of its obligations under this Agreement, to the best of its knowledge, use the services of any person who is debarred or suspended under 21 U.S.C. §335. To the best of its knowledge, Hovione does not currently have, and it will not hire, as an officer or an employee any person who has been convicted of a felony under Applicable Laws.

9.2.6. Notice. Hovione will promptly notify Ardelyx if at any time during the Term if it becomes aware that any of the foregoing representations and warranties has been breached or is untrue.

9.3. Ardelyx Warranties. Ardelyx represents and warrants to Hovione that:

9.3.1. To the best of Ardelyx's knowledge, the use of Ardelyx Background IP (other than Background IP generated by Hovione in performance of the Development Agreement) as contemplated in the Manufacturing Services will not infringe the intellectual property rights of any Third Party and Ardelyx will promptly notify Hovione in writing should it become aware of any claims asserting such infringement.

9.3.2. Upon delivery to Hovione, the Ardelyx Materials will comply with the applicable specifications, and have been manufactured in accordance with cGMP (if applicable).

9.3.3. Ardelyx will comply with all Applicable Laws in its use of the Product.

9.3.4. Ardelyx will not release any Batch of Product for commercial sale if Ardelyx does not hold all necessary Regulatory Approvals to market and sell the Product.

9.4. Disclaimer of Implied Warranties. EXCEPT AS EXPRESSLY SET OUT IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY, REPRESENTATION OR CONDITION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW.

10. Limitations on Liability

10.1. Product Rejection claims. Subject to Section 10.3, and except for any claim for expenses related to a Recall under Section 6.7.1, the remedies described in Section 6.4 will be Ardelyx's sole remedy for Deficient Product.

10.2. Consequential Damages. Subject to Section 10.3, under no circumstances whatsoever will either Party be liable to the other for any consequential, special, punitive or other indirect liability, damage, costs, penalty, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages PROVIDED, HOWEVER, THAT THIS LIMITATION WILL NOT APPLY TO DAMAGES RESULTING FROM BREACHES BY A PARTY OF ITS DUTY OF CONFIDENTIALITY AND NON-USE IMPOSED UNDER SECTION 12.

10.3. Limitation of Liability. Subject to Section 10.4, Hovione's liability for Losses arising from any single event under this Agreement (including without limitation any such event arising from Manufacturing) will be limited to [***]; the total liability of Hovione for Losses under this Agreement during [***] is limited to the lesser of (i) [***] US Dollars ($[***]) or (ii) the amount paid by Ardelyx under this Agreement and/or the Development Agreement during [***]; and, in any case, the total aggregate liability of Hovione for Losses under this Agreement is limited to [***] US Dollars ($[***]).

10.4. Exclusions. Nothing contained in this Agreement will act to exclude or limit either Party's (i) liabilities arising from failure to meet the confidentiality obligations under Section 12, (ii) liabilities arising from a Party's gross negligence or willful misconduct, or (iii) liability for personal injury or death caused by the negligence of either party or fraudulent misrepresentation. In addition, nothing contained in this Agreement will act to limit or exclude Hovione's or Ardelyx's performance obligations or liabilities under Section 6.4.1.1.

11. Indemnification.

11.1. Hovione Indemnity. Hovione agrees to defend and indemnify Ardelyx, its officers and employees, against all losses, damages, costs, claims, demands, subpoenas, judgments and liability ("Losses") asserted against or incurred by them in connection with any legal action or claim brought by third parties ("Third Party Claims") to the extent the Third Party Claim is the direct result of (a) a breach of [***], or (b) Hovione's [***] in performing this Agreement except, in each case, to the extent Ardelyx is obligated to indemnify Hovione under Section 11.2.

11.2. Ardelyx Indemnity. Ardelyx agrees to defend and indemnify Hovione, its officers and employees, against all Losses asserted against or incurred by them in connection with any Third Party Claim to the extent the Third Party Claim is the result of (a) the manufacturing (insofar as it relates to Ardelyx's obligations pursuant to this Agreement or the Development Agreement), packaging, marketing, distribution, import, use or sale by Ardelyx or its Licensees of the Product (including without limitation any claim of infringement of any patent or trademark or the unauthorized use of a trade secret and any product liability claims), (b) a breach of [***], or (c) Ardelyx's [***] in performing this Agreement; except, in each case, to the extent Ardelyx is obligated to indemnify Hovione under Section 11.1.

11.3. Indemnity Procedure. A Party that intends to claim indemnification under Section 11.1 or Section 11.2 (the "Indemnitee") will notify the other Party (the "Indemnitor") promptly in writing of the applicable Third Party Claim, provided that the failure to give timely notice to the Indemnitor will not release the Indemnitor from any liability to the Indemnitee except to the extent the Indemnitor is actually prejudiced thereby. The Indemnitor will have the right, by notice to the Indemnitee, to assume the defense of the action or claim within fifteen (15) days after the Indemnitor's receipt of notice of the action or claim with counsel of the Indemnitor's choice and at the sole cost of the Indemnitor. If the Indemnitor assumes the defense, the Indemnitee may participate therein through counsel of its choice, but at the sole cost of the Indemnitee. The Party not assuming the defense of the claim will give reasonable assistance to the Party assuming the defense, and all reasonable out-of-pocket costs of this assistance will be for the account of the Indemnitor. No claim will be settled other than by the Party defending the claim, and then only with the consent of the other Party which will not be unreasonably withheld or delayed. The Indemnitee will have no obligation to consent to any settlement of any action or claim which imposes on the Indemnitee any liability or obligation which cannot be assumed and performed in full by the Indemnitor, and the Indemnitee will have no right to withhold its consent to any settlement of any action or claim if the settlement involves only the payment of money by the Indemnitor or its insurer.

