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DELTA REPORT

10-Q

ARDX - ARDELYX, INC.

10-Q - SEPTEMBER 30, 2024 COMPARED TO 10-Q - JUNE 30, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	3919
CHANGES	234
DELETIONS	1774
ADDITIONS	1911

REFINITIV

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**

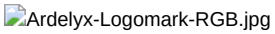
For the quarterly period ended June September 30, 2024

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 July 26, 2024 October 25, 2024, was 235,428,183. 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, are bundled 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 are not profitable and 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. 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)

	June 30, 2024	December 31, 2023
	September 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Assets		
Assets		
Current assets:	Current assets:	Current assets:
Cash and cash equivalents		
Short-term investments		
Accounts receivable		
Inventory		
Prepaid commercial manufacturing		
Prepaid expenses and other current assets		
Total current assets		
Inventory, non-current		
Prepaid commercial manufacturing, non-current		
Right-of-use assets		
Property and equipment, net		
Other assets		
Other assets		
Other assets		
Total assets		
Liabilities and stockholders' equity		
Current liabilities:		
Current liabilities:		
Current liabilities:		
Accounts payable		
Accounts payable		
Accounts payable		
Accrued compensation and benefits		
Current portion of operating lease liability		
Current portion of operating lease liability		
Current portion of operating lease liability		
Deferred revenue		
Accrued expenses and other current liabilities		
Total current liabilities		
Operating lease liability, net of current portion		
Long-term debt		
Deferred revenue, non-current		
Deferred royalty obligation related to the sale of future royalties		
Total liabilities		
Total liabilities		
Total liabilities		
Commitments and contingencies (Note 14)	Commitments and contingencies (Note 14)	Commitments and contingencies (Note 14)
Stockholders' equity:		
Common stock, $0.0001 par value; 500,000,000 shares authorized; 235,401,398 and 232,453,190 shares issued and outstanding as of June 30, 2024 and December 31, 2023		

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	
Common stock, $0.0001 par value; 500,000,000 shares authorized; 235,401,398 and 232,453,190 shares issued and outstanding as of June 30, 2024 and December 31, 2023	
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	
Common stock, $0.0001 par value; 500,000,000 shares authorized; 235,401,398 and 232,453,190 shares issued and outstanding as of June 30, 2024 and December 31, 2023	
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	
Additional paid-in capital	
Accumulated deficit	
Accumulated other comprehensive (loss) income	
Accumulated other comprehensive income	
Total stockholders' equity	
Total liabilities and stockholders' equity	

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

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

	Three Months Ended June 30,		Six Months Ended June 30,					
	Three Months Ended September 30,		Nine Months Ended September 30,					
	2024	2024	2023	2024	2023	2024	2023	2024	2023
Revenues:	Revenues:			Revenues:					
Product sales, net									
Product supply revenue									
Licensing revenue									
Non-cash royalty revenue related to the sale of future royalties									
Total revenues									
Total revenues									
Total revenues									
Cost of goods sold:									
Cost of product sales									
Cost of product sales									
Cost of product sales									
Other cost of revenue									
Total cost of goods sold									
Operating expenses:									
Research and development									
Research and development									
Research and development									
Selling, general and administrative									
Total operating expenses									
Loss from operations									
Income (loss) from operations									
Interest expense									
Non-cash interest expense related to the sale of future royalties									
Other income, net									
Loss before provision for income taxes									

Income (loss) before provision for income taxes
Provision for income taxes
Net loss
Net loss per share of common stock - basic and diluted
Shares used in computing net loss per share - basic and diluted
Comprehensive loss:
Comprehensive loss:
Comprehensive loss:
Net loss
Net loss
Net loss
Unrealized losses on available-for-sale securities
Comprehensive loss
Net income (loss)
Net income (loss) per share of common stock - basic and diluted
Shares used in computing net income (loss) per share - basic
Shares used in computing net income (loss) per share - diluted
Comprehensive income (loss):
Net income (loss)
Net income (loss)
Net income (loss)
Unrealized gains (losses) on available-for-sale securities
Comprehensive income (loss)

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 Six Nine Months ended June 30, 2024 September 30, 2024 and 2023
(Unaudited)
(in thousands, except shares)

	Three Months Ended June 30, 2024						Three Months Ended September 30, 2024				
	Common Stock Shares	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance as of March 31, 2024											
Balance as of March 31, 2024											
Balance as of March 31, 2024											
Balance as of June 30, 2024											
Balance as of June 30, 2024											
Balance as of June 30, 2024											
Issuance of common stock under employee stock purchase plan											
Issuance of common stock for services											
Issuance of common stock for services											
Issuance of common stock for services											
Issuance of common stock upon exercise of options											
Issuance of common stock upon exercise of options											

Issuance of common stock upon exercise of options											
Issuance of common stock upon vesting of restricted stock units											
Stock-based compensation											
Stock-based compensation											
Stock-based compensation											
Unrealized losses on available-for-sale securities											
Unrealized gains on available-for-sale securities											
Net loss											
Balance as of June 30, 2024											
Balance as of September 30, 2024											

	Six Months Ended June 30, 2024						Nine Months Ended September 30, 2024				
	Common Stock Shares	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance as of December 31, 2023											
Balance as of December 31, 2023											
Balance as of December 31, 2023											
Issuance of common stock under employee stock purchase plan											
Issuance of common stock for services											
Issuance of common stock upon exercise of options											
Issuance of common stock upon vesting of restricted stock units											
Stock-based compensation											
Stock-based compensation											
Stock-based compensation											
Unrealized losses on available-for-sale securities											
Net loss											
Balance as of June 30, 2024											
Balance as of September 30, 2024											

	Three Months Ended June 30, 2023						Three Months Ended September 30, 2023				
	Common Stock Shares	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance as of March 31, 2023											
Balance as of March 31, 2023											
Balance as of March 31, 2023											
Balance as of June 30, 2023											
Balance as of June 30, 2023											
Balance as of June 30, 2023											

	Six Months Ended June 30, 2023						Nine Months Ended September 30, 2023					
	Common Stock Shares	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance as of December 31, 2022											
Balance as of December 31, 2022											
Balance as of December 31, 2022											
Issuance of common stock under employee stock purchase plan											
Issuance of common stock for services											
Issuance of common stock upon exercise of options											
Issuance of common stock upon vesting of restricted stock units											
Issuance of common stock in at-the-market offerings											
Issuance of common stock in at-the-market offerings											
Issuance of common stock in at-the-market offerings											
Stock-based compensation											
Unrealized losses on available-for-sale securities											
Net loss											
Balance as of June 30, 2023											
Balance as of September 30, 2023											

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

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

	Six Months Ended June 30,		Nine Months Ended September 30,	
	2024	2024	2023	2024	2023
Operating activities	**Operating activities**		**Operating activities**		
Net loss					
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization expense					
Depreciation and amortization expense					
Depreciation and amortization expense					
Non-cash lease expense					
Stock-based compensation					
Non-cash interest expense					
Non-cash interest expense					
Non-cash interest expense					
Non-cash royalty revenue related to the sale of future royalties					
Other, net					
Changes in operating assets and liabilities:					
Accounts receivable					
Accounts receivable					
Accounts receivable					
Inventory					
Prepaid commercial manufacturing					
Prepaid expenses and other assets					
Accounts payable					
Accrued compensation and benefits					
Operating lease liabilities					
Accrued and other liabilities					
Deferred revenue					
Net cash used in operating activities					
Investing activities					
Proceeds from maturities and redemptions of investments					
Proceeds from maturities and redemptions of investments					
Proceeds from maturities and redemptions of investments					
Purchases of investments					
Purchases of property and equipment					
Purchases of property and equipment					
Purchases of property and equipment					
Net cash provided by (used in) investing activities					
Financing activities					
Proceeds from 2022 Loan Agreement, net of issuance costs					
Proceeds from 2022 Loan Agreement, net of issuance costs					
Proceeds from 2022 Loan Agreement, net of issuance costs					
Proceeds from issuance of common stock in at the market offering, net of issuance costs					
Proceeds from issuance of common stock in at the market offering, net of issuance costs					
Proceeds from issuance of common stock in at the market offering, net of issuance costs					
Proceeds from issuance of common stock under equity incentive and stock purchase plans					
Net cash provided by financing activities					

Net cash provided by financing activities	
Net cash provided by financing activities	
Net increase (decrease) in cash and cash equivalents	
Cash and cash equivalents at beginning of period	
Cash and cash equivalents at end of period	
Supplementary disclosure of cash flow information:	
Cash paid for interest	
Cash paid for interest	
Cash paid for interest	
Cash paid for income taxes	
Supplementary disclosure of non-cash activities:	
Right-of-use assets obtained in exchange for lease obligations	
Right-of-use assets obtained in exchange for lease obligations	
Right-of-use assets obtained in exchange for lease obligations	
Issuance of common stock for services	

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 six nine months ended June 30, 2024 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 June 30, 2024 September 30, 2024, we had cash, cash equivalents and short-term investments of approximately $186.0 $190.4 million. We have incurred operating losses since inception in 2007 and our accumulated deficit as of June 30, 2024 September 30, 2024 is $889.2 $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 June 30, 2024 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, 2024 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 June 30, 2024 September 30, 2024 and December 31, 2023 are summarized below (in thousands):

	June 30, 2024				September 30, 2024		
		Gross Unrealized					
	Amortized Cost						
	Amortized Cost						
	Amortized Cost	Gains	Losses	Fair Value	Gains	Losses	Fair Value
Cash and cash equivalents:							
Cash							
Cash							
Cash							
Money market funds							
Total cash and cash equivalents							
Total cash and cash equivalents							
Total cash and cash equivalents							
Short-term investments:							
U.S. government-sponsored agency bonds							
U.S. government-sponsored agency bonds							

U.S. government-sponsored agency bonds
U.S. treasury securities
Commercial paper
Corporate bonds
Asset-backed securities
Asset-backed securities
Asset-backed securities
Total short-term investments
Total short-term investments
Yankee bonds
Total short-term investments
Total cash, cash equivalents and investments

	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 loss 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 loss. income (loss).

All of the short-term our available-for sale securities held as of June 30, 2024 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 loss income (loss) to its fair value and establish that value as a new cost basis for the investment. Our unrealized losses as of June 30, 2024 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 June 30, 2024 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):

	June 30, 2024				September 30, 2024				
	Total Fair Value	Total Fair Value	Level 1	Level 2	Level 3	Total Fair Value	Level 1	Level 2	Level 3
Assets:									
Money market funds									
Money market funds									
Money market funds									
U.S. government-sponsored agency bonds									
U.S. treasury securities									
Commercial paper									
Corporate bonds									
Corporate bonds									
Corporate bonds									
Asset-backed securities									
Asset-backed securities									
Asset-backed securities									
Yankee bonds									
Total									
Total									
Total									

	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, and 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. As of June 30, 2024, the 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 there were no unobservable inputs. 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 June 30, 2024 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 June 30, 2024 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 June 30, 2024 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 June 30, 2024 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 June 30, 2024 September 30, 2024 and December 31, 2023 consisted of the following (in thousands):

	June 30, 2024 September 30, 2024	December 31, 2023 December 31, 2023
Raw materials		
Work in process		
Finished goods		
Total		
Reported as:		
Inventory		
Inventory		
Inventory		
Inventory, non-current		
Total		

In addition to inventory, we had prepaid commercial manufacturing of $14.8 $16.7 million and $23.2 million as of June 30, 2024 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 June 30, 2024 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 six nine months ended June 30, 2024 September 30, 2024 and 2023 were as follows (in thousands):

	Three Months Ended June 30, Three Months Ended September 30,			Six Months Ended June 30, Nine Months Ended September 30,				
	2024	2024	2023	2024	2023	2024	2023	2024	2023
Product sales, net:									
IBSRELA									
IBSRELA									
IBSRELA									
XPHOZAH									
Total product sales, net									
Product supply revenue									
Licensing revenue									
Non-cash royalty revenue related to the sale of future royalties									

Non-cash royalty revenue related to the sale of future royalties	
Non-cash royalty revenue related to the sale of future royalties	
Total revenues	

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
BioRidge Pharma, LLC	50.8 %	20.0 %	46.3 %	19.0 %
AmerisourceBergen Drug Corporation	14.2 %	21.1 %	15.8 %	21.3 %
Cardinal Health	13.5 %	22.4 %	14.6 %	22.3 %
McKesson Corporation	13.0 %	18.4 %	13.2 %	19.4 %

	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	Discounts and Chargebacks	Rebates, Wholesaler and GPO Fees	Copay and Returns	Total	Discounts and Chargebacks	Rebates, Wholesaler and GPO Fees	Copay and Returns	Total
Balance as of December 31, 2023									
Provisions									
Credits/payments									
Balance as of June 30, 2024									
Balance as of September 30, 2024									

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 June 30, 2024 September 30, 2024. We may also be eligible to receive approximately ¥8.5 billion for commercialization milestones, or approximately $52.8 $59.8 million at the currency exchange rate on June 30, 2024 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 June 30, 2024 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 loss. 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 loss 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 six nine months ended June 30, 2024 September 30, 2024, we recognized $0.6 million $0.8 million and $1.0 million $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 six nine months ended June 30, 2024 September 30, 2024, we recognized $13 thousand $5.3 million and $2.1 million $7.5 million, respectively, of product supply revenue pursuant to the 2017 Kyowa Kirin Agreement. During the three and six nine months ended June 30, 2023 September 30, 2023, we recognized $3.3 million $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 June 30, 2024 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 June 30, 2024 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 loss 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 six nine months ended June 30, 2024 and 2023, 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 $16.2 million $16.4 million at the currency exchange rate on June 30, 2024 September 30, 2024, of which $0.7 million has been received and recognized as revenue as of June 30, 2024 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 June 30, 2024 September 30, 2024.

During the three and six nine months ended June 30, 2024 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 June 30, 2024 September 30, 2024, to date in aggregate, we have recognized $40.2 million $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 loss. income (loss). During the three and six nine months ended June 30, 2024 September 30, 2024, we recognized $7.9 million $10.0 million and $12.6 million $22.7 million, respectively, as other cost of revenue related to the AstraZeneca Termination Agreement. During the three and six nine months ended June 30, 2023 September 30, 2023 we recognized $1.9 million $5.7 million and $3.0 million $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		2024		2023		2024		2023	
	Current	Current	Non-Current	Current	Non-Current		Current	Non-Current	Current	Non-Current
Balance at January 1,	Balance at January 1,	$ 7,182	$ 8,644	$4,211	$ 9,025	Balance at January 1,	$7,182	$ 8,644	$ 4,211	$ 9,025
Amounts invoiced as prepayments for product supply	Amounts invoiced as prepayments for product supply	731	5,213	816	3,478	Amounts invoiced as prepayments for product supply	2,654	8,212	1,182	4,530
Decrease for revenue recognized for product supply	Decrease for revenue recognized for product supply	(1,328)	—	(2,333)	—	Decrease for revenue recognized for product supply	(6,650)	—	(4,586)	—
Reclassify amounts to be recognized in the next twelve months	Reclassify amounts to be recognized in the next twelve months	4,244	(4,244)	3,265	(3,265)	Reclassify amounts to be recognized in the next twelve months	4,086	(4,086)	3,265	(3,265)
Balance at June 30,		$10,829	$ 9,613	$5,959	$ 9,238					
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 June 30, 2024 September 30, 2024, our effective interest rate used to amortize the liability is 28.8% 33.3%. During the three and six nine months ended June 30, 2024 September 30, 2024, we recognized $1.6 million $1.9 million and $3.3 million $5.2 million, respectively, of non-cash interest expense related to the deferred royalty obligation. During the three and six nine months ended June 30, 2023 September 30, 2023, we recognized $1.0 million $0.9 million and $1.9 million $2.9 million, respectively, of non-cash interest expense related to the deferred royalty obligation. As of June 30, 2024 September 30, 2024, we have received $0.4 million $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) (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) and , February 2023 (the Second Amendment) and October 2023 (the Third Amendment). We concluded that the First Amendment, and 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.

On October 17, 2023, we entered into a Third Amendment (the Third Amendment) to the 2022 Loan Agreement by and between us and the 2022 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) provides 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 and together with the Term A, B, and C Loans, the Four 2022 Loans) 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.

We concluded that the ThirdAs discussed in *Note 15. Subsequent Events*, on October 29, 2024, we entered into a Fourth Amendment was a modification (the Fourth Amendment) to the 2022 Original Loan Agreement. 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 Third Fourth Amendment, the maturity date for the Four 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 each of the Term C Loan and the Term D 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 Third Fourth Amendment, the period under which we are permitted to make interest-only payments on the Four Five 2022 Loans was extended to December 31, 2026, effective upon our decision to draw the Term B Loan in the amount of $22.5 million. Maturity Date.

We were obligated to pay 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, and $0.3 million on the funding date of the Term C Loan. 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 D E Loan commitment, if requested by us and approved by the Agent's investment committee, which shall be due on the earliest of (1) the funding of the Term D E Loan, (2) if we request June 30, 2025, and the 2022 Lenders provide the Term D Loan commitment, the day immediately preceding the amortization date, and (3) if we request and the 2022 Lenders provide the Term D Loan commitment, the prepayment, refinancing, substitution or replacement of any of the Term C Loan Five 2022 Loans on or prior to the date immediately preceding the amortization date. June 30, 2025.

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

We may voluntarily prepay all amounts outstanding under the Four Five 2022 Loans, subject to a prepayment premium of (i) 3% of the outstanding principal amount of the Four Five 2022 Loans if prepaid prior to or on October 17, 2024, (ii) 2% of the outstanding principal amount of the Four 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 Four Five 2022 Loans if prepaid after October 17, 2025 and prior to the maturity date. The Four 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). Notwithstanding the prepayment or termination of the 2022 Loan, We paid the 2022 Exit Fee will expire 10 years from to the Closing Date. 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 Four balance of the Five 2022 Term Loan balance 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 Four balance of the Five 2022 Loan balance. 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 Four 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 June 30, 2024 September 30, 2024 due to principal repayments beginning in January 2027. repayment on July 1, 2028. We have concluded that the provisions that could cause acceleration of the principal repayments are remote.

As of June 30, 2024 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		(1,047) (944)
Less: Unaccreted value of final fee		(3,654) (3,299)
Long-term debt		100,249 100,707
Less: Current portion of long-term debt		—
Long-term debt, net of current portion	$	100,249 100,707

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 chronic kidney disease (CKD) 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 is was recorded as a derivative liability and included in accounts payable and accrued expenses and other current liabilities on the accompanying condensed balance sheets. During the three months ended June 30, 2024 sheets as of September 30, 2024 and December 31, 2023, we achieved the Revenue Milestone and therefore expect to pay the $1.0 million 2022 Exit Fee to the Agent. respectively. As of June 30, 2024 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 June 30, 2024 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 loss income (loss) and were as follows for the six nine months ended June 30, 2024 September 30, 2024 and 2023 (in thousands):

	2024	2024	2023	2024	2023

Fair value of exit fee derivative liabilities at January 1,	
Changes in estimated fair value:	
Changes in estimated fair value:	
Changes in estimated fair value:	
2018 Exit Fee	
2018 Exit Fee	
2018 Exit Fee	
2022 Exit Fee	
Fair value of exit fee derivative liabilities at June 30,	
Fair value of exit fee derivative liabilities at September 30,	

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	Facilities	June 30, 2024	December 31, 2023	Facilities	September 30, 2024	December 31, 2023
Right-of-use assets	Right-of-use assets	$ 4,324	$ 5,589	Right-of-use assets	$ 3,625	$ 5,589
Current portion of lease liabilities						
Current portion of lease liabilities						
Current portion of lease liabilities		3,550	4,435		2,567	4,435
Operating lease liability, net of current portion	Operating lease liability, net of current portion	1,096	1,725	Operating lease liability, net of current portion	1,218	1,725
Total lease liabilities	Total lease liabilities	$ 4,646	$ 6,160	Total lease liabilities	$ 3,785	$ 6,160
Weighted-average remaining life (years)						
Weighted-average remaining life (years)						
Weighted-average remaining life (years)		1.4	1.6		1.7	1.6
Weighted-average discount rate	Weighted-average discount rate	6.7 %	6.8 %	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 loss, income (loss), were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,			
	Three Months Ended September 30,		Nine Months Ended September 30,			
	2024	2024	2023	2024	2023	2024	2023	2024	2023
Operating lease expense									
Cash paid for operating lease									

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

Remainder of 2024
2025
2026
2027
Thereafter
Thereafter
2028
Thereafter
Total undiscounted operating lease payments
Imputed interest expenses
Total operating lease liabilities
Less: Current portion of operating lease liability

Operating lease liability, net of current portion

NOTE 11. STOCKHOLDERS' EQUITY

At-the-Market Offering Agreements

In July 2020, we filed a registration statement on Form S-3, registration statement, 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, registration statement, 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 six nine months ended June 30, 2024 September 30, 2024, we completed no sales pursuant to the 2023 Open Market Sales Agreement. As of June 30, 2024 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 loss, income (loss), as follows (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,			
	Three Months Ended September 30,			Nine Months Ended September 30,			
	2024	2024	2023	2024	2023	2024	2023	2024	2023
Selling, general and administrative									
Research and development									
Total									
Total									
Total									

As of June 30, 2024 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		Unrecognized Compensation Expense		Average Remaining Vesting Period (Years)		Unrecognized Compensation Expense		Average Remaining Vesting Period (Years)
Stock option grants	Stock option grants	$ 59,511	2.9	2.9	Stock option grants	$ 59,155	2.8	2.8	
RSU grants	RSU grants	$ 50,934	3.2	3.2	RSU grants	$ 51,963	3.1	3.1	
ESPP	ESPP	$ 204	0.2	0.2	ESPP	$ 394	0.4	0.4	

Stock Options

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

	Number of Shares	Number of Shares	Weighted-Average Exercise Price per Share	Number of Shares	Weighted-Average Exercise Price per Share
Balance at December 31, 2023					

Options granted					
Options exercised					
Options forfeited or canceled					
Balance at June 30, 2024					
Exercisable at June 30, 2024					
Balance at September 30, 2024					
Exercisable at September 30, 2024					

Restricted Stock Units

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

	Number of RSUs	Number of RSUs	Weighted-Average Grant Date Fair Value Per Share	Number of RSUs	Weighted-Average Grant Date Fair Value Per Share
Non-vested restricted stock units at December 31, 2023					
Granted					
Vested					
Forfeited					
Non-vested restricted stock units at June 30, 2024					
Non-vested restricted stock units at September 30, 2024					

Employee Stock Purchase Plan

During the six nine months ended June 30, 2024 September 30, 2024, we sold approximately 0.3 0.5 million shares of our common stock under the ESPP. The shares were purchased by employees at an average purchase price of $4.10 $4.64 per share resulting in proceeds to us of approximately $1.0 $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 six nine months ended June 30, 2024 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 LOSS INCOME (LOSS) PER SHARE

Basic net loss income (loss) per share is calculated by dividing net loss 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 loss 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 six nine months ended June 30, 2024 September 30, 2024 and 2023, all potential common shares were determined to be anti-dilutive. anti-dilutive during those periods.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
Numerator:	**2024**	**2023**	**2024**	**2023**
Net loss	$ (16,454)	$ (17,121)	$ (42,972)	$ (43,894)
Denominator:				
Shares used in computing net loss per share - basic and diluted	234,571	214,951	233,819	211,009
Net loss per share of common stock - basic and diluted	$ (0.07)	$ (0.08)	$ (0.18)	$ (0.21)

	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 June 30,		Six Months Ended June 30,	
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Options to purchase common stock	27,818	20,659	27,250	20,260
Restricted stock units	7,971	3,008	7,497	2,969
ESPP shares issuable	168	278	197	242
Total	35,957	23,945	34,944	23,471

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 "Securities Class Actions) 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. A hearing The case was dismissed with prejudice on September 12, 2024. On October 9, 2024, plaintiff appealed the motion District Court's dismissal of the case to dismiss is currently set for October 3, 2024. the Ninth Circuit. We believe the plaintiff's 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 plaintiff's 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 United States 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 June 30, 2024 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 June 30, 2024 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®, was is approved by in the U.S. Food and Drug Administration (U.S. FDA) on October 17, 2023, 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 June 30, 2024 September 30, 2024, we had an accumulated deficit of $889.2 million $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 cost 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 which includes (including license fees, milestones and product supply revenue, 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 17, 2023 October 29, 2024 (collectively, the 2022 Loan Agreement), as well as from sales of IBSRELA and XPHOZAH.

Our Commercial Products

IBSRELA for IBS-C

Our unique discovery platform and deep understanding of the primary mechanism of sodium transport in the intestine resulted in our discovery and development of IBSRELA is a first-in-class U.S. FDA approved, 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. For our commercial launch of IBSRELA, we designed We deploy a market-responsive commercial strategy for IBSRELA and built 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 for IBS-C by the approximately 9,000 high-writing healthcare providers who account for approximately 50% of IBS-C prescriptions. 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 for IBS-C. 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, XPHOZAH, a first-in-class phosphate absorption inhibitor, 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 National Medical Products Administration (NMPA) 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 $16.2 $16.4 million at the currency exchange rate on June 30, 2024 September 30, 2024, of which $0.7 million has been received and recognized as revenue as of June 30, 2024 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 June 30, 2024 September 30, 2024. We may also be eligible to receive approximately ¥8.5 billion for commercialization milestones, or approximately $52.8 $59.8 million at the currency exchange rate on June 30, 2024 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 June 30, 2024 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 six nine months ended June 30, 2024 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 or 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 six nine months ended June 30, 2024 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 six nine months ended June 30, 2024 September 30, 2024 would have been $1.2 million $2.2 million and $2.4 million $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 six nine months ended June 30, 2023 September 30, 2023 would have been $2.0 million $1.0 million and $2.4 million $3.4 million higher, respectively, if we had not previously expensed certain material and production costs with respect to the units sold. As of June 30, 2024 September 30, 2024 and December 31, 2023, we had approximately $19.6 $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 $40.2 million $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 June 30, 2024 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 six nine months ended June 30, 2024 September 30, 2024 and 2023

Revenue

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

		Three Months Ended June 30,			Change 2024 vs. 2023			Six Months Ended June 30,			Change 2024 vs. 2023		
		Three Months Ended September 30,			Change 2024 vs. 2023			Nine Months Ended September 30,			Change 2024 vs. 2023		
	2024	2024	2023	$	%			2024	2023	$	%		
Product sales, net	Product sales, net	$72,591	$18,309	$54,282	296	296	%	$116,103	$29,664	$86,439	291		
Product supply revenue	Product supply revenue	13	3,260	3,260	(3,247)	(3,247)	(100)	(100)%	2,139	3,262	3,262	(1,123)	(1,123)
Licensing revenue	Licensing revenue	19	764	764	(745)	(745)	(98)	(98)%	36	776	776	(740)	(740)
Non-cash royalty revenue related to the sale of future royalties													
Non-cash royalty revenue related to the sale of future royalties													
Non-cash royalty revenue related to the sale of future royalties		599	—	—	599	599	(a)	(a)	967	—	—	967	9
Total revenues	Total revenues	$73,222	$22,333	$50,889	228	228	%	$119,245	$33,702	$85,543	254		

(a) Percent change is not meaningful.

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

	Three Months Ended June 30,		Change 2024 vs. 2023		Six Months Ended June 30,		Change 2024 vs. 2023		
	2024	2023	$	%	2024	2023	$	%	
Product sales, net:									
IBSRELA	$35,445	$18,309	$17,136	94 %	$63,806	$29,664	$34,142	115 %	$40,63
XPHOZAH	37,146	—	37,146	(a)	52,297	—	52,297	(a)	
Total product sales, net	$72,591	$18,309	$54,282	296 %	$116,103	$29,664	86,439	291 %	Total produ sales net

	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									
IBSRELA									
IBSRELA	$35,445	$18,309	$17,136	94 %	$63,806	$29,664	$34,142	115 %	$40,63
XPHOZAH	37,146	—	37,146	(a)	52,297	—	52,297	(a)	
Total product sales, net	$72,591	$18,309	$54,282	296 %	$116,103	$29,664	86,439	291 %	Total produ sales net

(a) Percent change is not meaningful.

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

The decrease in licensing revenue during the three and six nine months ended June 30, 2024 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 six nine months ended June 30, 2024 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 June 30,		Change 2024 vs. 2023		Six Months Ended June 30,		Change 2024 vs. 2023	

	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	$1,405	$ 913	492	186 %	$ 2,418	$ 864	$ 1,554	180 %
Other cost of revenue	8,031	5,034	2,997	168 %	14,146	4,162	9,984	240 %
Total cost of goods sold	$9,436	$5,947	$3,489	170 %	$16,564	$5,026	$11,538	230 %

The increase to cost of product sales during the three and six nine months ended June 30, 2024 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 six nine months ended June 30, 2024 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, which is partially offset by as well as cost of goods sold for decreased increased product supply sold to our collaboration partners.

Operating Expenses

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

	Three Months Ended June 30,		Change 2024 vs. 2023		Six Months Ended June 30,		Change 2024 vs. 2023	
	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	$12,762	$ 8,282	$ 4,480	54 %	$ 23,341	$17,375	$ 5,966	34 %
Selling, general and administrative	64,654	27,186	37,468	138 %	117,648	53,989	63,659	118 %
Total operating expenses	$77,416	$35,468	$41,948	118 %	$140,989	$71,364	$69,625	98 %

Research and Development

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

	Three Months Ended June 30,		Change 2024 vs. 2023		Six Months Ended June 30,		Change 2024 vs. 2023	
	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	$ 4,503	$3,171	$1,332	42 %	$ 7,255	$ 7,206	$ 49	1 %
Employee-related expenses	6,515	4,038	2,477	61 %	12,651	8,095	4,556	56 %

Facilities, equipment and depreciation expenses	Facilities, equipment and depreciation expenses	928		727	727		201		201	28		28	%		1,836		1,357		1,357	479		479	35									
Other	Other	816		346	346		470		470	136		136	%		1,599		717		717	882		882	123									
Total research and development expenses	Total research and development expenses	$12,762		$	$8,282		$		$4,480	54		54	%		$23,341		$		$17,375	$		$5,966	34		34	%						

The increase in our R&D expenses, including other R&D expenses, during the three and six nine months ended June 30, 2024 September 30, 2024 as compared to the same periods in 2023 is primarily the result of increased medical engagement with the scientific communities in the areas of gastroenterology and nephrology, as well as pediatric clinical trial and pharmacovigilance 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 $1.4 million $2.0 million and $2.6 million $4.6 million, respectively, during the three and six nine months ended June 30, 2024 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 six nine months ended June 30, 2024 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 $6.2 million $3.6 million and $9.7 million $13.3 million, respectively, during the three and six nine months ended June 30, 2024 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 June 30,		Change 2024 vs. 2023		Six Months Ended June 30,		Change 2024 vs. 2023																									
	Three Months Ended September 30,		Change 2024 vs. 2023		Nine Months Ended September 30,		Change 2024 vs. 2023																									
	2024		2024		2023		$		%		2024		2023		$		%		2024		2023											
Interest expense	Interest expense	$(3,326)	$		$(1,075)	$		$(2,251)	209	209	%		$(5,682)	$		$(2,103)	$		$(3,579)	170	170	%	Interest expense	$(3,357)	$		$(1,107)	$		$(2,250)			

The increase in interest expense during the three and six nine months ended June 30, 2024 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 June 30,	Change 2024 vs. 2023	Six Months Ended June 30,	Change 2024 vs. 2023
	Three Months Ended September 30,	Change 2024 vs. 2023	Nine Months Ended September 30,	Change 2024 vs. 2023

	2024		2024		2023		$		%		2024		2023		$		%		2024		2023		$	
Non-cash interest expense related to the sale of future royalties	Non-cash interest expense related to the sale of future royalties	$(1,576)	$	$(968)	$	$(608)	63	63	%	$(3,278)	$	$(1,937)	$	$(1,341)	69	69	%	Non-cash interest expense related to the sale of future royalties	$(1,924)	$	$(922)	$	$(1,002)	109	109

The increase in non-cash interest expense related to the sales of future royalties during the three and six nine months ended June 30, 2024 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 June 30,		Change 2024 vs. 2023		Six Months Ended June 30,		Change 2024 vs. 2023	
	Three Months Ended September 30,		Change 2024 vs. 2023		Nine Months Ended September 30,		Change 2024 vs. 2023	

	2024		2024		2023		$		%		2024		2023		$		%		2024		2023		$		%	
Other income, net	Other income, net	$2,145	$	$1,546	$	$599	39	39	%	$4,484	$	$2,848	$	$1,636	57	57	%	Other income, net	$2,282	$	$1,460	$	$822	56	56	%	$6,76

The increase in other income, net during the three and six nine months ended June 30, 2024 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):

		June 30, 2024	December 31, 2023	Change $	Change %								
		September 30, 2024	December 31, 2023	Change $	Change %								

Cash and cash equivalents	Cash and cash equivalents	$ 41,890	$	$ 21,470	$	$20,420	95	95	%	Cash and cash equivalents	$ 47,429	$	$21,470	$											
Short-term investments	Short-term investments	144,071	162,829	162,829	(18,758)	(18,758)	(12)	(12)	%	Short-term investments	142,973	162,829	162,829												
Total liquid funds																									
Total liquid funds																									
Total liquid funds		$185,961	$	$184,299	$	$ 1,662	1	1	%	$ 190,402		$	$ 184,299	$											

As of June 30, 2024 September 30, 2024, we had cash, cash equivalents and short-term investments of approximately $186.0 $190.4 million.

In January 2023, we filed a registration statement of 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 June 30, 2024 September 30, 2024 and 2023, we completed no sales pursuant to the

2023 Open Market Sales Agreement. As of June 30, 2024 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, therefore expect to pay 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 chronic kidney disease (CKD) 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. As discussed in *Note 9. Derivative Liabilities*, in connection with entering into the 2022 Loan Agreement, we entered into the 2022 Exit Fee agreement, as amended, whereby we agreed to pay an exit fee in the amount of 2% of the Term A Loan and Term B Loan by SLR if certain conditions are met. Notwithstanding the prepayment or termination of the 2022 Loan, the 2022 Exit Fee will expire on February 23, 2032.