12. Confidentiality

12.1. Definition. "Confidential Information" means any and all non-public scientific, technical, financial or business information, including without limitation any third-party confidential information, that is furnished or made available by or on behalf of one Party or its Affiliates (the "Discloser") to the other or its Affiliates (the "Recipient"),

on or after the Effective Date, whether in writing, orally, visually ((including, without limitation, video, streaming or picture) or through physical inspection, subject to the exceptions in this Section 12.1. The term "Confidential Information" does not include information that (a) is publicly known at the Effective Date or later becomes publicly known under circumstances involving no breach of this Agreement, (b) is lawfully and in good faith disclosed to the Recipient without an obligation of confidence by a third party who is not subject to a confidentiality obligation to the Discloser, (c) is independently developed by the Recipient without use of or reliance on the Discloser's Confidential Information, as evidenced by its written records; or (d) by a mutual written agreement by the Parties, is released from confidential status. Subject to the foregoing exceptions in this Sections 12.1, Ardelyx Confidential Information includes the Manufacturing Records, Specifications and Processing Instructions, and Hovione Confidential Information includes Hovione Background IP, Hovione Inventions and Incorporated Hovione IP. This Agreement constitutes the Confidential Information of both Parties.

12.2. Restriction. Discloser shall use commercially reasonable efforts to mark any Hovione Confidential Information "Confidential" or otherwise identify it as Confidential Information at the time of disclosure. Notwithstanding the foregoing, all information provided by one Party to the other, regardless of being marked or identified as confidential, shall be considered Confidential Information if it would be apparent to a reasonable person familiar with the Discloser's industry that such information is of a confidential or proprietary nature.

12.3. Confidentiality Obligation. The Discloser shall be the sole owner of its Confidential Information. Recipient will keep confidential and protect the confidentiality of Confidential Information and will not disclose or use any Confidential Information except with the Recipient's written permission or as permitted under this Agreement. Recipient will protect the Confidential Information disclosed to it by using reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will not be less than those exercised by Recipient for its own confidential or proprietary Confidential Information of a similar nature. Recipient may disclose Confidential Information to its Representatives who need to know such Confidential Information in order to perform Recipient's obligations or exercise Recipient's rights hereunder, and who are legally or contractually bound to protect the confidentiality of such Confidential Information under terms no less stringent than those set forth in this Section 12. Specifically, Ardelyx may disclose [***] to its Representatives in order to exercise its rights under the license grants set forth in Section 13.6.2 and such right shall survive termination of this Agreement, and Ardelyx shall have the right to disclose [***]. Each Party, in its capacity as a Recipient, will be liable for the acts and failures to act by its respective Representatives for the improper use, disclosure, distribution, protection or handling of the Confidential Information of the Discloser as the actions or failures were committed directly by the Recipient.

12.4. Permitted Disclosure. Recipient may disclose Confidential Information of the Discloser to the extent required, as advised by counsel, in response to a valid order of a

court or other governmental body, or as required by law, regulation or stock exchange rule applicable to it; provided that, to the extent lawful, the Recipient will (a) advise the Discloser in advance of the disclosure and (b) limit the required disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, and (c) reasonably cooperate with the Discloser, if requested, in seeking an appropriate protective order or other remedy, and (d) otherwise continue to perform its obligations under this Section 12 with respect to information so disclosed. If any public disclosure is required by law, the Parties will consult concerning the form of announcement prior to the public disclosure being made.

12.5. Return of Confidential Information. Upon the written request of the Discloser or termination of the Agreement pursuant to Section 8, the Recipient will promptly return or destroy the Confidential Information of the Discloser, as directed by the Discloser, except for one copy which may be maintained by the Recipient in the sole and exclusive custody of its legal department to be held for the sole purpose of assessing compliance with the terms of this Agreement. The retained copy will remain subject to all confidentiality provisions contained in this Agreement. During the Term, Ardelyx will not unreasonably require the return or destruction of Confidential Information that is necessary or useful for Hovione to perform the Manufacturing Services. Hovione will not unreasonably require the return of Confidential Information that is necessary for Ardelyx to exercise its rights under this Agreement, and, specifically, to exercise its rights as granted by Section 13 (Intellectual Property).

12.6. Remedies. The Parties acknowledge that monetary damages may not be sufficient to remedy a breach by either Party of this Section 12 and therefore agree that the non-breaching Party will be entitled to seek specific performance, injunctive or other equitable relief in any court of competent jurisdiction (notwithstanding Section 14.13) to prevent breaches of this Section 12 and to specifically enforce Section 12 in addition to any other remedies available at law or in equity. These remedies will not be the exclusive remedies for breach of this Section 12 but will be in addition to any and all other remedies available at law or in equity.

12.7. Survival. The obligations contained in this Section 12 will survive any termination of this Agreement for seven years from the last day of the Term.

13. Intellectual Property

13.1. Development Agreement. All inventions and other Intellectual Property arising from performance of Development Services, including without limitation project reports, final reports and Manufacturing Records, shall be owned in accordance with, and otherwise subject to, the terms and conditions of the Development Agreement.

13.2. Background IP. Ardelyx shall solely own all Ardelyx Background IP and Hovione shall solely own all Hovione Background IP (collectively, "Background IP"). For

clarity the Process for Manufacture of the Product, as of the Effective Date, constitutes Ardelyx Background IP.