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 $50.0 million of committed capital by March 15, 2024 (the Term C Loan); provided we have drawn the Term B Loan; and (2) provides provided us with the option to draw up to an additional $50.0 million $50.0 million of uncommitted capital by December 31, 2026, subject to approval by the Agent's Agent's investment committee (the Term D Loan); and (3) extended the interest-only period for the Four Loans to December 31, 2026, effective upon our decision to draw the Term B Loan in the amount of $22.5 million. In October 2023, we provided the Agent with notice of our decision to draw the Term B Loan to support the commercial launch of XPHOZAH and received the proceeds of the Term B 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 June 30, 2024 September 30, 2024 is $889.2 $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 June 30, 2024 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):

		Six Months Ended June 30,		Change 2024 vs. 2023				Nine Months Ended September 30,		Change 2024 vs. 2023			
		2024	2023	$	%			2024	2023	$	%		
Net cash used in operating activities	Net cash used in operating activities	$(55,120)	$(59,532)	$ 4,412	(7)%	Net cash used in operating activities	$(54,619)	$(80,999)	$				
Net cash provided by (used in) investing activities	Net cash provided by (used in) investing activities	20,961	(68,984)	89,945	(130)%	Net cash provided by (used in) investing activities	23,302	(101,681)	124,983				
Net cash provided by financing activities	Net cash provided by financing activities	54,579	62,434	(7,855)	(13)%	Net cash provided by financing activities	57,276	120,307	(63,031)				
Net increase (decrease) in cash and cash equivalents	Net increase (decrease) in cash and cash equivalents	$ 20,420	$(66,082)	$86,502	(131)%	Net increase (decrease) in cash and cash equivalents	$ 25,959	$(62,373)	$				

Cash Flows from Operating Activities

Net cash used in operating activities during the six nine months ended June 30, 2024 September 30, 2024 decreased by $4.4 million $26.4 million as compared to the same period in 2023 primarily due to adjustments to reconcile higher product sales, net, loss to net cash used in operating activities such as stock-based compensation, as well as net changes in our operating assets and liabilities. 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 six nine months ended June 30, 2024 September 30, 2024 increased by $89.9 million $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 six nine months ended June 30, 2024 September 30, 2024 decreased by $7.9 million $63.0 million as compared to the same period in 2023 primarily due to the receipt of $62.1 million $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 June 30, 2024 September 30, 2024, we had cash, cash equivalents and short-term investments of $186.0 $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 $0.3 $0.7 million for the six nine months ended June 30, 2024 September 30, 2024. As of June 30, 2024 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 June 30, 2024 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 June 30, 2024 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 June 30, 2024 September 30, 2024, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the six nine months ended June 30, 2024 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. A hearing The case was dismissed with prejudice on September 12, 2024. On October 9, 2024, plaintiff appealed the motion District Court's dismissal of the case to dismiss is currently set for October 3, 2024. the Ninth Circuit. We believe the plaintiff's 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 plaintiff's 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 June 30, 2024 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 June 30, 2024 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 are not profitable and have incurred significant 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 are not profitable and 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 June 30, 2024 September 30, 2024, we had an accumulated deficit of $889.2 $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 expected 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. 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 have recognized approximately $159.5 million in net revenue from product sales of IBSRELA through June 30, 2024. We we began selling XPHOZAH in the U.S. in November 2023 and have recognized approximately $54.8 million in net revenue from product sales of XPHOZAH through June 30, 2024. 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 in subsequent periods. 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;
- when, and 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, and the amount of the

add-on any applicable TDAPA payment, available during the TDAPA period, and whether, and the extent to which, the ESRD PPS base rate is adjusted following any applicable TDAPA period, in the event that legislative, regulatory or judicial action is taken to delay but not ultimately prevent the inclusion of oral only drugs in the ESRD PPS; 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 or our and would materially and adversely impact sales of XPHOZAH, business, 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 business, and 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 paid for 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 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. In the event of 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. Should XPHOZAH be brought into the ESRD PPS bundle in 2025, or at any time, we may be unable to sell XPHOZAH to dialysis providers on a profitable basis. 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 (Lender) pursuant to which the Lender agreed to provide us with a loan facility for up to $50.0 million with a maturity date of March 1, 2027 Investment Corp. as collateral agent (Agent or SLR), and on August 1, 2022, February 9, 2023 and October 17, 2023, we entered into amendments to the loan and security agreement lenders listed in the 2022 Loan Agreement (collectively, the 2022 Lenders). The 2022 Loan Agreement) 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 March 1, 2024 October 29, 2024, respectively. In addition, subject to the Lender approval of its investment committee,

we may be able to draw up to an additional $50.0 million by December 31, 2026 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 December 31, 2026, with principal repayments commencing on January 1, 2027. 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 chronic kidney disease (CKD) 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") (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") 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 June 30, 2024 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**		
David Rosenbaum, Michael Raab, President and Chief Development Executive Officer	Adoption	May 17, 2024	X		179,564	January 31, 2025
Justin Renz, Chief Financial and Operations Officer	Adoption	May 22, 2024	X		127,041	December 30, 2024
Robert Blanks, Chief Regulatory Officer	Adoption	June September 4, 2024	X		339,501 500,000	January 13, 2025 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	6/24/2014	3.1	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	8-K	6/20/2023	3.1	
3.3	Amended and Restated Bylaws.	8-K	6/24/2014	3.2	
10.1#	Ardelyx, Inc. Amended and Restated 2014 Equity Incentive Award Plan.				X
10.2#	Ardelyx, Inc. Amended and Restated 2014 Employee Stock Purchase Plan.				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 June 30, 2024 and December 31, 2023, (ii) Condensed Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2024 and 2023, (iii) Condensed Statements of Changes in Stockholders Equity for the three and six months ended June 30, 2024 and 2023, (iv) Condensed Statements of Cash Flows for the six months ended June 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

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: August 1, 2024 October 31, 2024

By: /s/ Robert Felsch

Robert Felsch

Senior Vice President and Chief Accounting Officer

(Principal Accounting Officer)

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Exhibit 10.1 10.2

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

ARDELYX, INC.
AMENDED AND RESTATED 2014 EQUITY INCENTIVE AWARD PLAN Commercial Supply Agreement

ARTICLE 1.

PURPOSE

The purpose of the Ardelyx, Inc. Amended and Restated 2014 Equity Incentive Award Plan (as it may be amended from time to time, the THIS COMMERCIAL SUPPLY AGREEMENT (this "Plan Agreement") is to promote the success and enhance the value made as of Ardelyx, Inc. October 21, 2024 (the "Company Effective Date") by linking 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 individual interests "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 members of the Board, Employees, and Consultants to those of the Company's stockholders and by providing such individuals with an incentive for outstanding performance to generate superior returns to the Company's stockholders. The Plan is further intended to provide flexibility to the Company in its ability to motivate, attract, and retain the services of members of the Board, Employees, and Consultants upon whose judgment, interest, and special effort the successful conduct of the Company's operation is largely dependent. The Plan amends and restates the 2014 Equity Incentive Award Plan (the "Original 2014 Plan") in its entirety, subject to stockholder approval of this Plan at the annual meeting of the Company's stockholders in 2024. In the event the Company's stockholders fail to approve the Plan as set forth herein at the annual meeting of the Company's stockholders in 2024, then this Plan shall be deemed void *ab initio* foregoing and the Original 2014 Plan shall continue in effect in accordance with its terms.

ARTICLE 2.

DEFINITIONS AND CONSTRUCTION

Wherever covenants contained herein, the Parties hereto agree that the following provisions shall govern the performance of Services hereunder:

1. Definitions. The following terms are used in the Plan they shall have the meanings specified below, will, unless the context clearly indicates otherwise. The singular pronoun shall include otherwise requires, have the plural where the context so indicates. respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

2.1 1.1. "Administrator Adverse Supply Event" shall mean the entity that conducts the general administration of the Plan as provided in Article 12 hereof. With reference to the duties of the Administrator under the Plan which have been delegated to means one or more persons pursuant of the following: (i) Hovione is unable to Section 12.6 hereof, [***] that is required by [***], or as (ii) [***] orders a halt to which any further performance of the Board has assumed, the term "Administrator" shall refer to such person(s) unless the Committee or the Board has revoked such delegation or the Board has terminated the assumption of such duties. Manufacturing Services for a Product.

2.2 1.2. "Affiliate" shall mean any Parent or Subsidiary.

2.3 "Applicable Accounting Standards" shall mean Generally Accepted Accounting Principles in the United States, International Financial Reporting Standards or such other accounting principles or standards as may apply to the Company's financial statements under United States federal securities laws from time to time.

2.4 “Applicable Law” shall mean any applicable law, including without limitation, (i) provisions of the Code, the Securities Act, the Exchange Act and any rules or regulations

thereunder; (ii) corporate, securities, tax or other laws, statutes, rules, requirements or regulations, whether federal, state, local or foreign; and (iii) rules of any securities exchange or automated quotation system on means a business entity which, the Shares are listed, quoted or traded.

2.5 “Award” shall mean an Option, a Restricted Stock award, a Restricted Stock Unit award, a Performance Award, a Dividend Equivalents award, a Deferred Stock award, a Deferred Stock Unit award, a Stock Payment award or a Stock Appreciation Right, which may be awarded or granted under the Plan (collectively, “Awards”).

2.6 “Award Agreement” shall mean any written notice, agreement, terms and conditions, contract or other instrument or document evidencing an Award, including through electronic medium, which shall contain such terms and conditions with respect to an Award as the Administrator shall determine consistent with the Plan.

2.7 “Board” shall mean the Board of Directors of the Company.

2.8 “Change in Control” shall mean the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission) whereby any “person” or related “group” of “persons” (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its subsidiaries, an employee benefit plan maintained by the Company or any of its subsidiaries or a “person” that, prior to such transaction, directly or indirectly, controls, owns a controlling interest in a Party, is controlled by a Party, or is under common control with Party; where “control” means the Company) directly lawful right to determine (by ownership of shares or indirectly acquires beneficial ownership (within otherwise) the election of the majority of directors (or equivalent managers) of a business entity;

1.3. “Additional Services” has the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company’s securities outstanding immediately after such acquisition; or specified in Section 3.1;

(b) 1.4. During any period of two consecutive years, individuals who, at “Annual Commitment” has the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described meaning specified in Section 2.9(a) or 2.9(c)) whose election by the Board or nomination for election by the Company’s stockholders was approved by a vote of at least two-thirds of the Directors then still in office who either were Directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or 2.2;

(c) 1.5. The consummation by “API” means the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company’s assets active pharmaceutical ingredient tenapanor in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction: free base form;

(i) 1.6. which results "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 Company's voting 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 outstanding immediately before 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 transaction continuing to represent (either by remaining outstanding Manufacturing Services, or by being converted into voting securities within the Territory of the Company 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 person that, 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 result significant reduction in the market for the Product in a jurisdiction of the transaction, controls, directly or indirectly, Territory.

1.17. "cGMPs" means the Company or owns, directly or indirectly, all or substantially all 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 Company's assets or otherwise succeeds 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 business of the Company (the Company or such person, the "Successor Entity")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall efforts to be treated for purposes of this Section 2.9(c)(ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction; or

(d) The Company's stockholders approve a liquidation or dissolution of the Company.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event expended by either Party with respect to any portion 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 an Award that provides for Product, the deferral of compensation and is subject to Section 409A of the Code, the transaction or event described in subsection (a), (b), (c) or (d) with respect to such Award (or portion thereof) must also constitute a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5) to the extent required by Section 409A.

The Committee shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control of the Company has occurred pursuant to the above definition, and the scheduled date of the occurrence Hovione Release (by confirmation or certification, as agreed in the Quality Agreement) and made available for shipment [***], as confirmed by Hovione upon receipt of such Change 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 Control 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 incidental matters relating thereto; provided that any exercise other documents Specified in Appendix D of authority is in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation. the Quality Agreement;

2.9 1.50. "Code Manufacture" shall mean means performance of any Manufacturing Services.

1.51. "Manufacturing Services" means the Internal Revenue Code spray-drying and quality control, quality assurance, stability testing, packaging, and related services for the manufacture of 1986, 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, together with the regulations and official guidance promulgated thereunder, whether issued prior or subsequent to the grant of any Award. time;

2.10 1.64. "Committee Recall" shall mean has the Compensation Committee of the Board, a subcommittee of the Compensation Committee of the Board or another committee or subcommittee of the Board, appointed as provided meaning specified in Section 12.1 hereof. 6.7;

2.11 1.65. "Common Stock Recipient" shall mean has the common stock of the Company, par value $0.0001 per share. meaning specified in Section 12.1;

2.12 1.66. "Company Regulatory Approval" shall have 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 Article 1 hereof. Appendix B to the Quality Agreement;

2.13 1.71. "Consultant Supply Failure" shall mean any consultant means (a) Hovione's Manufacture of [***] Batches of Deficient Product, or advisor engaged (b) with respect to provide services Product scheduled for Delivery pursuant to the Company Firm Orders during [***], a failure by Hovione to deliver to Ardelyx or any Affiliate who qualifies as a consultant or advisor under its designee at least [***] within [***] of the applicable rules scheduled Delivery Dates, absent [***], *provided, however*, that in the case of the Securities and Exchange Commission for registration of shares on a Form S-8 Registration Statement or any successor Form thereto. [***]. A Supply Failure may result from [***]. The Parties acknowledge that [***].

2.14 1.72. "Deferred Stock Term" shall mean a right to receive Shares awarded means the Initial Term and any and all renewal terms applicable under Section 9.4 hereof. 8.1;

2.15 1.73. "Deferred Stock Unit Territory" shall mean a right to receive Shares awarded under Section 9.5 hereof. means [***];

2.16 1.74. "Director Third Party Claim" shall mean a member of has the Board, as constituted from time to time. meaning specified in Section 11.1;

2.17 1.75. "Dividend Equivalent Third Party Subcontractors" shall mean a right to receive has the equivalent value (in cash or Shares) of dividends paid on Shares, awarded under meaning specified in Section 9.2 hereof. 2.8;

2.18 1.76. "DRO Third Party Rights" shall mean a "domestic relations order" as defined by means the Code or Title I Intellectual Property of the Employee Retirement Income Security Act of 1974, as amended from time to time, or the rules thereunder. any third party;

2.19 1.77. "Effective Date Work Order" shall have has the meaning set forth in Section 13.1. 3.1 and

2.20 1.78. "Eligible Individual Year" shall mean any person who is an Employee, a Consultant or a Non-Employee Director, as determined by means in the Administrator.

2.21 "Employee" shall mean any officer or other employee (as determined in accordance with Section 3401(c) first year of this Agreement, the time from the Effective Date up to and including December 31 of the Code same calendar year, and after that will mean a calendar year, except for in the Treasury Regulations thereunder) case of the Company calendar year in which this Agreement is terminated or any Affiliate.

2.22 "Equity Restructuring" shall mean a nonreciprocal transaction between expires, in which case the Company and its stockholders, such as a stock dividend, stock split, spin-off, rights offering or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other securities of the Company) or the share price of Common Stock (or other securities) and causes a change in the per share value of the Common Stock underlying outstanding stock-based Awards.

2.23 "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

2.24 "Fair Market Value" shall mean, as of any given date, the value of a Share determined as follows:

(a) If the Common Stock is (i) listed on any established securities exchange (such as the New York Stock Exchange, the Nasdaq Capital Market, Nasdaq Global Market and the Nasdaq Global Select Market), (ii) listed on any national market system or (iii) listed, quoted or traded on any automated quotation system, its Fair Market Value shall Year will be the closing sales price for a Share as quoted date beginning on such exchange or system for such date or, if there is no closing

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sales price for a Share January 1 of that Year and ending on the date in question, the closing sales price for a Share on the last preceding date for which such quotation exists, as reported in The Wall Street Journal or such other source as the Administrator deems reliable;

(b) If the Common Stock is not listed on an established securities exchange, national market system or automated quotation system, but the Common Stock is regularly quoted by a recognized securities dealer, its Fair Market Value shall be the mean of the high bid and low asked prices for such date or, if there are no high bid and low asked prices for a Share on such date, the high bid and low asked prices for a Share on the

last preceding date for which such information exists, as reported in The Wall Street Journal or such other source as the Administrator deems reliable; or

(c) If the Common Stock is neither listed on an established securities exchange, national market system or automated quotation system nor regularly quoted by a recognized securities dealer, its Fair Market Value shall be established by the Administrator in good faith.

2.25 "Greater Than 10% Stockholder" shall mean an individual then owning (within the meaning effective termination of Section 424(d) of the Code) more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any "parent corporation" or "subsidiary corporation" (as defined in Sections 424(e) and 424(f) of the Code, respectively).

2.26 "Holder" shall mean a person who has been granted an Award.

2.27 "Incentive Stock Option" shall mean an Option that is intended to qualify as an incentive stock option and conforms to the applicable provisions of Section 422 of the Code.

2.28 "Non-Employee Director" shall mean a Director of the Company who is not an Employee.

2.29 "Non-Employee Director Equity Compensation Policy" shall have the meaning set forth in Section 4.6 hereof.

2.30 "Non-Qualified Stock Option" shall mean an Option that is not an Incentive Stock Option or which is designated as an Incentive Stock Option but does not meet the applicable requirements of Section 422 of the Code.

2.31 "Option" shall mean a right to purchase Shares at a specified exercise price, granted under Article 5 hereof. An Option shall be either a Non-Qualified Stock Option or an Incentive Stock Option; provided, however, that Options granted to Non-Employee Directors and Consultants shall only be Non-Qualified Stock Options.

2.32 "Option Term" shall have the meaning set forth in Section 5.4 hereof.

2.33 "Original 2014 Plan" shall have the meaning set forth in Article 1 hereof. this Agreement.

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2.34 2. " Manufacturing Services

2.1. Parent Performance Standard". Hovione shall mean any entity (other than perform the Company), whether domestic or foreign, Manufacturing Services in an unbroken chain of entities ending accordance with the Company if each Processing Instructions and supply Product manufactured in accordance with the Specifications, for the Price, in accordance with the material provisions of the entities other than Quality Agreement, Applicable Law, cGMP and the Company beneficially owns, at 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 of to time during the determination, securities or interests representing more than fifty percent (50%) of Term and by mutual agreement between the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.35 "Performance Award" shall mean a cash bonus award, stock bonus award, performance award or incentive award that is paid in cash, Shares or a combination of both, awarded under Section 9.1 hereof.

2.36 "Performance Stock Unit" shall mean a Performance Award awarded under Section 9.1 hereof which is denominated in units of value including dollar value of shares of Common Stock.

2.37 "Permitted Transferee" shall mean, with respect to a Holder, any "family member" of the Holder, as defined under the General Instructions to Form S-8 Registration Statement under the Securities Act or any successor Form thereto, or Parties, Ardelyx may request any other transferee specifically approved by the Administrator, after taking into account Applicable Law.

2.38 "Plan" related Manufacturing Services, excluding any Development Services which shall have the meaning set forth in Article 1 hereof.

2.39 "Prior Plan" shall mean the Ardelyx, Inc. 2016 Employment Commencement Incentive Plan.

2.40 "Program" shall mean any program adopted by the Administrator pursuant to the Plan containing the terms and conditions intended to govern a specified type of Award granted under the Plan and pursuant to which such type of Award may be granted under the Plan.

2.41 "Restricted Stock" shall mean an award of Shares made under Article 7 hereof that is subject to certain restrictions and may be subject to risk of forfeiture or repurchase. the Development Agreement, and such additional Manufacturing Services shall be charged separately as may be agreed by and between the Parties.

2.42 2.2. " Annual CommitmentRestricted Stock Unit .

(a) " shall mean a contractual right awarded under Article 8 hereof Conditional upon Ardelyx's timely payments as required in accordance with the Equipment Agreement and beginning in Year 2024, subject to receive 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 future a Share 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 Fair Market Value of a Share 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 cash.

2.43 "Securities Act" shall mean the Securities Act of 1933, as amended.

2.44 "Shares" shall mean shares of Common Stock.

2.45 "Share Limit" shall have the meaning set forth relevant Purchase Orders) in Section 3.1(a) hereof.

2.46 "Stock Appreciation Right" shall mean a stock appreciation right granted under Article 10 hereof.

2.47 "Stock Appreciation Right Term" shall have the meaning set forth in Section 10.4 hereof. such Year.

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2.48 (c) "Stock Payment" 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 mean (a) a payment in the form remain at [***] until completion of Shares, or (b) an option or other right to purchase Shares, as part of a bonus, deferred compensation or other arrangement, awarded under Section 9.3 hereof. Scale-Up, at which time [***].

2.49 2.3. "Existing Orders Subsidiary". 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 mean any entity (other than govern the Company), whether domestic or foreign, in an unbroken chain Manufacture of entities beginning 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 the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing more than fifty percent (50%) of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.50 "Substitute Award" shall mean an Award granted under the Plan upon the assumption of, or in substitution for, outstanding equity awards previously granted by a company or other entity in connection with a corporate transaction, such as a merger, combination, consolidation or acquisition of property or stock; provided, however, that in no event shall the term "Substitute Award" be construed to refer to an award made in connection with the cancellation and repricing of an Option or Stock Appreciation Right.

2.51 "Termination of Service" shall mean:

(a) As to a Consultant, the time when the engagement of a Holder as a Consultant to the Company or an Affiliate is terminated for any reason, with or without cause, including, without limitation, by resignation, discharge, death or retirement, but excluding terminations where the Consultant simultaneously commences or remains in employment or service with the Company or any Affiliate.

(b) As to a Non-Employee Director, the time when a Holder who is a Non-Employee Director ceases to be a Director for any reason, including, without limitation, a termination by resignation, failure to be elected, death or retirement, but excluding terminations where the Holder simultaneously commences or remains in employment or service with the Company or any Affiliate.

(c) As to an Employee, the time when the employee-employer relationship between a Holder and the Company or any Affiliate is terminated for any reason, including, without limitation, a termination by resignation, discharge, death, disability or retirement; but excluding terminations where the Holder simultaneously commences or remains in employment or service with the Company or any Affiliate.

◦ The Administrator, in its sole discretion, shall determine the effect of all matters and questions relating to Terminations of Service, Product itself, including without limitation the question of whether a Termination of Service resulted from a discharge Product Warranties set forth in Section 9.2.3. Thereafter, this Agreement shall govern any such order for cause Product Manufacturing placed and all questions of whether particular leaves of absence constitute a Termination of Service; not yet delivered for the Year 2024.

2.4. provided, however, that, [***]. So long as Ardelyx is otherwise in substantial compliance with respect to Incentive Stock Options, unless the Administrator otherwise provides in the terms of this Agreement, including without limitation, the Program, Annual Commitment obligations hereunder, Hovione will not at any time during the Award 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 a leave 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 absence, change in status Product from Hovione Portugal, at least sufficient to retain the Hovione Portugal facility as an employee to an independent contractor or other change alternative supplier's site in the employee-employer relationship applicable regulatory filing for Product. Ardelyx shall constitute 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 Termination of Service only if, and to the extent that, such leave of third party,

absence, change in status or other change interrupts employment entering into any contract with any third party for the purposes supply of Section 422(a)(2) 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 Code 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 then applicable regulations respective allocation of benefits arising therefrom, to the extent the proposed changes improve the cost and/or efficiency of Manufacturing Services and revenue rulings under said Section.

▪ For purposes of (b) [***]. Hovione will not undertake or permit any modifications to the Plan, a Holder's employee-employer relationship Manufacturing Site that materially affect the Product or consultancy relations shall be deemed 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 terminated 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 the Affiliate employing or contracting with such Holder ceases to remain an Affiliate following any merger, sale of stock or other corporate transaction or event (including, without limitation, a spin-off).

ARTICLE 3.

SHARES SUBJECT TO THE PLAN

1.1 Number of Shares.

(a) Subject to Sections 13.1, 13.2 and 3.1(b) hereof, the aggregate number of Shares which may be issued or transferred pursuant to Awards under the Plan is (i) 58,457,566 and (ii) any of the 6,500,000 Shares which as of the Effective Date are Component becomes subject to awards under purchase lead time beyond the Prior Plan that, on Binding Forecast time frame, or after Hovione is otherwise unable to obtain, in a timely manner, a particular Component necessary for Manufacturing, the Effective Date, terminate, expire Parties will negotiate in good faith an appropriate amendment to this Agreement and will cooperate to reduce or lapse for eliminate any reason without supply problems from the delivery of Shares to the holder thereof or for which the Shares are forfeited or repurchased for the original purchase prices thereof (the "Share Limit"). Notwithstanding anything in this Section 3.1 to the contrary, the number of shares of Stock that may be issued or transferred pursuant to Incentive Stock Options under the Plan shall not exceed an aggregate of 58,457,566 Shares, subject to adjustment pursuant to Section 13.2. Notwithstanding the foregoing, Shares added to the Share Limit pursuant to Section 3.1(a)(ii) or Section 3.1(a)(iii) hereof shall be available for issuance as Incentive Stock Options only to the extent that making such Shares available for issuance as Incentive Stock Options would not cause any Incentive Stock Option to cease to qualify as such. Notwithstanding the foregoing, to the extent permitted under Applicable Law, Awards that provide for the delivery of Shares subsequent to the applicable grant date may be granted in excess of the Share Limit if such Awards provide for the forfeiture or cash settlement of such Awards to the extent that insufficient Shares remain under the Share Limit in this Section 3.1 at the time that Shares would otherwise be issued in respect of such Award.

(b) If any Shares subject to an Award are forfeited or expire or such Award is settled for cash (in whole or in part), the Shares subject to such Award shall, to the extent of such forfeiture, expiration or cash settlement, again be available for future grants of Awards under the Plan and shall be added back to the Share Limit. Any Shares repurchased by the Company pursuant to Section 7.4 hereof at the same price paid by the Holder or a lower price so that such Shares are returned to the Company shall again be available for the grant of an Award pursuant to the Plan and shall be added back to the Share Limit. Notwithstanding anything to the contrary contained herein, the following Shares shall not be added to the Shares authorized for grant under Section 3.1(a) hereof and shall not be available for future grants of Awards: (i) Shares tendered by a Holder or withheld by the Company in payment of the exercise price of an Option; (ii) Shares tendered by the Holder or withheld by the Company to satisfy any tax withholding obligation with respect to an Award; (iii) Shares subject to Stock Appreciation Rights that are not issued in connection with the stock settlement of the Stock Appreciation Rights on exercise suppliers.

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thereof; and (iv) Shares purchased on the open market by the Company with the cash proceeds from the exercise Options. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards shall not be counted against the Shares available for issuance under the Plan. Notwithstanding the provisions of this Section 3.1(b), no Shares may again be optioned, granted or awarded if such action would cause an Incentive Stock Option to fail to qualify as an incentive stock option under Section 422 of the Code.

(c) 38 Substitute Awards shall not reduce the Shares authorized for grant under the Plan and Shares subject to such Substitute Awards shall not be added back to the Shares available for Awards under the Plan as provided in Section 3.1(b) above. Additionally, in the event that a company acquired by the Company or any Affiliate or with which the Company or any Affiliate combines has shares available under a pre-existing plan approved by its stockholders and not adopted in contemplation of such acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not reduce the Shares authorized for grant under the Plan (and Shares subject to such Awards shall not be added to the Shares available for Awards under the Plan as provided in Section 3.1(b) above); provided that Awards using such available Shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination and shall only be made to individuals who were not employed by or providing services to the Company or its Affiliates immediately prior to such acquisition or combination.

3.1 Stock Distributed. Any Shares distributed pursuant to an Award may consist, in whole or in part, of authorized and unissued Common Stock, treasury Common Stock or Common Stock purchased on the open market.

3.2 Limitation on Number of Shares Subject to Awards to Non-Employee Directors. The maximum aggregate value of Awards (with such value determined as of the date of grant under Applicable Accounting Standards) that may be granted to any Non-Employee Director during any calendar year shall be $1,000,000.

ARTICLE 4.

GRANTING OF AWARDS

4.1 Participation. The Administrator may, from time to time, select from among all Eligible Individuals, those to whom an Award shall be granted and shall determine the nature and amount of each Award, which shall not be inconsistent with the requirements of the Plan. Except as provided in Section 4.6 hereof regarding the grant of Awards pursuant to the Non-Employee Director Equity Compensation Policy, no Eligible Individual shall have any right to be granted an Award pursuant to the Plan.

4.2 2.11. Award Agreement Packaging. Each Award 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 evidenced subject to the Development Agreement ("Additional Services"), as specified in a written work order signed by an Award Agreement that sets forth 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 conditions and limitations for such Award, which may include the term of the Award, the provisions this Agreement (including any deviations of applicable in the event of the Holder's Termination of Service, and the Company's authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind an Award. Award Agreements evidencing Incentive Stock Options shall contain such terms and conditions as may be necessary to meet contained on any such Work Order) and such Additional Services shall be charged separately as may be agreed by and between the applicable provisions of Section 422 of the Code. Parties on such Work Order.

4.3 3.2. Limitations Applicable to Section 16 Persons Change Control Requests. Notwithstanding Ardelyx and Hovione will cooperate on any other provision of requested changes to the Plan, Processing Instructions, Specifications or accompanying documents (a "Product Change Control Request") in accordance with the Plan, and any Award granted or awarded to any individual who is then subject to Section 16 of the Exchange Act, shall be subject to any additional limitations change control process set forth in any applicable exemptive rule under Section 16 the Quality Agreement. Upon acceptance of the Exchange Act (including Rule 16b-3 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 Exchange Act 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 amendments thereto) that are requirements 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 exemptive rule. To ten (10) Batches. Thereafter, Hovione shall ensure that, on an annual basis, the extent permitted Product Yield complies with [***] (the "[***]"). Parties acknowledge and agree that the [***] shall contain an allowed statistical deviation, as agreed by Applicable Law, the Plan Parties, which may change during the Term as more Batches of Product are manufactured and Awards granted or awarded hereunder 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 deemed amended 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 extent necessary Parties agree that the [***] and annual revision calculation shall be based only on Batches of Product released to conform Ardelyx in accordance with the Quality Agreement and shall not include Batches containing Deficient Product, whether or not the Deficient Product was released to such applicable exemptive rule. Ardelyx.

4.4 (ii) At-Will Employment; Voluntary Participation. Nothing in the Plan or in any Program or Award Agreement hereunder shall confer upon any Holder any right to continue in the employ of, or as a Director or Consultant for, the Company or any Affiliate, or shall interfere with or

restrict in any way the rights of the Company and any Affiliate, which rights are hereby expressly reserved, to discharge any Holder at any time for any reason whatsoever, with or without cause, and with or without notice, or to terminate or change all other terms and conditions of employment or engagement, except to the extent expressly provided otherwise in a written agreement between the Holder and the Company or any Affiliate. Participation by each Holder in the Plan shall be voluntary and nothing in the Plan shall be construed as mandating that any Eligible Individual shall participate in the Plan.

4.5 Foreign Holders. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws in countries other than the United States in which the Company and its Affiliates operate or have Employees, Non-Employee Directors or Consultants, or in order to comply with the requirements of any foreign securities exchange, the Administrator, in its sole discretion, Hovione shall have the power 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 authority to: (a) determine which Affiliates 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 covered by the Plan; (b) determine which Eligible Individuals outside the United States are eligible to participate carried forward as a

credit in the Plan; (c) modify 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 Award granted change to Eligible Individuals outside the United States scope of the Manufacturing Services as set forth in Section 3.2, the corresponding Change Order will set forth any adjustments to comply with applicable foreign laws 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 listing requirements value added tax, duty, custom, inspection or testing fee, or any other tax, fee or charge of any such foreign securities exchange; (d) establish subplans nature whatsoever imposed by any governmental authority on or measured by the transactions contemplated hereunder between Hovione and modify exercise procedures and other terms and procedures, Ardelyx (other than Hovione's income tax), will be paid by Ardelyx in addition to the extent Price. In the event Hovione is required to pay any such actions 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 be necessary provide Hovione at the time an order is submitted an exemption certificate or advisable (any such subplans and/or modifications shall be attached other document acceptable to the Plan as appendices); authority imposing the tax, fee or charge.

4.5. provided Efforts to Achieve Price Reductions, however, that no such subplans and/. 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 modifications shall

increase other extraordinary costs being incurred by any party without the share limitations contained in Sections 3.1 and 3.3 hereof; and (e) take any action, before or after an Award is made, that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals or listing requirements prior written consent of any such foreign securities exchange. Notwithstanding the foregoing, other party. To the Administrator may not take any actions hereunder, and no Awards shall be granted, that would violate extent successful, the Code, the Exchange Act, the Securities Act, any other securities law or governing statute, the rules of

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parties shall discuss and negotiate in good faith the securities exchange or automated quotation system on which allocation of costs savings resulting from this cost reduction program.

5. Purchasing Product

5.1. Forecasts. Within thirty (30) days after the Shares are listed, quoted or traded or any other Applicable Law. For purposes Effective Date, Ardelyx will deliver to Hovione a written forecast of the Plan, all references volume of Product that Ardelyx expects to foreign laws, rules, regulations or taxes shall be references to order from Hovione in each of the laws, rules, regulations and taxes of any applicable jurisdiction other than the United States or a political subdivision thereof.

4.6 Non-Employee Director Awards. The Administrator may, in its discretion, provide that Awards granted to Non-Employee Directors shall be granted pursuant to a written non-discretionary formula established by the Administrator next [***] (the "Non-Employee Director Equity Compensation Policy Forecast"). The first [***] of each Forecast will be binding on the Parties (the "Binding Forecast") and the remaining [***] will be [***], subject to good faith estimates that may be increased or decreased by no more than [***] percent ([***]%) during the limitations entire period from such month's first appearance on the Forecast until such month becomes part of the Plan. The Non-Employee Director Equity Compensation Policy shall set forth the type of Award(s) to be granted to Non-Employee Directors, the number of Shares to be subject to Non-Employee Director Awards, the conditions on which such Awards shall be granted, become exercisable and/ Binding Forecast or payable and expire, and such other terms and conditions as the Administrator shall determine in its discretion. The Non-Employee Director Equity Compensation Policy may be modified otherwise agreed by the Administrator from time to time in its discretion.

4.7 Parties (the "Stand-Alone and Tandem Awards Non-binding Forecast"). Awards granted pursuant to the Plan may, in the sole discretion of the Administrator, be granted either alone, in addition to, or in tandem with, any other Award granted pursuant to the Plan. Awards granted in addition to or in tandem with other Awards may be granted either Ardelyx will provide an updated Forecast at the same time as or at a different time from the grant of such other Awards.

ARTICLE 5.

GRANTING OF OPTIONS

5.1 Granting of Options to Eligible Individuals. The Administrator is authorized to grant Options to Eligible Individuals from time to time, in its sole discretion, on such terms and conditions as it may determine which shall not be inconsistent with the Plan.