13.3. Ardelyx Inventions. Ardelyx shall solely own all Inventions arising from [***] (collectively, "Ardelyx Inventions"). Hovione hereby assigns to Ardelyx, and agrees to assign to Ardelyx, all right, title and interest in and to the Ardelyx Inventions.

13.4. Hovione Inventions. As between the Parties, Hovione shall solely own all Inventions arising from [***] that do not constitute Ardelyx Inventions (collectively, "Hovione Inventions"). Hovione shall [***]. Each Party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

13.5. Incorporated Hovione Background IP. Prior to Hovione's use of Background IP in a manner which could result in the incorporation of, embodiment within, or reference to, any such Hovione Background IP in the Product or Process, Hovione shall first (i) provide Ardelyx with a written description of any such Hovione Background IP proposed to be so used or incorporated and (ii) obtain Ardelyx's prior written consent to proceed to use the Hovione Background IP in the manner so described, whereupon the Parties shall promptly negotiate commercially reasonable terms for, and Hovione shall grant to Ardelyx, a license to practice all such Hovione Background IP in accordance with the terms and conditions as negotiated between the Parties and prior to incorporation thereof.

13.6. Licenses.

13.6.1. License under Ardelyx Background IP. For the Term of this Agreement, Ardelyx hereby grants to each of Hovione Portugal and Hovione NJ a non-exclusive, paid-up, royalty-free, non-transferable license to use Ardelyx Background IP and Ardelyx Inventions solely and specifically as needed in order to perform the Manufacturing Services for Ardelyx in accordance with this Agreement. The foregoing license does not extend to [***] absent separate written consent by Ardelyx in each case.

13.6.2. License under Incorporated Hovione IP. In addition to any license(s) negotiated pursuant to Section 13.5, [***] (collectively, the "Incorporated Hovione IP"), Hovione hereby [***]. With respect to any license to practice Hovione Incorporated IP hereunder or to any license(s) negotiated pursuant to Section 13.5, Ardelyx will be solely responsible for the actions of any third party to which Ardelyx sublicenses its rights to Incorporated Hovione IP and will indemnify and hold harmless Hovione against all costs, expenses, damages, or losses of any nature arising out of such sublicensee's use of Incorporated Hovione IP, including, but not limited to, any use of such Incorporated Hovione IP outside the bounds of Ardelyx's license under this Section. Ardelyx will cause any such sublicensee to be bound by, and to comply with, (a) the limitations on Ardelyx's use of the Incorporated Hovione IP under the license granted in this Section, and (b)

confidentiality requirements relating to the Incorporated Hovione IP that are no less strict than those contained in this Agreement.

13.7. Ardelyx Affiliates and Licensees. Notwithstanding any license granted by Ardelyx to its Licensees or Affiliates, during the Term Hovione agrees not to [***] without Ardelyx's express written instruction or consent, which may be granted or withheld in Ardelyx's sole discretion.

13.8. No Additional Rights. Except as expressly set out in this Agreement, neither Party has, nor will it acquire, any interest in any of the other Party's Intellectual Property unless otherwise expressly agreed to in writing. Neither Party will use any Intellectual Property of the other Party, except as specifically authorized by the other Party in writing or as required for the performance of its obligations or exercise of its rights under this Agreement.

14. Miscellaneous

14.1. Insurance. Each Party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that Party under this Agreement through the term of this Agreement and for a period of [***] after that. This insurance will have policy limits of not less than: (i) $[***] for each occurrence for personal injury or property damage liability; and (ii) $[***] in the aggregate per annum for product and completed operations liability. If requested each Party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of thirty (30) days' written notice to the insured of a cancellation of, or material change in, the insurance.

14.2. No Agency or Partnership. The Parties are independent contractors and this Agreement does not create between the Parties any other relationship such as, by way of example only, that of employer and employee, principal and agent, joint-venturers, co-partners, or any similar relationship, the existence of which is expressly denied by the Parties.

14.3. No Waiver. Neither Party's failure to require the other Party to comply with any provision of this Agreement will be considered a waiver of the provision or any other provision of this Agreement, with the exception of Section 8.2.1 of this Agreement.

14.4. Assignment. Ardelyx may assign this Agreement to an Affiliate or to any successor in interest to all or substantially all of Ardelyx's business to which this Agreement relates. Hovione may assign this Agreement: (i) to any of its Affiliates or (ii) to a successor to or purchaser of all or substantially all of its business, if (I) performance of activities hereunder remains at the Manufacturing Sites, (II) the FDA registration number for the Manufacturing Sites do not change and (III) the assignee executes an agreement with Ardelyx whereby it agrees to be bound by the obligations of this Agreement owed to

Ardelyx. Neither Party may otherwise assign this Agreement or any of its associated rights or obligations hereunder without the written consent of the other Party, and any assignment in violation of this Agreement will be void.