5.2 Qualification of Incentive Stock Options. No Incentive Stock Option shall be granted to any person who is not an Employee of the Company or any subsidiary corporation (as defined in Section 424(f) of the Code) of the Company. No person who qualifies as a Greater Than 10% Stockholder may be granted an Incentive Stock Option unless such Incentive Stock Option conforms to the applicable provisions of Section 422 of the Code. Any Incentive Stock Option granted under the Plan may be modified by the Administrator, with the consent of the Holder, to disqualify such Option from treatment as an "incentive stock option" under Section 422 of the Code. least quarterly. To the extent that any updated portion of a Forecast exceeds the aggregate fair market value 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 stock with 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 to which “incentive stock options” (within of Year 2025, and each Year throughout the meaning of Section 422 remainder of the Code, 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 without regard Hovione expressly reserves the right to Section 422(d) 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 Code) are exercisable 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 first time by a Holder during applicable Batch in writing. If Ardelyx identifies any calendar year under deficiency with the Plan, and all other plans Manufacturing Records it should provide prompt notice to Hovione which shall occur no later than [***] after receipt of the Company complete Certificate of Analysis and any subsidiary or parent corporation thereof (each as defined in Section 424(f) and (e) of the Code, respectively), exceeds $100,000, the Options shall be treated as Non-Qualified Stock Options to the extent required by Section 422 of the Code. completed Manufacturing Records. The rule [***] period set forth in the preceding sentence shall be applied by taking Options and other “incentive stock options” into account in tolled until Hovione has delivered the order in which they were granted and the Fair Market Value of stock shall be determined as of complete Manufacturing Records (*i.e.* the time between the respective options were

granted. In addition, to the extent that any Options otherwise fail to qualify as Incentive Stock Options, such Options shall be treated as Nonqualified Stock Options.

5.3 Option Exercise Price. Except as provided in Article 13 hereof, the exercise price per Share subject to each Option shall be set by the Administrator, but shall not be less than one hundred percent (100%) of the Fair Market Value notice from Ardelyx of a Share on the date the Option is granted (or, as to Incentive Stock Options, on the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code). In addition, in the case of Incentive Stock Options granted to a Greater Than 10% Stockholder, such price shall not be less than one hundred ten percent (110%) of the Fair Market Value of a Share on the date the Option is granted (or the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code).

5.4 Option Term. The term of each Option (the "Option Term") shall be set by the Administrator in its sole discretion; provided, however, that the Option Term shall not be more than ten (10) years from the date the Option is granted, or five (5) years from the date an Incentive Stock Option is granted to a Greater Than 10% Stockholder. The Administrator shall determine the time period, including the time period following a Termination of Service, during which the Holder has the right to exercise the vested Options, which time period may not extend beyond the last day of the Option Term. Except as limited by the requirements of Section 409A or Section 422 of the Code deficient Manufacturing Batch and regulations and rulings thereunder, the Administrator may extend the Option Term of any outstanding Option, may extend the time period during which vested Options may be exercised following any Termination of Service of the Holder, and may amend any other term or condition of such Option relating to such a Termination of Service.

5.5 Option Vesting.

(a) The period during which the right to exercise, in whole or in part, an Option vests in the Holder shall be set by the Administrator and the Administrator may determine that an Option may not be exercised in whole or in part for a specified period after it is granted. Such vesting may be based on service with the Company or any Affiliate, any performance criteria, or any other criteria selected by the Administrator. At any time after the grant of an Option, the Administrator may, in its sole discretion and subject to whatever terms and conditions it selects, accelerate the vesting of the Option, including following a Termination of Service; provided, that in no event shall an Option become exercisable following its expiration, termination or forfeiture.

(b) No portion of an Option which is unexercisable at a Holder's Termination of Service shall thereafter become exercisable, except as may be otherwise provided by the Administrator either in the Program, the Award Agreement or by action of the Administrator following the grant of the Option.

5.6 Substitute Awards. Notwithstanding the foregoing provisions of this Article 5 to the contrary, in the case of an Option that is a Substitute Award, the price per share of the shares subject to such Option may be less than the Fair Market Value per share on the date of grant; provided that the excess of: (a) the aggregate Fair Market Value (as reissuance of the date such Substitute Award is granted) complete Manufacturing Records to Ardelyx will not be included in calculating the [***] period set forth above). Hovione shall retain copies of the shares subject to Manufacturing Records for such period set forth in the Substitute Award, over (b) the aggregate exercise

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price thereof does not exceed the excess of: (x) the aggregate fair market value (as Quality Agreement. Upon Ardelyx's approval of the time immediately preceding Manufacturing Records of at least [***] Batches, Hovione shall make available for Delivery the transaction giving rise respective Batches of Product to Ardelyx or its designee in accordance with the Substitute Award, such fair market value 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 determined [***] 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 Administrator) name and address of the shares of recipient and the predecessor entity that were subject 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 grant assumed Specifications or substituted Processing Instructions (other than for confirmatory testing required by downstream manufacturers), then the Company, over (y) the aggregate exercise price cost of such shares.

5.7 Substitution of Stock Appreciation Rights. The Administrator may provide in the applicable Program special handling, packaging or the Award Agreement evidencing the grant of an Option that the Administrator, in its sole discretion, shall have the right services will be borne entirely by

Ardelyx at Hovione's prevailing rates. Ardelyx will use Commercially Reasonable Efforts to substitute a Stock Appreciation Right for such Option at any time prior to or upon exercise of such Option; provided that such Stock Appreciation Right shall be exercisable with respect to the same number of Shares for which such substituted Option would have been exercisable, and shall also have the same exercise price, vesting schedule and remaining Option Term as the substituted Option.

ARTICLE 6.

EXERCISE OF OPTIONS

6.1 Partial Exercise. An exercisable Option may be exercised in whole or in part. However, an Option shall not be exercisable with respect to fractional Shares and the Administrator may require that, by the terms of the Option, a partial exercise must be with respect to a minimum number of Shares.

6.2 Manner of Exercise. All or a portion of an exercisable Option shall be deemed exercised upon take delivery of all of Product within [***] after the following Delivery Date. Thereafter, Hovione will store Product for up to the Secretary of the Company, or such other person or entity designated by the Administrator, or his, her or its office, as applicable:

(a) A written or electronic notice complying with the applicable rules established by the Administrator stating that the Option, or a portion thereof, is exercised. The notice shall be signed by the Holder or other person then entitled [***], subject to exercise the Option or such portion of the Option;

(b) Such representations and documents as the Administrator, in its sole discretion, deems necessary or advisable to effect compliance with all Applicable Law. The Administrator may, in its sole discretion, also take whatever additional actions it deems appropriate to effect such compliance including, without limitation, placing legends on share certificates and issuing stop-transfer notices to agents and registrars;

(c) In the event that the Option shall be exercised pursuant to Section 11.3 hereof by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Option, as determined in the sole discretion of the Administrator; and

(d) Full payment of the exercise price and applicable withholding taxes to the stock administrator of the Company for the shares with respect to which the Option, or portion thereof, is exercised, in a manner permitted by Section 11.1 and 11.2 hereof. storage fees at Hovione's prevailing rates.

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6.3 5.6. Notification Regarding Disposition Invoices and Payment. The Holder shall give the Company prompt written or electronic notice of any disposition of Shares acquired by exercise of an Incentive Stock Option which occurs within (a) two (2) years from the date of granting (including the date the Option is modified, extended or renewed for purposes of Section 424(h) of the Code) of such Option to such Holder, or (b) one (1) year after the transfer of such shares to such Holder.

ARTICLE 7.

AWARD OF RESTRICTED STOCK

7.1 Award of Restricted Stock.

(a) The Administrator is authorized to grant Restricted Stock to Eligible Individuals, Hovione will issue and shall determine the terms and conditions, including the restrictions applicable to each award of Restricted Stock, which terms and conditions shall not be inconsistent with the Plan, and may impose such conditions on the issuance of such Restricted Stock as it deems appropriate.

(b) The Administrator shall establish the purchase price, if any, and form of payment for Restricted Stock; provided, however, that if a purchase price is charged, such purchase price shall be no less than the par value, if any, of the Shares to be purchased, unless otherwise permitted

by Applicable Law. In all cases, legal consideration shall be required deliver its invoice for each issuance delivery of Restricted Stock to the extent required by Applicable Law.

7.2 Rights as Stockholders. Subject to Section 7.4 hereof, Product upon issuance of Restricted Stock, the Holder shall have, unless otherwise provided by the Administrator, all the rights of a stockholder with respect to said Shares, subject to the restrictions in the applicable Program or in each individual Award Agreement, including the right to receive all dividends and other distributions paid or made with respect to the Shares; provided, however, that, in the sole discretion of the Administrator, any extraordinary distributions with respect to the Shares shall be subject to the restrictions Hovione Release as set forth in Section 7.3 hereof. 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.

7.3 6. Restrictions Product Rejection and Recalls

6.1. Acceptance. All shares Within [***] following Ardelyx's receipt of Restricted Stock (including 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 shares received by Holders thereof with 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 shares of Restricted Stock as a result of stock dividends, stock splits or any other form of recapitalization) shall, Product Rejection relating to Deficient Product that (i) [***] ("[***]"), Ardelyx will in all cases give written notice within [***] after the terms Delivery Date of the applicable Program 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 each individual Award Agreement, be subject to such restrictions and vesting requirements as writing within [***] of its receipt of the Administrator shall provide. Such restrictions may include, without limitation, restrictions concerning voting rights and transferability and such restrictions may lapse separately or in combination at such times and pursuant to such circumstances or based on such criteria as selected by the Administrator, including, without limitation, criteria based on the Holder's duration of employment, directorship or consultancy rejection notice that it disagrees with the Company, Company or Affiliate performance, individual performance or other criteria selected by basis for rejection. In the Administrator. By action taken after event Hovione and Ardelyx are unable to agree as to whether the Restricted Stock is issued, the Administrator may, on such terms and conditions as it may determine to be appropriate, accelerate the vesting Product has been appropriately rejected, [***]. The conclusion of such Restricted Stock by removing 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 all of (ii) Deficient Product is otherwise due to Ardelyx's Fault, then Hovione shall promptly [***]. If the restrictions imposed by the terms of the Program and/or the Award Agreement. Restricted Stock may Parties determine that replacement can not be sold done through reprocessing or encumbered until all restrictions are

terminated 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 expire. (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

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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

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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 respect 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 share of Restricted Stock, dividends which are paid prior 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 vesting shall only Section 10.3, under no circumstances whatsoever will either Party be paid out liable to the Participant 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 share Third Party Claim is the direct result of Restricted Stock vests. (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.

7.4 11.2. Repurchase or Forfeiture of Restricted Stock Ardelyx Indemnity. Except 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 otherwise determined 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 Administrator 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 grant 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 Award Confidential Information, which precautions will not be less than those exercised by Recipient for its own confidential or thereafter, if 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 price was paid by 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 Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Holder's rights license grants set forth in unvested Restricted Stock then subject to restrictions shall lapse, Section 13.6.2 and such Restricted Stock right shall be surrendered to the Company survive termination of this Agreement, and cancelled without consideration. If a price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Company Ardelyx shall have the right to repurchase from disclose [***]. Each Party, in its capacity as a Recipient, will be liable for the Holder acts and failures to act by its respective Representatives for the unvested Restricted Stock then subject to restrictions at a cash price per share equal 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 price paid extent required, as advised by the Holder for such Restricted Stock or such other amount as may be specified counsel, in the Program or the Award Agreement. Notwithstanding the foregoing, the Administrator in its sole discretion may provide that in the event response to a valid order of certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service or any other event, the Holder's rights in unvested Restricted Stock shall not lapse, such Restricted Stock shall vest and, if applicable, the Company shall not have a right of repurchase.

7.5 Certificates for Restricted Stock. Restricted Stock granted pursuant to the Plan may be evidenced in such manner as the Administrator shall determine. Certificates or book entries evidencing shares of Restricted Stock must include an appropriate legend referring to the terms, conditions, and restrictions applicable to such Restricted Stock. The Company may, in its sole discretion, (a) retain physical possession of any stock certificate evidencing shares of Restricted Stock until the restrictions thereon shall have lapsed and/or (b) require that the stock certificates evidencing shares of Restricted Stock be held in custody by a designated escrow agent (which may but need not be the Company) until the restrictions thereon shall have lapsed, and that the Holder deliver a stock power, endorsed in blank, relating to such Restricted Stock.

7.6 Section 83(b) Election. If a Holder makes an election under Section 83(b) of the Code to be taxed with respect to the Restricted Stock as of the date of transfer of the Restricted Stock rather than as of the date or dates upon which the Holder would otherwise be taxable under Section 83(a) of the Code, the Holder shall be required to deliver a copy of such election to the Company promptly after filing such election with the Internal Revenue Service.

ARTICLE 8.
AWARD OF RESTRICTED STOCK UNITS

8.1 Grant of Restricted Stock Units. The Administrator is authorized to grant Awards of Restricted Stock Units to any Eligible Individual selected by the Administrator in such amounts and subject to such terms and conditions as determined by the Administrator.

8.2 Term. Except as otherwise provided herein, the term of a Restricted Stock Unit award shall be set by the Administrator in its sole discretion.

8.3 Purchase Price. The Administrator shall specify court or other governmental body, or as required by law, regulation or stock exchange rule applicable to it; provided that, to the purchase price, if any, extent lawful, the Recipient will (a) advise the Discloser in advance of the disclosure and (b) limit the required disclosure to be paid the extent practicable and permissible by the Holder 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 the Company perform its obligations under this Section 12 with respect to information so disclosed. If any Restricted Stock Unit award; public disclosure is required by law, the Parties will consult concerning the form of announcement prior to the public disclosure being made.

12.5. provided Return of Confidential Information, however, that value. Upon the written request of the consideration shall not be less than Discloser or termination of the par value Agreement pursuant to Section 8, the Recipient will promptly return or destroy the Confidential Information of a Share, unless otherwise permitted by Applicable Law.

8.4 Vesting of Restricted Stock Units. At the time of grant, the Administrator shall specify the date or dates on which the Restricted Stock Units shall become fully vested and nonforfeitable, and may specify such conditions to vesting Discloser, as it deems appropriate, including, without limitation, vesting based upon the Holder's duration of service to the Company or any Affiliate, Company performance, individual performance or other specific criteria, in each case on a specified date or dates or over any period or periods, as determined directed by the Administrator.

8.5 Maturity and Payment. At the time of grant, the Administrator shall specify the maturity date applicable to each grant of Restricted Stock Units Discloser, except for one copy which shall be no earlier than the vesting date or dates of the Award and may be determined at the election of the Holder (if permitted maintained by the applicable Award Agreement); provided that, except as otherwise determined by the Administrator, set forth in any applicable Award Agreement, and subject to compliance with Section 409A of the Code, in no event shall the maturity date relating to each Restricted Stock Unit occur following the later of (a) the fifteenth (15th) day of the third (3rd) month following the end of calendar year in which the Restricted Stock Unit vests; or (b) the fifteenth (15th) day of the third (3rd) month following the end of the Company's fiscal year in which the Restricted Stock Unit vests. On the maturity date, the Company shall, subject to Section 11.4(e) hereof, transfer to the Holder one unrestricted, fully transferable Share for each Restricted Stock Unit scheduled to be paid out on such date and not previously forfeited, or, Recipient in the sole discretion and exclusive custody of its legal department to be held for the Administrator, an amount in cash equal to the Fair Market Value sole purpose of such shares on the maturity date or a combination of cash and Common Stock as determined by the Administrator.

8.6 Payment upon Termination of Service. An Award of Restricted Stock Units shall only be payable while the Holder is an Employee, a Consultant or a member of the Board, as applicable; provided, however, that the Administrator, in its sole and absolute discretion may provide (in an Award Agreement or otherwise) that a Restricted Stock Unit award may be paid subsequent to a Termination of Service in certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service

8.7 No Rights as a Stockholder. Unless otherwise determined by the Administrator, a Holder who is awarded Restricted Stock Units shall possess no incidents of ownership assessing compliance with respect to the Shares represented by such Restricted Stock Units, unless and until the same are transferred to the Holder pursuant to the terms of this Plan 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, the Award Agreement.

8.8 Dividend Equivalents. Subject specifically, to exercise its rights as granted by Section 9.2 hereof, the Administrator may, in its sole discretion, provide that Dividend Equivalents shall be earned by a Holder of Restricted Stock Units based on dividends declared on the Common Stock, to be credited as of dividend payment dates during the period between the date an Award of Restricted Stock Units is granted to a Holder and the maturity date of such Award.

ARTICLE 9.

- **AWARD OF PERFORMANCE AWARDS, DIVIDEND EQUIVALENTS, STOCK PAYMENTS, DEFERRED STOCK, DEFERRED STOCK UNITS**

9.1 Performance Awards13 (Intellectual Property).

(a)12.6. The Administrator is authorized to grant Performance Awards, including Awards of Performance Stock Units, to any Eligible Individual. The value of Performance Awards, including Performance Stock Units, may be linked to any one or more performance criteria or other specific criteria determined by the Administrator, in each case on a specified date or dates or over any period or periods determined by the Administrator. Performance Awards, including Performance Stock Unit awards may be paid in cash, Shares, or a combination of cash and Shares, as determined by the Administrator.

(b) Without limiting Section 9.1(a) hereof, the Administrator may grant Performance Awards to any Eligible Individual in the form of a cash bonus payable upon the attainment of objective performance goals, or such other criteria, whether or not objective, which are established by the Administrator, in each case on a specified date or dates or over any period or periods determined by the Administrator.

9.2 Dividend Equivalents.

(a) Dividend Equivalents may be granted by the Administrator based on dividends declared on the Common Stock, to be credited as of dividend payment dates during the period between the date an Award is granted to a Holder and the date such Award vests, is exercised, is distributed or expires, as determined by the Administrator. Such Dividend Equivalents shall be converted to cash or additional shares of Common Stock by such formula and at such time and subject to such limitations as may be determined by the Administrator. Notwithstanding anything to the contrary in the Plan, dividends or Dividend Equivalents with respect to an Award that is subject to vesting and that are based on dividends paid prior to the vesting of such Award shall only be paid out to the Holder to the extent that the vesting conditions are subsequently satisfied and the Award vests.

(b) No Dividend Equivalents shall be payable with respect to Options or Stock Appreciation Rights.

9.3 Stock Payments Remedies. The Administrator is authorized Parties acknowledge that monetary damages may not be sufficient to make Stock Payments 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 Eligible Individual. The number other remedies available at law or value of Shares of any Stock Payment shall be determined by the Administrator and may be based upon one or more performance criteria or any other specific criteria, including service to the Company or any Affiliate, determined by the Administrator. Shares underlying a Stock Payment which is subject to a vesting schedule or other conditions or criteria set by the Administrator in equity. These remedies will not be issued until those conditions have been satisfied. Unless otherwise provided by the Administrator, a Holder exclusive remedies for breach of a Stock Payment shall have no rights as a Company stockholder with respect this Section 12 but will be in addition to such Stock Payment until such time as the Stock Payment has vested any and the Shares underlying the Award have been issued to the Holder. Stock all other remedies available at law or in equity.

Payments may, but are not required to, be made in lieu of base salary, bonus, fees or other cash compensation otherwise payable to such Eligible Individual.

9.4 12.7. Deferred Stock Survival. The Administrator is authorized to grant Deferred Stock to obligations contained in this Section 12 will survive any Eligible Individual. The number termination of shares this Agreement for seven years from the last day of Deferred Stock shall be determined by the Administrator and may (but is not required to) be based on one or more performance criteria or other specific criteria, including service to the Company or any Affiliate, as the Administrator determines, in each case on a specified date or dates or over any period or periods determined by the Administrator. Shares underlying a Deferred Stock award which is subject to a vesting schedule or other conditions or criteria set by the Administrator will be issued on the vesting date(s) or date(s) that those conditions and criteria have been satisfied, as applicable. Unless otherwise provided by the Administrator, a Holder of Deferred Stock shall have no rights as a Company stockholder with respect to such Deferred Stock until such time as the Award has vested and any other applicable conditions and/or criteria have been satisfied and the Shares underlying the Award have been issued to the Holder. Term.

9.5 13. Deferred Stock Units. The Administrator is authorized to grant Deferred Stock Units to any Eligible Individual. The number of Deferred Stock Units shall be determined by the Administrator and may (but is not required to) be based on one or more performance criteria or other specific criteria, including service to the Company or any Affiliate, as the Administrator determines, in each case on a specified date or dates or over any

period or periods determined by the Administrator. Each Deferred Stock Unit shall entitle the Holder thereof to receive one share of Common Stock on the date the Deferred Stock Unit becomes vested or upon a specified settlement date thereafter (which settlement date may (but is not required to) be the date of the Holder's Termination of Service). Shares underlying a Deferred Stock Unit award which is subject to a vesting schedule or other conditions or criteria set by the Administrator will not be issued until on or following the date that those conditions and criteria have been satisfied. Unless otherwise provided by the Administrator, a Holder of Deferred Stock Units shall have no rights as a Company stockholder with respect to such Deferred Stock Units until such time as the Award has vested and any other applicable conditions and/or criteria have been satisfied and the Shares underlying the Award have been issued to the Holder. Intellectual Property

9.613.1. Term. The term of a Performance Award, Dividend Equivalent award, Stock Payment award, Deferred Stock award and/or Deferred Stock Unit award shall be set by the Administrator in its sole discretion.

9.7 Purchase Price. The Administrator may establish the purchase price of a Performance Award, Shares distributed as a Stock Payment award, shares of Deferred Stock or Shares distributed pursuant to a Deferred Stock Unit award; provided, however, that value of the consideration shall not be less than the par value of a Share, unless otherwise permitted by Applicable Law.

9.8 Termination of Service. A Performance Award, Stock Payment award, Dividend Equivalent award, Deferred Stock award and/or Deferred Stock Unit award is distributable only while the Holder is an Employee, Director or Consultant, as applicable. The Administrator, however, in its sole discretion may provide that the Performance Award, Dividend Equivalent

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award, Stock Payment award, Deferred Stock award and/or Deferred Stock Unit award may be distributed subsequent to a Termination of Service in certain events, including a Change in Control, the Holder's death, retirement or disability or any other specified Termination of Service.

ARTICLE 10.

- **AWARD OF STOCK APPRECIATION RIGHTS**

10.1 Grant of Stock Appreciation Rights.

(a) The Administrator is authorized to grant Stock Appreciation Rights to Eligible Individuals from time to time, in its sole discretion, on such terms and conditions as it may determine consistent with the Plan.

(b) A Stock Appreciation Right shall entitle the Holder (or other person entitled to exercise the Stock Appreciation Right pursuant to the Plan) to exercise all or a specified portion of the Stock Appreciation Right (to the extent then exercisable pursuant to its terms) and to receive from the Company an amount determined by multiplying the difference obtained by subtracting the exercise price per Share of the Stock Appreciation Right from the Fair Market Value on the date of exercise of the Stock Appreciation Right by the number of Shares with respect to which the Stock Appreciation Right shall have been exercised, subject to any limitations the Administrator may impose. Except as described in (c) below or in Section 13.2 hereof, the exercise price per Share subject to each Stock Appreciation Right shall be set by the Administrator, but shall not be less than one hundred percent (100%) of the Fair Market Value on the date the Stock Appreciation Right is granted.

(c) Notwithstanding the foregoing provisions of Section 10.1(b) hereof to the contrary, in the case of a Stock Appreciation Right that is a Substitute Award, the price per Share of the Shares subject to such Stock Appreciation Right may be less than one hundred percent (100%) of the Fair Market Value per share on the date of grant; provided that the excess of: (i) the aggregate Fair Market Value (as of the date such Substitute Award is granted) of the shares subject to the Substitute Award, over (ii) the aggregate exercise price thereof does not exceed the excess of: (x) the aggregate fair market value (as of the time immediately preceding the transaction giving rise to the Substitute Award, such fair market value to be determined by the Administrator) of the shares of the predecessor entity that were subject to the grant assumed or substituted for by the Company, over (y) the aggregate exercise price of such shares.

10.2 Stock Appreciation Right Vesting.

(a) The period during which the right to exercise, in whole or in part, a Stock Appreciation Right vests in the Holder shall be set by the Administrator and the Administrator may determine that a Stock Appreciation Right may not be exercised in whole or in part for a specified period after it is granted. Such vesting may be based on service with the Company or any Affiliate, any performance criteria or any other criteria selected by the Administrator. At any time after grant of a Stock Appreciation Right, the Administrator may, in its sole discretion

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and subject to whatever terms and conditions it selects, accelerate the period during which a Stock Appreciation Right vests.

(b) No portion of a Stock Appreciation Right which is unexercisable at Termination of Service shall thereafter become exercisable, except as may be otherwise provided by the Administrator either in the applicable Program or Award Development Agreement or by action of the Administrator following the grant of the Stock Appreciation Right, including following a Termination of Service; provided, that in no event shall a Stock Appreciation Right become exercisable following its expiration, termination or forfeiture.

10.3 Manner of Exercise. All or a portion inventions and other Intellectual Property arising from performance of an exercisable Stock Appreciation Right shall be deemed exercised upon delivery of all of the following to the stock administrator of the Company, or such other person or entity designated by the Administrator, or his, her or its office, as applicable:

(a) A written or electronic notice complying with the applicable rules established by the Administrator stating that the Stock Appreciation Right, or a portion thereof, is exercised. The notice shall be signed by the Holder or other person then entitled to exercise the Stock Appreciation Right or such portion of the Stock Appreciation Right;

(b) Such representations and documents as the Administrator, in its sole discretion, deems necessary or advisable to effect compliance with all applicable provisions of the Securities Act and any other federal, state or foreign securities laws or regulations. The Administrator may, in its sole discretion, also take whatever additional actions it deems appropriate to effect such compliance; and

(c) In the event that the Stock Appreciation Right shall be exercised pursuant to this Section 10.3 hereof by any person or persons other than the Holder, appropriate proof of the right of such person or persons to exercise the Stock Appreciation Right.

10.4 Stock Appreciation Right Term. The term of each Stock Appreciation Right (the "Stock Appreciation Right Term") shall be set by the Administrator in its sole discretion; provided, however, that the term shall not be more than ten (10) years from the date the Stock Appreciation Right is granted. The Administrator shall determine the time period, including the time period following a Termination of Service, during which the Holder has the right to exercise the vested Stock Appreciation Rights, which time period may not extend beyond the expiration date of the Stock Appreciation Right Term. Except as limited by the requirements of Section 409A of the Code and regulations and rulings thereunder or the first sentence of this Section 10.4, the Administrator may extend the Stock Appreciation Right Term of any outstanding Stock Appreciation Right, may extend the time period during which vested Stock Appreciation Rights may be exercised following any Termination of Service of the Holder, and may amend any other term or condition of such Stock Appreciation Right relating to such a Termination of Service.

10.5 Payment. Payment of the amounts payable with respect to Stock Appreciation Rights pursuant to this Article 10 shall be in cash, Shares (based on its Fair Market Value as of

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the date the Stock Appreciation Right is exercised), or a combination of both, as determined by the Administrator.

ARTICLE 11.

• ADDITIONAL TERMS OF AWARDS

11.1 Payment. The Administrator shall determine the methods by which payments by any Holder with respect to any Awards granted under the Plan shall be made, including, without limitation: (a) cash or check, (b) Shares (including, in the case of payment of the exercise price of an Award, Shares issuable pursuant to the exercise of the Award) or Shares held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences, in each case, having a Fair Market Value on the date of delivery equal to the aggregate payments required, (c) delivery of a written or electronic notice that the Holder has placed a market sell order with a broker with respect to Shares then issuable upon exercise or vesting of an Award, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the aggregate payments required; provided that payment of such proceeds is then made to the Company upon settlement of such sale, or (d) other form of legal consideration acceptable to the Administrator. The Administrator shall also determine the methods by which Shares shall be delivered or deemed to be delivered to Holders. Notwithstanding any other provision of the Plan to the contrary, no Holder who is a Director or an "executive officer" of the Company within the meaning of Section 13(k) of the Exchange Act shall be permitted to make payment with respect to any Awards granted under the Plan, or continue any extension of credit with respect to such payment, with a loan from the Company or a loan arranged by the Company in violation of Section 13(k) of the Exchange Act.

11.2 Tax Withholding. The Company or any Affiliate shall have the authority and the right to deduct or withhold, or require a Holder to remit to the Company, an amount sufficient to satisfy federal, state, local and foreign taxes (including the Holder's FICA, employment tax or other social security contribution obligation) required by law to be withheld with respect to any taxable event concerning a Holder arising as a result of the Plan. The Administrator shall determine the methods by which payments by any Holder with respect to the tax withholding obligations with respect to any Awards granted under the Plan shall be made, which methods may include any of the methods permitted under Section 11.1 above. Without limiting the foregoing, the Administrator, in its sole discretion and in satisfaction of the foregoing requirement , may withhold, or allow a Holder to elect to have the Company withhold, Shares otherwise issuable under an Award (or allow the surrender of Shares). The number of Shares which may be so withheld or surrendered shall be limited to the number of Shares which have a Fair Market Value on the date of withholding or repurchase equal to the aggregate amount of such liabilities based on the minimum statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such supplemental taxable income or such higher rate as may be approved by the Administrator (which rates shall in no event exceed the maximum individual statutory tax rate in the applicable jurisdiction at the time of such withholding (or such other rate as may be required to avoid the liability classification of the applicable award under generally accepted accounting principles in the United States of

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America)); provided, however, that the number of Shares withheld, delivered or returned shall be rounded up to the nearest whole share sufficient to cover the applicable tax withholding obligation to the extent rounding up to the nearest whole share does not result in the liability classification of the applicable Award under generally accepted accounting principles in the United States of America. The Administrator shall determine the fair market value of the Shares, consistent with applicable provisions of the Code, for tax withholding obligations due in connection with a broker-assisted cashless Option or Stock Appreciation Right exercise involving the sale of Shares to pay the Option or Stock Appreciation Right exercise price or any tax withholding obligation.

11.3 Transferability of Awards.

(a) Except as otherwise provided in Sections 11.3(b) and 11.3(c) hereof:

(i) No Award under the Plan may be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a DRO, unless and until such Award has been exercised, or the Shares underlying such Award have been issued, and all restrictions applicable to such Shares have lapsed;

(ii) No Award or interest or right therein shall be liable for the debts, contracts or engagements of the Holder or the Holder's successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, hypothecation, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy) unless and until such Award has been exercised, or the Shares underlying such Award have been

issued, and all restrictions applicable to such Shares have lapsed, and any attempted disposition of an Award prior to the satisfaction of these conditions shall be null and void and of no effect, except to the extent that such disposition is permitted by clause (i) of this provision; and

(iii) During the lifetime of the Holder, only the Holder may exercise an Award (or any portion thereof) granted to such Holder under the Plan, unless it has been disposed of pursuant to a DRO; after the death of the Holder, any exercisable portion of an Award may, prior to the time when such portion becomes unexercisable under the Plan or the applicable Program or Award Agreement, be exercised by the Holder's personal representative or by any person empowered to do so under the deceased Holder's will or under the then applicable laws of descent and distribution.

(b) Notwithstanding Section 11.3(a) hereof, the Administrator, in its sole discretion, may determine to permit a Holder or a Permitted Transferee of such Holder to transfer an Award other than an Incentive Stock Option (unless such Incentive Stock Option is to become a Non-Qualified Stock Option) to any one or more Permitted Transferees, subject to the following terms and conditions: (i) an Award transferred to a Permitted Transferee shall not be assignable or transferable by the Permitted Transferee (other than to another Permitted Transferee of the applicable Holder) other than by will or the laws of descent and distribution;

(ii) an Award transferred to a Permitted Transferee shall continue to be subject to all the terms and conditions of the Award as applicable to the original Holder (other than the ability to further transfer the Award); and (iii) the Holder (or transferring Permitted Transferee) and the Permitted Transferee shall execute any and all documents requested by the Administrator, Development Services, including without limitation documents to (A) confirm the status of the transferee as a Permitted Transferee, (B) satisfy any requirements for an exemption for the transfer under applicable federal, state project reports, final reports and foreign securities laws and (C) evidence the transfer.

(c) Notwithstanding Section 11.3(a) hereof, a Holder may, in the manner determined by the Administrator, designate a beneficiary to exercise the rights of the Holder and to receive any distribution with respect to any Award upon the Holder's death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and any Program or Award Agreement applicable to the Holder, except to the extent the Plan, the Program and the Award Agreement otherwise provide, and to any additional restrictions deemed necessary or appropriate by the Administrator. If the Holder is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than the Holder's spouse or domestic partner, as applicable, as his or her beneficiary with respect to more than fifty percent (50%) of the Holder's interest in the Award shall not be effective without the prior written or electronic consent of the Holder's spouse or domestic partner, as applicable. If no beneficiary has been designated or survives the Holder, payment Manufacturing Records, shall be made to the person entitled thereto pursuant to the Holder's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by a Holder at any time; provided that the change or revocation is filed with the Administrator prior to the Holder's death.

11.4 Conditions to Issuance of Shares.

(a) Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates or make any book entries evidencing Shares pursuant to the exercise of any Award, unless and until the Board or the Committee has determined, with advice of counsel, that the issuance of such shares is in compliance with all Applicable Law, and the Shares are covered by an effective registration statement or applicable exemption from registration. In addition to the terms and conditions provided herein, the Board or the Committee may require that a Holder make such reasonable covenants, agreements, and representations as the Board or the Committee, in its discretion, deems advisable in order to comply with Applicable Law.

(b) All Share certificates delivered pursuant to the Plan and all Shares issued pursuant to book entry procedures are subject to any stop-transfer orders and other restrictions as the Administrator deems necessary or advisable to comply with Applicable Law. The Administrator may place legends on any Share certificate or book entry to reference restrictions applicable to the Shares.

(c) The Administrator shall have the right to require any Holder to comply with any timing or other restrictions with respect to the settlement, distribution or exercise of any

Award, including a window-period limitation, as may be imposed in the sole discretion of the Administrator.

(d) No fractional Shares shall be issued and the Administrator shall determine, in its sole discretion, whether cash shall be given in lieu of fractional Shares or whether such fractional Shares shall be eliminated by rounding down.

(e) Notwithstanding any other provision of the Plan, unless otherwise determined by the Administrator or required by any Applicable Law, the Company shall not deliver to any Holder certificates evidencing Shares issued in connection with any Award and instead such Shares shall be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator).

11.5 Forfeiture and Claw-Back Provisions. Pursuant to its general authority to determine the terms and conditions applicable to Awards under the Plan, the Administrator shall have the right to provide, in an Award Agreement or otherwise, or to require a Holder to agree by separate written or electronic instrument, that:

(a) (i) Any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of the Award, or upon the receipt or resale of any Shares underlying the Award, must be paid to the Company, and (ii) the Award shall terminate and any unexercised portion of the Award (whether or not vested) shall be forfeited, if (x) a Termination of Service occurs prior to a specified date, or within a specified time period following receipt or exercise of the Award, or (y) the Holder at any time, or during a specified time period, engages in any activity in competition with the Company, or which is inimical, contrary or harmful to the interests of the Company, as further defined by the Administrator or (z) the Holder incurs a Termination of Service for “cause” (as such term is defined in the sole discretion of the Administrator, or as set forth in a written agreement relating to such Award between the Company and the Holder); and

(b) All Awards (including any proceeds, gains or other economic benefit actually or constructively received by the Holder upon any receipt or exercise of any Award or upon the receipt or resale of any Shares underlying the Award) shall be subject to the provisions of any claw-back policy implemented by the Company, including, without limitation, any claw-back policy adopted to comply with the requirements of Applicable Law, including, without limitation, the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder, to the extent set forth in such claw-back policy and/or in the applicable Award Agreement.