14.5. Force Majeure. Neither Party will be liable for the failure to perform its obligations under this Agreement if the failure is caused by an event beyond that Party's reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, cyber-attacks, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order, regulation, or enforcement decision of any Authority (a "Force Majeure Event"). A Party claiming a right to excused performance under this Section 14.5 will promptly notify the other Party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance, and will use Commercially Reasonable Efforts to mitigate the contingency and recommence its performance of the obligation as soon as commercially practicable. If a Force Majeure Event causes a partial but not complete inability to perform its obligations under this Agreement, that Party will perform to the maximum extent it is able to. If a Force Majeure Event results in a partial reduction in manufacturing capacity at a Hovione NJ or Hovione Portugal, as applicable: (a) to the extent reasonably practical, Hovione will supply Ardelyx from another Hovione site, (b) Hovione will otherwise use Commercially Reasonable Efforts to [***], and (c) Ardelyx may [***]; and (d) within [***] after the occurrence of a Force Majeure Event which results in a partial reduction in manufacturing capacity at a Hovione NJ or Hovione Portugal, Ardelyx may in its discretion do any of the following: (i) [***] to the extent fulfilment thereof by Hovione is impacted by the Force Majeure Event, without any further liability on Ardelyx's part, including [***], and/or (ii) [***]. If a Force Majeure Event claimed by one Party is not resolved within [***], then (A) the other Party may terminate this Agreement on written notice or (B) on the other Party's written request, the Parties shall negotiate in good faith adequate consequences of such Force Majeure Event, including if appropriate a reduction of the Annual Commitment.

14.6. Notices. Any notice, approval, instruction or other written communication required or permitted under this Agreement will be sufficient if made or given to the other Party by personal delivery or confirmed receipt email or by sending the same by first class mail, postage prepaid, return receipt requested, to the respective addresses or email addresses set out below:

If to Ardelyx:

Ardelyx, Inc.
400 5th Ave., Suite 210
Waltham, MA 02451 USA
Attention: [***]
With a copy to: [***]

If to Hovione:

Hovione LLC
40 Lake Drive
East Windsor, NJ 08520, USA
Attention: [***]
With a copy to: [***]

or to any other address given to the other Party in accordance with the terms of this Section 14.6. Notices or written communications made or given by personal delivery, national courier or email will be considered to have been sufficiently made or given upon confirmation of receipt.

14.7. Interpretation. The division of this Agreement into Sections, Subsections, and Appendices, and the insertion of headings, are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section or Appendix refers to the specified Section or Appendix to this Agreement. In this Agreement, the term "this Agreement" and similar expressions refer to this Agreement as a whole and not to any particular part, Section or Appendix of this Agreement. Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa. All monetary amounts stated in this Agreement are in United States Dollars ($).

14.8. Severability. If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

14.9. Entire Agreement. This Agreement, together with its Appendices, [***] and the Quality Agreement constitutes the full, complete, final and integrated agreement between the Parties relating to the subject matter of the Agreement and supersedes all previous written or oral negotiations, commitments, representations, agreements, transactions, or understandings concerning the subject matter of this Agreement (for clarity excluding Development Services subject to the Development Agreement). The basis of the Parties' agreement is set out expressly and they have not been induced by or relied on any statement or representation that is not set out in this Agreement. Any modification, amendment, or supplement to this Agreement must be in writing and signed by authorized representatives of both Parties. In case of conflict among terms, the following order of precedence shall apply: (i) the Quality Agreement shall prevail with respect to matters of Product quality, (ii) [***] will prevail with respect to matters of Equipment and Scale Up, and (iii) this Agreement shall prevail with respect to all other matters.

14.10. No Third Party Benefit or Right. Nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement (except that Ardelyx Licensees may enforce their rights

under Section 7.5). The rights of the Parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement are not subject to the consent of any other person.

14.11. Execution in Counterparts. This Agreement may be executed in two or more counterparts, by original or electronic (including "pdf") signature, each of which will be considered an original, but all of which together will constitute one and the same instrument.

14.12. Use of Name. Neither Party may use the other Party's name, trademarks or logo or any variations of them, alone or with any other word or words, without the prior written consent of the other Party, unless required in connection with a Regulatory Approval or any communications with a Regulatory Authority.

14.13. Governing Law. This Agreement and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation are governed by the laws of the State of New York, United States of America, without regard to any conflicts-of-law principle that directs the application to another jurisdiction's law. Both parties hereby submit to the exclusive jurisdiction of: (i) [***] or (ii) [***]. The Parties expressly agree that the UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

14.14. Dispute Resolution.

14.14.1. Both Parties understand and appreciate that their long-term mutual interest shall be best served by effecting a rapid and fair resolution of any claims or disputes which may arise out of services performed under this contract or from any dispute concerning contract terms. Therefore, both Parties agree to use Commercially Reasonable Efforts to resolve all such disputes as rapidly as practicable on a fair and equitable basis. Toward this end both Parties agree to develop and follow a process for presenting, rapidly assessing, and settling claims on a fair and equitable basis.

14.14.2. If any dispute or claim arising under this Agreement cannot be readily resolved by the Parties pursuant to the process described in Section 14.14.1, the Parties agree to refer the matter to a panel consisting of one (1) senior executive employed by each Party who is not directly involved in the claim or dispute for review and resolution. A copy of the contract terms, agreed upon facts (and areas of disagreement), and concise summary of the basis for each side's contentions shall be provided to both such senior executives who shall review the same, confer, and attempt to reach a mutual resolution of the issue.

14.14.3. If within [***] days after a dispute or claim has been escalated in accordance with Section 14.14.2, the matter has not been resolved utilizing the process set forth in this Section, and the Parties are unwilling to accept the non-binding decision of the panel, any Party may seek resolution of said dispute in accordance with Section 14.13.

* * *

This Agreement is signed by the authorized representatives of the parties on the dates shown below and will take effect from the Effective Date.

ARDELYX, INC.

By: /s/ Thierry Bilbault

Name: Thierry Bilbault

Title: Sr VP Technical Operations

Date:10/25/2024

HOVIONE, LLC.

By: /s/ Jean-Luc Herbeaux

Name: Jean-Luc Herbeaux

Title: Chief Executive Officer

Date: 10/23/2024

HOVIONE, LLC.