11.6 Prohibition on Repricing. Subject to Section 13.2 hereof, the Administrator shall not, without the approval of the stockholders of the Company, (i) authorize the amendment of any outstanding Option or Stock Appreciation Right to reduce its price per share, or (ii) cancel any Option or Stock Appreciation Right in exchange for cash or another Award when the Option or Stock Appreciation Right price per share exceeds the Fair Market Value of the underlying Shares.

11.7 Leave of Absence. Unless the Administrator provides otherwise, vesting of Awards granted hereunder shall be suspended during any unpaid leave of absence. A Holder shall not cease to be considered an Employee, Non-Employee Director or Consultant, as applicable, in the case of any (a) leave of absence approved by the Company, (b) transfer between locations of the Company or between the Company and any of its Affiliates or any successor thereof, or (c) change in status (Employee to Director, Employee to Consultant, etc.), provided that such change does not affect the specific terms applying to the Holder’s Award.

ARTICLE 12.

- **ADMINISTRATION**

12.1 Administrator. The Committee (or another committee or a subcommittee of the Board or the Compensation Committee of the Board assuming the functions of the Committee under the Plan) shall administer the Plan (except as otherwise permitted herein) and, unless otherwise determined by the Board, shall consist solely of two or more Non-Employee Directors appointed by and holding office at the pleasure of the Board, each of whom is intended to qualify as both a "non-employee director" as defined by Rule 16b-3 of the Exchange Act or any successor rule and an "independent director" under the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded; provided that any action taken by the Committee shall be valid and effective, whether or not members of the Committee at the time of such action are later determined not to have satisfied the requirements for membership set forth in this Section 12.l or otherwise provided in any charter of the Committee. Except as may otherwise be provided in any charter of the Committee, appointment of Committee members shall be effective upon acceptance of appointment. Committee members may resign at any time by delivering written or electronic notice to the Board. Vacancies in the Committee may only be filled by the Board. Notwithstanding the foregoing, (a) the full Board, acting by a majority of its members in office, shall conduct the general administration of the Plan with respect to Awards granted to Non-Employee Directors and, with respect to such Awards, the terms "Administrator" and "Committee" as used in the Plan shall be deemed to refer to the Board and (b) the Board or Committee may delegate its authority hereunder to the extent permitted by Section 12.6 hereof.

12.2 Duties and Powers of Administrator. It shall be the duty of the Administrator to conduct the general administration of the Plan owned in accordance with, its provisions. The Administrator shall have the power to interpret the Plan, the Program and the Award Agreement, and to adopt such rules for the administration, interpretation and application of the Plan as are not inconsistent therewith, to interpret, amend or revoke any such rules and to amend any Program or Award Agreement; provided that the rights or obligations of the Holder of the Award that is the otherwise subject of any such Program or Award Agreement are not affected materially and adversely by such amendment, unless the consent of the Holder is obtained or such amendment is otherwise permitted under Section 13.10 hereof. Any such grant or award under the Plan need not be the same with respect to each Holder. Any such interpretations and rules with respect to Incentive Stock Options shall be consistent with the provisions of Section 422 of the Code. In its sole discretion, the Board may at any time and from time to time exercise any and all rights and

duties of the Committee under the Plan except with respect to matters which under Rule 16b-3 under the Exchange Act or any successor rule, or the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded are required to be determined in the sole discretion of the Committee.

12.3 Action by the Committee. Unless otherwise established by the Board or in any charter of the Committee, a majority of the Committee shall constitute a quorum and the acts of a majority of the members present at any meeting at which a quorum is present, and acts approved in writing by all members of the Committee in lieu of a meeting, shall be deemed the acts of the Committee. Each member of the Committee is entitled to, in good faith, rely or act upon any report or other information furnished to that member by any officer or other employee of the Company or any Affiliate, the Company's independent certified public accountants, or any executive compensation consultant or other professional retained by the Company to assist in the administration of the Plan.

12.4 Authority of Administrator. Subject to the Company's Bylaws, the Committee's Charter and any specific designation in the Plan, the Administrator has the exclusive power, authority and sole discretion to:

(a) Designate Eligible Individuals to receive Awards;

(b) Determine the type or types of Awards to be granted to each Eligible Individual;

(c) Determine the number of Awards to be granted and the number of Shares to which an Award will relate;

(d) Determine the terms and conditions of any Award granted pursuant to the Plan, including, but not limited to, the exercise price, grant price, or purchase price, any performance criteria, any restrictions or limitations on the Award, any schedule for vesting, lapse of forfeiture restrictions or restrictions on the exercisability of an Award, and accelerations or waivers thereof, and any provisions related to non-competition and recapture of gain on an Award, based in each case on such considerations as the Administrator in its sole discretion determines;

(e) Determine whether, to what extent, and pursuant to what circumstances an Award may be settled in, or the exercise price of an Award may be paid in cash, Shares, other Awards, or other property, or an Award may be canceled, forfeited, or surrendered;

(f) Prescribe the form of each Award Agreement, which need not be identical for each Holder;

(g) Decide all other matters that must be determined in connection with an Award;

(h) Establish, adopt, or revise any rules and regulations as it may deem necessary or advisable to administer the Plan;

(i) Interpret the terms of, and any matter arising pursuant to, the Plan, any Program or any Award Agreement;

(j) Make all other decisions and determinations that may be required pursuant to the Plan or as the Administrator deems necessary or advisable to administer the Plan; and

(k) Accelerate wholly or partially the vesting or lapse of restrictions of any Award or portion thereof at any time after the grant of an Award, subject to whatever terms and conditions it selects and Section 13.2(d) hereof.

12.5 Decisions Binding. The Administrator's interpretation of the Plan, any Awards granted pursuant to the Plan, any Program, any Award Agreement and all decisions and determinations by the Administrator with respect to the Plan are final, binding, and conclusive on all parties.

12.6 Delegation of Authority. To the extent permitted by Applicable Law, the Board or Committee may from time to time delegate to a committee of one or more members of the Board or one or more officers of the Company the authority to grant or amend Awards or to take other administrative actions pursuant to Article 12; provided,however, that in no event shall an officer of the Company be delegated the authority to grant awards to, or amend awards held by, the following individuals: (a) individuals who are subject to Section 16 of the Exchange Act, or (b) officers of the Company (or Directors) to whom authority to grant or amend Awards has been delegated hereunder. Any delegation hereunder shall be subject to the restrictions and limits that the Board or Committee specifies at the time of such delegation, and the Board may at any time rescind the authority so delegated or appoint a new delegatee. At all times, the delegatee appointed under this Section 12.6 hereof shall serve in such capacity at the pleasure of the Board and the Committee.

ARTICLE 13.

MISCELLANEOUS PROVISIONS

13.1 Amendment, Suspension or Termination of the Plan.

(a) This Plan shall be effective on the date it is adopted by the Board (the "Effective Date"), provided, that the stockholders of the Company approve the Plan within twelve (12) months following the Effective Date.

(b) Except as otherwise provided in this Section 13.1, the Plan may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Board or the Committee. However, without approval of the Company's stockholders given within twelve (12) months before or after the action by the Administrator, no action of the

Administrator may, except as provided in Section 13.2 hereof, (a) increase the limits imposed in Section 3.1 hereof on the maximum number of shares which may be issued under the Plan, or (b) reduce the price per share of any outstanding Option or Stock Appreciation Right granted under the Plan,

or (c) cancel any Option or Stock Appreciation Right in exchange for cash or another Award when the Option or Stock Appreciation Right price per share exceeds the Fair Market Value of the underlying Shares. Except as provided in Section 13.10 hereof, no amendment, suspension or termination of the Plan shall, without the consent of the Holder, materially and adversely affect any rights or obligations under any Award theretofore granted or awarded, unless the Award itself otherwise expressly so provides. No Awards may be granted or awarded during any period of suspension or after termination of the Plan, and in no event may any Incentive Stock Option be granted under the Plan after the tenth (10th) anniversary of the Effective Date.

13.2 Changes in Common Stock or Assets of the Company, Acquisition or Liquidation of the Company and Other Corporate Events.

(a) In the event of any stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of the Company's stock or the share price of the Company's stock other than an Equity Restructuring, the Administrator may make equitable adjustments, if any, to reflect such change with respect to (i) the aggregate number and kind of shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Section 3.1 hereof on the maximum number and kind of shares which may be issued under the Plan); (ii) the number and kind of shares of Common Stock (or other securities or property) subject to outstanding Awards; (iii) the number and kind of shares of Common Stock (or other securities or property) for which grants are subsequently to be made to new and continuing Non-Employee Directors pursuant to Section 4.6 hereof; (iv) the terms and conditions of any outstanding Awards (including, without limitation, any applicable performance targets or criteria with respect thereto); and (v) the grant or exercise price per share for any outstanding Awards under the Plan.

(b) In the event of any transaction or event described in Section 13.2(a) hereof or any unusual or nonrecurring transactions or events affecting the Company, any Affiliate of the Company, or the financial statements of the Company or any Affiliate, or of changes in Applicable Law, the Administrator, in its sole discretion, and on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event and either automatically or upon the Holder's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any Award under the Plan, to facilitate such transactions or events or to give effect to such changes in laws, regulations or principles:

(i) To provide for either (A) termination of any such Award in exchange for an amount of cash and/or other property, if any, equal to the amount that would

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have been attained upon the exercise of such Award or realization of the Holder's rights (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction or event described in this Section 13.2 the Administrator determines in good faith that no amount would have been attained upon the exercise of such Award or realization of the Holder's rights, then such Award may be terminated by the Company without payment) or (B) the replacement of such Award with other rights or property selected by the Administrator in its sole discretion having an aggregate value not exceeding the amount that could have been attained upon the exercise of such Award or realization of the Holder's rights had such Award been currently exercisable or payable or fully vested;

(ii) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by similar options, rights or awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices;

(iii) To make adjustments in the number and type of shares of the Company's stock (or other securities or property) subject to outstanding Awards, and in the number and kind of outstanding Restricted Stock or Deferred Stock and/or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards and Awards which may be granted in the future;

(iv) To provide that such Award shall be exercisable or payable or fully vested with respect to all shares covered thereby, notwithstanding anything to the contrary in the Plan or the applicable Program or Award Agreement; and

(v) To provide that the Award cannot vest, be exercised or become payable after such event.

(c) In connection with the occurrence of any Equity Restructuring, and notwithstanding anything to the contrary in Sections 13.2(a) and 13.2(b) hereof:

(i) The number and type of securities subject to each outstanding Award and the exercise price or grant price thereof, if applicable, shall be equitably adjusted; and/or

(ii) The Administrator shall make such equitable adjustments, if any, as the Administrator in its discretion may deem appropriate to reflect such Equity Restructuring with respect to the aggregate number and kind of shares that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Section 3.1 hereof on the maximum number and kind of shares which may be issued under the Plan).

The adjustments provided under this Section 13.2(c) shall be nondiscretionary and shall be final and binding on the affected Holder and the Company.

(d) Change in Control.

(i) Notwithstanding any other provision of the Plan, in the event of a Change in Control, each outstanding Award shall be assumed or an equivalent Award substituted by the successor corporation or a parent or subsidiary of the successor corporation, in each case, as determined by the Administrator.

(ii) In the event that the successor corporation in a Change in Control and its parents and subsidiaries refuse to assume or substitute for any Award in accordance with Section 13.2(d)(i) hereof, each such non-assumed/substituted Award, except for any Performance Awards, shall become fully vested and, as applicable, exercisable and shall be deemed exercised, immediately prior to the consummation of such transaction, and all forfeiture restrictions on any or all such Awards shall lapse at such time. For the avoidance of doubt, the vesting of any Performance Awards not assumed in a Change in Control will not be automatically accelerated pursuant to this Section 13.2(d)(ii) and will instead vest pursuant to, the terms and conditions of the applicable Award Agreement upon a Change in Control where the successor corporation and its parents and subsidiaries refuse to assume or substitute for any Award in accordance with Section 13.2(d)(i) hereof. If an Award vests and, as applicable, is exercised in lieu of assumption or substitution in connection with a Change in Control, the Administrator shall notify the Holder of such vesting and any applicable exercise period, and the Award shall terminate upon the Change in Control. For the avoidance of doubt, if the value of an Award that is terminated in connection with this Section 13.2(d)(ii) is zero or negative at the time of such Change in Control, such Award shall be terminated upon the Change in Control without payment of consideration therefor. Development Agreement.

(e) 13.2. The Administrator may, in its sole discretion, include such further provisions Background IP. Ardelyx shall solely own all Ardelyx Background IP and limitations in any Award, agreement or certificate, as it may deem equitable and in the best interests of the Company that are not inconsistent with the provisions of the Plan.

(f) Hovione shall solely own all Hovione Background IP (collectively, "No adjustment or action described in this Section 13.2 or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause the Plan to violate Section 422(b)(1) of the Code. Furthermore, no such adjustment or action shall be authorized to the extent such adjustment or action would result in short-swing profits liability under Section 16 of the Exchange Act or violate the exemptive conditions of Rule 16b-3 of the Exchange Act unless the Administrator determines that the Award is not to comply with such exemptive conditions.

(g) Background IPThe existence of the Plan, the Program, the Award Agreement and the Awards granted hereunder shall not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, warrants or rights to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise. "). For

(h) In clarity the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the Shares or the share price Process for Manufacture of the Common Stock including any Equity Restructuring, for reasons Product, as of administrative convenience, the Company 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 its sole discretion may refuse to permit the exercise of any Award during a period of thirty (30) days prior and to the consummation 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 transaction. 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.

13.3 13.6. Approval of Plan by Stockholders 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 Plan will be submitted for the approval of the Company's stockholders within twelve (12) months after the date of the Board's initial adoption of the Plan. Awards may be granted or awarded prior foregoing license does not extend to such stockholder approval; provided that such Awards shall not be exercisable, shall not vest and the restrictions thereon shall not lapse and no Shares shall be issued pursuant thereto prior to the time when the Plan is approved [***] absent separate written consent by the stockholders; and provided, further, that if such approval has not been obtained at the end of said twelve (12) month period, all Awards previously granted or awarded under the Plan shall thereupon be canceled and become null and void. Ardelyx in each case.

13.4 13.6.2. No Stockholders Rights. Except as otherwise provided herein, a Holder shall have none of the rights of a stockholder with respect to Shares covered by any Award until the Holder becomes the record owner of such Shares.

13.5 Paperless Administration License under Incorporated Hovione IP. In addition to any license(s) negotiated pursuant to Section 13.5, [***] (collectively, the event that "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 Company establishes, for itself or using the services actions of a any third party an automated system for the documentation, granting to which Ardelyx sublicenses its rights to Incorporated Hovione IP and will indemnify and hold harmless Hovione against all costs, expenses, damages, or exercise losses of Awards, any nature arising out of such as a system using an internet website or interactive voice response, then the paperless documentation, granting or exercise sublicensee's use of Awards by a Holder may be permitted through the Incorporated Hovione IP, including, but not limited to, any use of such an automated system.

13.6 Effect Incorporated Hovione IP outside the bounds of Plan upon Other Compensation Plans. The adoption 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 Plan shall not affect any other compensation or incentive plans in effect for the Company or any Affiliate. Nothing in the Plan shall be construed to limit the right of the Company or any Affiliate: (a) to establish any other forms of incentives or compensation for Employees, Directors or Consultants of the Company or any Affiliate, or (b) to grant or assume options or other rights or awards otherwise than Incorporated Hovione IP under the Plan license granted in connection with any proper corporate purpose including without limitation, the grant or assumption of options in connection with the acquisition by

purchase, lease, merger, consolidation or otherwise, of the business, stock or assets of any corporation, partnership, limited liability company, firm or association.

13.7 Compliance with Laws. The Plan, the granting this Section, and vesting of Awards under the Plan and the issuance and delivery of Shares and the payment of money under the Plan or under Awards granted or awarded hereunder are subject to compliance with all Applicable Law, and to such approvals by any listing, regulatory or governmental authority as may, in the opinion of counsel for the Company, be necessary or advisable in connection therewith. Any securities delivered under the Plan shall be subject to such restrictions, and the person acquiring such securities shall, if requested by the Company, provide such assurances and representations to the Company as the Company may deem necessary or desirable to assure compliance with all Applicable Law. To the extent permitted by Applicable Law, the Plan and Awards granted or (b)

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awarded 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 shall 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 deemed amended 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 necessary reasonably practical, Hovione will supply Ardelyx from another Hovione site, (b) Hovione will otherwise use Commercially Reasonable Efforts to conform to such Applicable Law.

13.8 Titles [***], and Headings, References to Sections (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 Code 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 Exchange Act (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 titles division of this Agreement into Sections, Subsections, and headings Appendices, and the insertion of the Sections in the Plan 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 event 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 conflict, 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 text 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 Plan, rather than such titles other Party, unless required in connection with a Regulatory Approval or headings, shall control. References to sections of the Code or the Exchange Act shall include any amendment or successor thereto. communications with a Regulatory Authority.

13.9 14.13. Governing Law. The Plan This Agreement and any agreements hereunder shall be administered, interpreted and enforced under 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 internal laws of the State of Delaware New York, United States of America, without regard to conflicts 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 laws thereof or 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 other jurisdiction. 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.