By: /s/ Marco Gil

Name: Marco Gil

Title: Sr VP Sales & Marketing

Date: 10/25/2024

HOVIONE FARMACIENCIA, S.A.

By: /s/ Jean-Luc Herbeaux

Name: Jean-Luc Herbeaux

Title: Chief Executive Officer

Date: 10/23/2024

HOVIONE FARMACIENCIA, S.A.

By: /s/ Marco Gil

Name: Marco Gil

Title: Sr VP Sales & Marketing

Date: 10/25/2024

Appendix 1

PRICING

[***]

Appendix 2

EXCHANGE RATE CLAUSE

[***]

Appendix 3

API REIMBURSEMENT PRICE

[***]

FOURTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FOURTH AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "**Amendment**") is entered into as of October 29, 2024, by and among SLR INVESTMENT CORP., a Maryland corporation with an office located at 500 Park Avenue, 3rd Floor, New York, NY 10022 ("**SLR**"), as collateral agent (in such capacity, together with its successors and assigns, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 hereof or otherwise a party to the Loan Agreement from time to time including SLR in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and ARDELYX, INC., a Delaware corporation with offices located at 400 Fifth Avenue, Suite 210, Waltham, MA 02451 (the "**Borrower**").

A. Collateral Agent, Borrower and Lenders have entered into that certain Loan and Security Agreement dated as of February 23, 2022 (as amended, supplemented or otherwise modified from time to time, including but not limited to, by that certain First Amendment to Loan and Security Agreement dated as of August 1, 2022, that certain Second Amendment to Loan and Security Agreement dated as of February 9, 2023, that certain Third Amendment to Loan and Security Agreement dated as of October 17, 2023 and this Amendment, collectively, the "**Loan Agreement**"), pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof; and

B. Borrower, Collateral Agent and the Required Lenders have agreed to amend certain provisions of the Loan Agreement as provided herein, subject to, and in accordance with, the terms and conditions set forth herein, and in reliance upon the representations and warranties set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, the Required Lenders and Collateral Agent hereby agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.1 Section 1.4 (Definitions). The following terms and their respective definitions hereby are added or amended and restated in their entirety, as applicable, to Section 1.4 of the Loan Agreement as follows:

> "**Applicable Rate**" means a per annum interest rate equal to the greater of (a)(i) one percent (1.00%) per annum for all Term A Loans and Term B Loans and (ii) four and seven tenths of one percent (4.70%) for all Term C Loans, Term D Loans and Term E Loans, and (b)(i) 0.022% plus (ii) 1-month CME Term SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website (or on any successor or substitute page of the CME Term SOFR Administrator, or any successor to or substitute for the CME Term SOFR Administrator, as determined by Collateral Agent in a manner consistent with other loans in Collateral Agent's portfolio), which determination by Collateral Agent shall be conclusive in the absence of manifest error; provided that if, at any time, Lenders notify Collateral Agent that Lenders have determined that (x) Lenders are unable to determine or ascertain such rate, or (y) the applicable regulator has made public statements to the effect that the rate published by the CME Term SOFR Administrator is no longer used for determining interest rates for loans, then the Applicable Rate shall be equal to an alternate benchmark rate and spread agreed between Collateral Agent and Borrowers, giving due consideration to (i) market convention or (ii) selection, endorsement or recommendation by a Relevant Governmental Body. Such alternative benchmark rate and spread shall be binding unless the Required Lenders object within five (5) days following notification of such amendment.

"**Fourth Amendment Effective Date**" is October 29, 2024.

"**Maturity Date**" is, for each Term Loan, July 1, 2028.

"**Term E Draw Period**" is the period commencing on the Fourth Amendment Effective Date and ending on June 30, 2025.

2.2 Section 1.4 (Definitions). The term "Amortization Date" and its definition are hereby removed from Section 1.4 of the Loan Agreement.

2.3 Section 2.2(a) (Term Loans). Section 2.2(a) is hereby amended to amend and restate subclause (iv) in its entirety and to add subclause (v) as follows:

"(iv) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Fourth Amendment Effective Date in an aggregate principal amount of Fifty Million Dollars ($50,000,000) and disbursed in a single advance according to each Lender's Term D Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term D Loan**" and collectively as the "**Term D Loans**"). After repayment, no Term D Loan may be re-borrowed.

(v) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Term E Draw Period to make term loans to Borrower in an aggregate principal amount of Fifty Million Dollars ($50,000,000) and disbursed in a single advance according to each Lender's Term E Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term E Loan**" and collectively as the "**Term E Loans**"; each Term A Loan, Term B Loan, Term C Loan, Term D Loan and Term E Loan is hereinafter referred to singly as a "**Term Loan**" and the Term A Loans, the Term B Loans, Term C Loans, Term D Loans and Term E Loans are hereinafter referred to collectively as the "**Term Loans**"). After repayment, no Term E Loan may be re-borrowed."

2.4 Section 2.2 (Term Loans). Section 2.2(b) of the Loan Agreement is hereby amended and restated to read as follows:

"(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter, to each Lender in accordance with its Pro Rata Share, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon the effective rate of interest applicable to the Term Loan as determined in Section 2.3(a). Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date after such Funding Date. All unpaid principal and accrued and unpaid interest with respect to each such Term Loan is due and payable in full on the Maturity Date. The Term Loans may only be prepaid in accordance with Sections 2.2(c) and 2.2(d)."

2.5 Section 2.3(a) (Interest Rate). Section 2.3(a) of the Loan Agreement is hereby amended and restated to read as follows:

"(a) Interest Rate. Subject to Section 2.3(b), (i) with respect to the Term A Loans and the Term B Loans, the principal amount outstanding under such Term Loans shall accrue interest at a floating per annum rate equal to the Applicable Rate in effect from time to time *plus* 7.95%, which aggregate interest rate shall be determined by Collateral Agent in accordance with the definition of "Applicable Rate" on the third Business Day prior to the Funding Date of such Term A Loan or Term B Loan, as applicable, and on the date occurring on the first Business Day of the month prior to each Payment Date occurring thereafter, which interest shall be payable monthly in arrears in

accordance with Sections 2.2(b) and 2.3(e), (ii) with respect to the Term C Loans, the principal amount outstanding under such Term Loans shall accrue interest at a floating per annum rate equal to the Applicable Rate in effect from time to time *plus* 4.25%, which aggregate interest rate shall be determined by Collateral Agent in accordance with the definition of "Applicable Rate" on the third Business Day prior to the Funding Date of such Term C Loan and on the date occurring on the first Business Day of the month prior to each Payment Date occurring thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e), and (iii) with respect to the Term D Loans and Term E Loans, the principal amount outstanding under such Term Loans shall accrue interest at a floating per annum rate equal to the Applicable Rate in effect from time to time *plus* 4.00%, which aggregate interest rate shall be determined by Collateral Agent in accordance with the definition of "Applicable Rate" on the third Business Day prior to the Funding Date of such Term D Loan or Term E Loan and on the date occurring on the first Business Day of the month prior to each Payment Date occurring thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Except as set forth in Section 2.2(b), such interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full (or any payment is made hereunder)."

2.6 Schedule 1.1 (Lenders and Commitments). Schedule 1.1 of the Loan Agreement is hereby amended and restated in its entirety with Schedule 1.1 attached hereto as Exhibit A.

3. Limitation of Amendments.

3.1 The amendments set forth in Section 2 above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right, remedy or obligation which Lenders or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Collateral Agent and the Required Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and the Required Lenders as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date) and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Collateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by or on behalf of the Borrower to the Collateral Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not contravene (i) any material law or regulation binding on or affecting Borrower, (ii) any material contractual restriction with a Person binding on

Borrower, (iii) any applicable order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

4.6 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Loan Document. Borrower, Lenders and Collateral Agent agree that this Amendment shall be a Loan Document. Except as expressly set forth herein, the Loan Agreement and the other Loan Documents shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.

6. Release by Borrower.

6.1 FOR GOOD AND VALUABLE CONSIDERATION, Borrower hereby forever relieves, releases, and discharges Collateral Agent and each Lender and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the Effective Date through and including the date of execution of this Amendment solely to the extent such claims arise out of or are in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing (collectively "**Released Claims**").

6.2 By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected in relation to the Released Claims; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Collateral Agent or Lenders with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

6.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Collateral Agent and the Lenders to enter into this Amendment, and that Collateral Agent and the Lenders would not have done so but for Collateral Agent's and the Lenders' expectation that such release is valid and enforceable in all events.

7. Reaffirmation. Borrower hereby confirms the grant of the security interest in the Collateral to Collateral Agent and confirms and agrees that such security interest secures the Obligations.

8. Effectiveness. This Amendment shall be deemed effective as of the date hereof upon (i) the due execution and delivery of this Amendment by each party hereto, (ii) the due execution and delivery to Collateral Agent and Lenders of a certificate of Borrower in substantially the form as previously provided to Collateral Agent, (iii) the due execution and delivery of the Third Amendment to Fee Letter dated as of the date hereof by each party thereto, and (iv) delivery by Borrower to Collateral Agent of (a) the updated Perfection Certificate, (b) a duly executed legal opinion of counsel dated as of the date hereof, and (c) such other documents, agreements, side letters, certificates and/or schedules as Collateral Agent may reasonably request to effect the purpose to this Amendment.

9. Counterparts. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument. Delivery by electronic transmission (e.g. ".pdf") of an executed counterpart of this Amendment shall be effective as a manually executed counterpart signature thereof.

10. Electronic Execution. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Collateral Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

11. Governing Law. THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAW OTHER THAN THE LAW OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL CONTINUE TO APPLY TO THAT EXTENT.

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IN WITNESS WHEREOF, the parties hereto have caused this Fourth Amendment to Loan and Security Agreement to be executed as of the date first set forth above.

BORROWER:

ARDELYX, INC.

By /s/ Justin Renz
Name: Justin Renz
Title: Chief Financial and Operations Officer

COLLATERAL AGENT AND LENDER:

SLR INVESTMENT CORP.

By /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

LENDERS:

SCP PRIVATE CREDIT INCOME FUND SPV, LLC
SCP PRIVATE CREDIT INCOME BDC SPV LLC
SCP PRIVATE CORPORATE LENDING FUND SPV LLC
SCP CAYMAN DEBT MASTER FUND SPV LLC
SLR CP SF DEBT FUND SPV, LLC
SLR HC ONSHORE FUND LP
SLR HC FUND SPV LLC
SLR HC BDC LLC
SLR HC BDC SPV LLC
SLR 1818 L.P.
SLR 1818 SPV LLC
SLR PRIVATE CREDIT FUND II L.P.
SLR PRIVATE CREDIT FUND II SPV LLC
SLR PRIVATE CREDIT BDC II LLC
SLR PRIVATE CREDIT BDC II SPV LLC
SLR PRIVATE CORPORATE LENDING FUND II L.P.
SLR PRIVATE CORPORATE LENDING FUND II SPV (ABL) LLC
SLR CAYMAN DEBT MASTER FUND II SPV LLC
CRPTF-SLR CREDIT PARTNERSHIP L.P.
CRPTF-SLR CREDIT SPV LLC

By /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

Exhibit A

SCHEDULE 1.1

Lenders and Commitments

Term A Loans

Lender	Term A Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$9,475,251.16	34.46%
SCP PRIVATE CREDIT INCOME FUND SPV, LLC	$4,449,548.38	16.18%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$3,319,342.73	12.07%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$3,024,807.06	11.00%
SCP CAYMAN DEBT MASTER FUND SPV LLC	$1,297,190.99	4.72%
SLR CP SF DEBT FUND SPV, LLC	$1,038,567.36	3.78%
SLR HC FUND SPV LLC	$4,044,074.37	14.71%
SLR HC BDC SPV LLC	$851,217.95	3.10%
TOTAL	**$27,500,000.00**	**100.00%**

Term B Loans

Lender	Term B Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$7,752,478.23	34.46%
SCP PRIVATE CREDIT INCOME FUND SPV, LLC	$3,640,539.58	16.18%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$2,715,825.87	12.07%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$2,474,842.14	11.00%
SCP CAYMAN DEBT MASTER FUND SPV LLC	$1,061,338.08	4.72%
SLR CP SF DEBT FUND SPV, LLC	$849,736.93	3.78%
SLR HC FUND SPV LLC	$3,308,788.12	14.71%
SLR HC BDC SPV LLC	$696,451.05	3.10%
TOTAL	**$22,500,000.00**	**100.00%**

Term C Loans

Lender	Term C Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$15,874,439.36	31.75%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$5,640,588.30	11.28%
SCP CAYMAN DEBT MASTER FUND SPV LLC	$2,418,970.93	4.84%
SLR HC FUND SPV LLC	$7,081,161.26	14.16%
SLR HC BDC SPV LLC	$1,345,156.00	2.69%
SLR 1818 SPV LLC	$6,168,352.10	12.34%
SLR PRIVATE CREDIT FUND II SPV LLC	$3,434,372.33	6.87%
SLR PRIVATE CREDIT BDC II SPV LLC	$750,433.17	1.50%
SLR PRIVATE CORPORATE LENDING FUND II SPV (ABL) LLC	$1,770,395.23	3.54%
SLR CAYMAN DEBT MASTER FUND II SPV LLC	$1,815,120.06	3.63%

CRPTF-SLR CREDIT SPV LLC	$3,701,011.26	7.40%
TOTAL	**$50,000,000.00**	**100.00%**

Term D Loans

Lender	Term D Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$6,648,079.42	13.30%
SLR HC ONSHORE FUND LP	$5,356,205.21	10.71%
SLR HC BDC LLC	$556,076.58	1.11%
SLR 1818 L.P.	$7,942,631.37	15.89%
SLR PRIVATE CREDIT FUND II L.P.	$7,467,405.75	14.93%
SLR PRIVATE CREDIT BDC II LLC	$1,219,610.14	2.44%
SLR PRIVATE CORPORATE LENDING FUND II L.P.	$6,929,658.18	13.86%
CRPTF-SLR CREDIT PARTNERSHIP L.P.	$13,880,333.35	27.76%
TOTAL	**$50,000,000.00**	**100.00%**

Term E Loans

Lender	Term E Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$6,648,079.42	13.30%
SLR HC ONSHORE FUND LP	$5,356,205.21	10.71%
SLR HC BDC LLC	$556,076.58	1.11%
SLR 1818 L.P.	$7,942,631.37	15.89%
SLR PRIVATE CREDIT FUND II L.P.	$7,467,405.75	14.93%
SLR PRIVATE CREDIT BDC II LLC	$1,219,610.14	2.44%
SLR PRIVATE CORPORATE LENDING FUND II L.P.	$6,929,658.18	13.86%
CRPTF-SLR CREDIT PARTNERSHIP L.P.	$13,880,333.35	27.76%
TOTAL	**$50,000,000.00**	**100.00%**

Aggregate Commitments

Lender	Term Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	$46,398,327.59	23.20%
SCP PRIVATE CREDIT INCOME FUND SPV, LLC	$8,090,087.96	4.05%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	$6,035,168.60	3.02%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	$11,140,237.50	5.57%
SCP CAYMAN DEBT MASTER FUND SPV LLC	$4,777,500.00	2.39%
SLR CP SF DEBT FUND SPV, LLC	$1,888,304.29	0.94%
SLR HC ONSHORE FUND LP	$10,712,410.42	5.36%
SLR HC FUND SPV LLC	$14,434,023.75	7.22%
SLR HC BDC LLC	$1,112,153.16	0.56%
SLR HC BDC SPV LLC	$2,892,825.00	1.45%
SLR 1818 L.P.	$15,885,262.74	7.94%
SLR 1818 SPV LLC	$6,168,352.10	3.08%
SLR PRIVATE CREDIT FUND II L.P.	$14,934,811.50	7.47%
SLR PRIVATE CREDIT FUND II SPV LLC	$3,434,372.33	1.72%
SLR PRIVATE CREDIT BDC II LLC	$2,439,220.28	1.22%
SLR PRIVATE CREDIT BDC II SPV LLC	$750,433.17	0.38%
SLR PRIVATE CORPORATE LENDING FUND II L.P.	$13,859,316.36	6.93%

SLR PRIVATE CORPORATE LENDING FUND II SPV (ABL) LLC	$1,770,395.23	0.89%
SLR CAYMAN DEBT MASTER FUND II SPV LLC	$1,815,120.06	0.91%
CRPTF-SLR CREDIT PARTNERSHIP L.P.	$27,760,666.70	13.88%
CRPTF-SLR CREDIT SPV LLC	$3,701,011.26	1.85%
TOTAL	**$200,000,000.00**	**100.00%**

July 25, 2024
Eric Foster

Dear Eric,
On behalf of Ardelyx (the "Company"), I am pleased to offer you employment in the exempt position of Chief Commercial Officer, reporting to Mike Raab, President and Chief Executive Officer. In this role, you will be a member of the Executive Leadership Team. If you accept this offer, you and the Company will enter into a Change in Control Severance Agreement that will further define some of the provisions set forth in this offer letter (the "Severance Agreement"). Please note that this employment offer is contingent upon the successful completion of a reference and background check paid for by the Company. Negative information may result in the rescission of this offer.
Your first day of full-time employment with Ardelyx is currently scheduled for Monday August 5, 2024, which may be changed based upon the agreement between you and the Company. Your salary for this position will be $500,000 on an annualized basis, less applicable tax and other withholdings in accordance with the Company's normal payroll procedure.
You will be eligible to participate in various Company equity and benefit plans, including group health insurance, 401(k), the Employee Stock Purchase Plan and Flexible Time Off (FTO). In addition to your initial equity grants described below, you will be eligible to receive annual equity grants at the discretion of the Board of Directors, based on both individual and Company performance and the status of the Company's equity plans from which employee equity may be granted.

In addition, you will be eligible to participate in our annual bonus plan. This bonus will be awarded at the discretion of the Board of Directors and based on both individual and Company performance. The target bonus for this position is 45% of base salary. This bonus is discretionary, and the business and individual objectives are set by you and your manager. Your bonus for 2024 will not be pro-rated for the time you are employed by the Company during the year, but will be calculated as though you were employed by the Company throughout all of 2024.

Subject to the approval of the Company's Compensation Committee of the Board of Directors, or its designee, and after your first day of employment, you will be granted an option to purchase 230,000 shares of Company common stock (the "Stock Option") and restricted stock units covering 180,000 shares of common stock ("RSUs"). The exercise price for the Stock Option will be equal to the fair market value of Ardelyx stock on your option grant date. Your Stock Option will vest over a period of 4 years, with 25% of the shares vesting at the end of your first year of employment, and the remainder vesting monthly over the following three years. Your RSUs will vest as follows: 25% of the shares vesting on the first Company designated RSU vest date following the first anniversary of your commencement of employment and the remainder vesting quarterly over the next three years on the Company's quarterly designated RSU vest dates. Equity compensation will be subject to the terms and conditions of the

Company's equity incentive plan and standard forms of stock option and RSU agreements, which you will be required to accept as a condition of receiving the option and RSU.

Your employment with the Company is "at will." This means it is for no specified term and may be terminated by you or the Company at any time, with or without cause or notice. In addition, subject to the terms of the Severance Agreement, the Company reserves the right to modify your compensation, position, duties or reporting relationship to meet business needs and to decide on appropriate discipline.

As a condition of your employment, you will be required to sign the Company's standard form of employee nondisclosure and assignment agreement, and to provide the Company with documents establishing your identity and right to work in the United States. Those documents must be provided to the Company within three business days of your employment start date.

In the event of any dispute or claim relating to or arising out of your employment relationship with the Company, this agreement, or the termination of your employment with the Company for any reason (including, but not limited to, any claims of breach of contract, defamation, wrongful termination or age, sex, sexual orientation, race, color, national origin, ancestry, marital status, religious creed, physical or mental disability or medical condition or other discrimination, retaliation or harassment), you and the Company agree that all such disputes shall be fully resolved by confidential, binding arbitration conducted by a single arbitrator through the American Arbitration Association ("AAA") under the AAA's National Rules for the Resolution of Employment Disputes then in effect, which are available online at the AAA's website at www.adr.org. You and the Company hereby waive your respective rights to have any such disputes or claims tried before a judge or jury.

This agreement, the Severance Agreement and the non-disclosure, stock option and RSU agreements referred to above constitute the entire agreement between you and the Company regarding the terms and conditions of your employment, and they supersede all prior or contemporaneous negotiations, representations or agreements between you and the Company. The provisions of this agreement regarding "at will" employment and arbitration may only be modified by a document signed by you and an authorized representative of the Company.

Please sign and date this letter on the spaces provided below to acknowledge your acceptance of the terms of this agreement on or before Monday, July 29, 2024.

Eric, we look forward to having you join the Ardelyx team.

Sincerely,

Ardelyx, Inc.

By: /s/ Mike Raab
Mike Raab, President and Chief Executive Officer

I agree to and accept employment with Ardelyx on the terms and conditions set forth in this agreement. I understand and agree that my employment with the Company is at-will.

Date: July 26, 2024 /s/ Eric Foster
Eric Foster

Exhibit 31.1

CERTIFICATION

I, Michael Raab, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ardelyx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 31, 2024

By: /s/ Michael Raab

Michael Raab
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Justin Renz, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ardelyx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 31, 2024

By: /s/ Justin Renz

Justin Renz
Chief Financial & Operations Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Ardelyx, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Michael Raab, President and Chief Executive Officer of the Company, and Justin Renz, Chief Financial & Operations Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: October 31, 2024 By: /s/ Michael Raab

Michael Raab
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: October 31, 2024 By: /s/ Justin Renz

Justin Renz
Chief Financial & Operations Officer
(Principal Financial Officer)