13.10 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 409A. To 14.14.1, the extent that Parties agree to refer the Administrator determines that any Award granted under matter to a panel consisting of one (1) senior executive employed by each Party who is not directly involved in the Plan is subject to Section 409A claim or dispute for review and resolution. A copy of the Code, contract terms, agreed upon facts (and areas of disagreement), and concise summary of the Program 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

[***]

Exhibit 10.5

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 such Award is granted and the Award Agreement evidencing such Award shall incorporate Lenders have provided to Borrower certain loans in accordance with the terms and conditions required by Section 409A thereof; and

B. Borrower, Collateral Agent and the Required Lenders have agreed to amend certain provisions of the Code. To the extent applicable, the Plan, the Program Loan Agreement as provided herein, subject to, and any Award Agreements shall be interpreted in accordance with, Section 409A 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 Code promises, covenants and Department of Treasury regulations agreements contained herein, and other interpretive guidance issued thereunder, including without limitation 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:

"**ApplicableRate**" 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 regulations rate, or other guidance (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 issued after re-borrowed.

(v) Subject to the Effective Date. Notwithstanding any provision 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 Plan 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 contrary, Term Loan as determined in Section 2.3(a). Borrower agrees to pay, on the event that following Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the Effective period between the Funding Date of such Term Loan and the Administrator determines that any Award 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 subject 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 409A of the Code and related Department of Treasury guidance (including such Department of Treasury guidance as may be issued after the Effective Date) 2.3(b), the Administrator may adopt such amendments to the Plan and the applicable Program and Award Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Administrator determines are necessary or appropriate to (a) exempt the Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided (i) with respect to the Award, 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) comply 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 the requirements of Section 409A any Loan Document, as amended hereby.

3.2 This Amendment shall be construed in connection with and as part of the Code Loan Documents and related Department 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 Treasury guidance the date hereof (except to the extent such representations and thereby avoid 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 application 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

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Borrower, (iii) any applicable order, judgment or decree of any penalty taxes 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 such Section. 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

13.11 4.6 No Rights to Awards. No Eligible Individual 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 person 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 have 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 to be granted any Award pursuant to the Plan, and neither the Company nor the Administrator is obligated to treat Eligible Individuals, Holders of mistake of fact or law or any other persons uniformly. 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.

13.12 6.3 Unfunded Status 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 Awards 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.

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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 Plan is intended words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be an "unfunded" plan 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 incentive compensation. With respect 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 any payments not yet made Loan and Security Agreement to a Holder pursuant 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

[*Signature Page* to *an Award, nothing contained* *Fourth Amendment to Loan and Security Agreement*]

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%**

Exhibit 10.6

July 25, 2024
Eric Foster

Dear Eric,

On behalf of Ardelyx (the “Company”), I am pleased to offer you employment in the Plan or any Program or Award Agreement shall give the Holder any rights that are greater than those exempt position of a general creditor of the Company or any Affiliate.

13.13 Indemnification. To the extent allowable pursuant Chief Commercial Officer, reporting to Applicable Law, each Mike Raab, President and Chief Executive Officer. In this role, you will be a member of the Committee or 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 any officer or other employee to whom authority to administer any component Company performance and the status of the Plan 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 delegated shall 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 indemnified and held harmless pro-rated for the time you are employed by the Company from any loss, cost, liability, 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 expense that may its designee, and after your first day of employment, you will be imposed upon or reasonably incurred by such member in connection 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 or resulting from any claim, action, suit, or 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

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proceeding Company's equity incentive plan and standard forms of stock option and RSU agreements, which you will be required to which he or she may be a party or in which he or she may be involved by reason of any action or failure to act pursuant to the Plan and against and from any and all amounts paid by him or her in satisfaction of judgment in such action, suit, or proceeding against him or her; provided he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such persons may be entitled pursuant to the Company's Certificate of Incorporation or Bylaws, accept as a matter condition of law, or otherwise, or any power that receiving the Company may have to indemnify them or hold them harmless.option and RSU.

13.14 Relationship to other Benefits. No payment pursuant to the Plan shall be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Affiliate except to the extent otherwise expressly provided in writing in such other plan or an agreement thereunder.

13.15 Expenses. The expenses of administering the Plan shall be borne by the Company and its Affiliates.

* * * * *

Exhibit 10.2

ARDELYX, INC.
AMENDED AND RESTATED 2014 EMPLOYEE STOCK PURCHASE PLAN

ARTICLE I.
PURPOSE, SCOPE AND ADMINISTRATION OF THE PLAN

I.1 Purpose and Scope. The purpose of the Amended and Restated Ardelyx, Inc. 2014 Employee Stock Purchase Plan, as it may be amended from time to time (the "Plan") is to assist employees of Ardelyx, Inc., a Delaware corporation, (the "Company") and its Designated Subsidiaries in acquiring a stock ownership interest in the Company pursuant to a plan which is intended to qualify as an "employee stock purchase plan" under Section 423 of the Code and to help such employees provide for their future security and to encourage them to remain in the Your employment of the Company and its Subsidiaries. The Plan amends and restates the 2014 Employee Stock Purchase Plan (the "Original 2014 Plan") in its entirety, subject to stockholder approval of this Plan at the annual meeting of the Company's stockholders in 2024. In the event the Company's stockholders fail to approve the Plan as set forth herein at the annual meeting of the Company's stockholders in 2024, then this Plan shall be deemed void ab initio and the Original 2014 Plan shall continue in effect in accordance with its terms.

ARTICLE II.
DEFINITIONS

Whenever the following terms are used in the Plan, they shall have the meaning specified below unless the context clearly indicates to the contrary. The singular pronoun shall include the plural where the context so indicates.

II.1 "Agent" means the brokerage firm, bank or other financial institution, entity or person(s), if any, engaged, retained, appointed or authorized to act as the agent of the Company or an Employee with regard to the Plan.

II.2 "Administrator" shall mean the Committee, or such individuals to which authority to administer the Plan has been delegated under Section 7.1 hereof.

II.3 "Board" shall mean the Board of Directors of the Company.

II.4 "Code" shall mean the Internal Revenue Code of 1986, as amended.

II.5 "Committee" shall mean the Compensation Committee of the Board.

II.6 "Common Stock" shall mean the common stock of the Company.

II.7 "Company" shall have such meaning as set forth in Section 1.1 hereof.

II.8 "Compensation" of an Employee shall mean the regular straight-time earnings or base salary paid to the Employee from the Company on each Payday as compensation for services to the Company or any Designated Subsidiary, before deduction for any salary deferral contributions made by the Employee to any tax-qualified or nonqualified

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deferred compensation plan, including overtime, shift differentials, vacation pay, salaried production schedule premiums, holiday pay, jury duty pay, funeral leave pay, paid time off, military pay, prior week adjustments and weekly bonus, but excluding bonuses and commissions, education or tuition reimbursements, imputed income arising under any group insurance or benefit program, travel expenses, business and moving reimbursements, income received in connection with any stock options, restricted stock, restricted stock units or other compensatory equity awards and all contributions made by the Company or any Designated Subsidiary for the Employee's benefit under any employee benefit plan now or hereafter established. Such Compensation shall be calculated before deduction of any income or employment tax withholdings, but shall be withheld from the Employee's net income.

II.9 "Designated Subsidiary" shall mean each Subsidiary that have been designated by the Board or Committee from time to time in its sole discretion as eligible to participate in the Plan, including any Subsidiary in existence on the Effective Date and any Subsidiary formed or acquired following the Effective Date, in accordance with Section 7.2 hereof.

II.10 "Effective Date" shall have the meaning set forth in Section 7.5 hereof.

II.11 "Eligible Employee" shall mean an Employee who (a) is customarily scheduled to work at least twenty (20) hours per week, (b) whose customary employment is more than five (5) months in a calendar year and (c) after the granting of the Option would not be deemed for purposes of Section 423(b)(3) of the Code to possess five percent (5%) or more of the total combined voting power or value of all classes of stock of the Company or any Subsidiary. For purposes of clause (c), the rules of Section 424(d) of the Code with regard to the attribution of stock ownership shall apply in determining the stock ownership of an individual, and stock which an Employee may purchase under outstanding options shall be treated as stock owned by the Employee. Notwithstanding the foregoing, the Administrator may exclude from participation in the Plan as an Eligible Employee (x) any Employee that is a "highly compensated employee" of the Company or any Designated Subsidiary (within the meaning of Section 414(q) of the Code), or that is such a "highly compensated employee" (A) with compensation above a specified level, (B) who is an officer and/or (C) is subject to the disclosure requirements of Section 16(a) of the Exchange Act and/or (y) any Employee who is a citizen or resident of a foreign jurisdiction (without regard to whether they are also a citizen of the United States or a resident alien (within the meaning of Section 7701(b)(1)(A) of the Code)) if either (i) the grant of the Option is prohibited under the laws of the jurisdiction governing such Employee, or (ii) compliance with the laws of the foreign jurisdiction would cause the Plan or the Option to violate the requirements of Section 423 of the Code; *provided* that any exclusion in

clauses (x), and/or (y) shall be applied in an identical manner under each Offering Period to all Employees of the Company and all Designated Subsidiaries, in accordance with Treasury Regulation Section 1.423-2(e).

II.12 "Employee" shall mean any person who renders services to the Company or a Designated Subsidiary in the status of an employee within the meaning of Section 3401(c) of the Code. "Employee" shall not include any director of the Company or a Designated Subsidiary

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who does not render services to the Company or a Designated Subsidiary in the status of an employee within the meaning of Section 3401(c) of the Code. For purposes of the Plan, the employment relationship shall be treated as continuing intact while the individual is on military leave, sick leave or other leave of absence approved by the Company or Designated Subsidiary and meeting the requirements of Treasury Regulation Section 1.421-1(h)(2). Where the period of leave exceeds three (3) months, or such other period specified in Treasury Regulation Section 1.421-1(h)(2), and the individual's right to reemployment is not guaranteed either by statute or by contract, the employment relationship shall be deemed to have terminated on the first day immediately following such three (3)-month period, or such other period specified in Treasury Regulation Section 1.421-1(h)(2).

II.13 "Enrollment Date" shall mean the first date of each Offering Period.

II.14 "Exercise Date" shall mean the last Trading Day of each Offering Period, except as provided in Section 5.2 hereof.

II.15 "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

II.16 "Fair Market Value" shall mean, as of any date, the value of Common Stock determined as follows:

(a) If the Common Stock is (i) listed on any established securities exchange (such as the New York Stock Exchange, the Nasdaq Capital Market, Nasdaq Global Market and the Nasdaq Global Select Market), (ii) listed on any national market system or (iii) listed, quoted or traded on any automated quotation system, its Fair Market Value shall be the closing sales price for a share of Common Stock as quoted on such exchange or system for such date or, if there is no closing sales price for a share of Common Stock on the date in question, the closing sales price for a share of Stock on the last preceding date for which such quotation exists, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable;

(b) If the Common Stock is not listed on an established securities exchange, national market system or automated quotation system, but the Common Stock is regularly quoted by a recognized securities dealer, its Fair Market Value shall be the mean of the high bid and low asked prices for such date or, if there are no high bid and low asked prices for a share of Common Stock on such date, the high bid and low asked prices for a share of Common Stock on the last preceding date for which such information exists, as reported in *The Wall Street Journal* or such other source as the Administrator deems reliable; or

(c) If the Common Stock is neither listed on an established securities exchange, national market system or automated quotation system nor regularly quoted by a recognized securities dealer, its Fair Market Value shall be established by the Administrator in good faith.

II.17 "Grant Date" shall mean the first Trading Day of an Offering Period.

II.18 "New Exercise Date" shall have such meaning as set forth in Section 5.2(b) hereof.

II.19 "Offering Period" shall mean the six (6)-month period commencing on each March 1 and September 1 following the Effective Date, except as otherwise provided under Section 5.3 hereof; *provided*, *however*, that the first Offering Period commencing on or after the Effective Date shall commence and end on the dates determined by the Administrator. The duration and timing of Offering Periods may be changed by the Board or Committee, in its sole discretion. In no event may an Offering Period exceed twenty-seven (27) months.

II.20 "Option" shall mean the right to purchase shares of Common Stock pursuant to the Plan during each Offering Period.

II.21 "Option Price" shall mean the purchase price of a share of Common Stock hereunder as provided in Section 4.2 hereof.

II.22 "Original 2014 Plan" shall have the meaning set forth in Section 1.1 hereof.

II.23 "Parent" means any entity that is a parent corporation of the Company within the meaning of Section 424 of the Code and the Treasury Regulations thereunder.

II.24 "Participant" shall mean any Eligible Employee who elects to participate in the Plan.

II.25 "Payday" shall mean the regular and recurring established day for payment of Compensation to an Employee of the Company or any Designated Subsidiary.

II.26 "Plan" shall have such meaning as set forth in Section 1.1 hereof.

II.27 "Plan Account" shall mean a bookkeeping account established and maintained by the Company in the name of each Participant.

II.28 "Section 423 Option" shall have such meaning as set forth in Section 3.1(b) hereof.

II.29 "Subsidiary" shall mean any entity that is a subsidiary corporation of the Company within the meaning of Section 424 of the Code and the Treasury Regulations thereunder. In addition, with respect to any sub-plans adopted under Section 7.1(d) hereof which are designed to be outside the scope of Section 423 of the Code, Subsidiary shall include any corporate or noncorporate entity in which the Company has a direct or indirect equity interest or significant business relationship.

II.30 "Trading Day" shall mean a day on which the principal securities exchange on which the Common Stock is listed is open for trading or, if the Common Stock is not listed on a securities exchange, shall mean a business day, as determined by the Administrator in good faith.

II.31 "Withdrawal Election" shall have such meaning as set forth in Section 6.1(a) hereof.

ARTICLE III.
PARTICIPATION

III.1 Eligibility.

(a) Any Eligible Employee who shall be employed by the Company or a Designated Subsidiary on a given Enrollment Date for an Offering Period shall be eligible to participate in the Plan during such Offering Period, subject to the requirements of Articles IV and V hereof, and the limitations imposed by Section 423(b) of the Code and the Treasury Regulations thereunder.

(b) No Eligible Employee shall be granted an Option under the Plan which permits the Participant's rights to purchase shares of Common Stock under the Plan, and to purchase stock under all other employee stock purchase plans of the Company, any Parent or any Subsidiary subject to the Section 423 of the Code (any such Option or other option, a "Section 423 Option"), to accrue at a rate which exceeds $25,000 of fair market value of such stock (determined at the time the Section 423 Option is granted) for each calendar year in which any Section 423 Option granted to the Participant is outstanding at any time. For purposes of the limitation imposed by this subsection,

(i) the right to purchase stock under a Section 423 Option accrues when the Section 423 Option (or any portion thereof) first becomes exercisable during the calendar year,

(ii) the right to purchase stock under a Section 423 Option accrues at the rate provided in the Section 423 Option, but in no case may such rate exceed $25,000 of fair market value of such stock (determined at the time such option is granted) for any one calendar year, and

(iii) a right to purchase stock which has accrued under a Section 423 Option may not be carried over to any other Section 423 Option; *provided* that Participants may carry forward amounts so accrued that represent a fractional share of stock and were withheld but not applied towards the purchase of Common Stock under an earlier Offering Period, and may apply such amounts towards the purchase of additional shares of Common Stock under a subsequent Offering Period.

- The limitation under this Section 3.1(b) shall be applied in accordance with Section 423(b)(8) of the Code and the Treasury Regulations thereunder.

III.2 Election to Participate; Payroll Deductions

(a) Except as provided in Section 3.3 hereof, an Eligible Employee may become a Participant in the Plan only by means of payroll deduction. Each individual who

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is an Eligible Employee as of an Offering Period's Enrollment Date may elect to participate in such Offering Period and the Plan by delivering to the Company a payroll deduction authorization no later such period of time prior to the applicable Enrollment Date as determined by the Administrator, in its sole discretion.

(b) Subject to Section 3.1(b) hereof, payroll deductions (i) shall be equal to at least one percent (1%) of the Participant's Compensation as of each Payday of the Offering Period following the Enrollment Date, but not more than the lesser of fifteen percent (15%) of the Participant's Compensation as of each Payday of the Offering Period following the Enrollment Date or $25,000 per Offering Period; and (ii) may be expressed either as (A) a whole number percentage, or (B) a fixed dollar amount. Amounts deducted from a Participant's Compensation with respect to an Offering Period pursuant to this Section 3.2 shall be deducted each Payday through payroll deduction and credited to the Participant's Plan Account.

(c) Following at least one (1) payroll deduction, a Participant may decrease (to as low as zero) the amount deducted from such Participant's Compensation only once during an Offering Period upon ten (10) calendar days' prior written notice to the Company. A Participant may not increase the amount deducted from such Participant's Compensation during an Offering Period.

(d) Notwithstanding the foregoing, upon the termination of an Offering Period, each Participant in such Offering Period shall automatically participate in the immediately following Offering Period at the same payroll deduction percentage or fixed amount as in effect at the termination of the prior Offering Period, unless such Participant delivers to the Company a different election with respect to the successive Offering Period in accordance with Section 3.1(a) hereof, or unless such Participant becomes ineligible for participation in the Plan.

III.3 Leave of Absence. During leaves of absence approved by the Company meeting the requirements of Treasury Regulation Section 1.421-1(h)(2) under the Code, a Participant may continue participation in the Plan by making cash payments to the Company on his or her normal payday equal to his or her authorized payroll deduction.

ARTICLE IV.
PURCHASE OF SHARES

IV.1 Grant of Option. Each Participant shall be granted an Option with respect to an Offering Period on the applicable Grant Date. Subject to the limitations of Section 3.1(b) hereof, the number of shares of Common Stock subject to a Participant's Option shall be determined by dividing (a) such Participant's payroll deductions accumulated prior to such Exercise Date and retained in the Participant's Plan Account on such

Exercise Date by (b) the applicable Option Price; *provided* that in no event shall a Participant be permitted to purchase during each Offering Period more than 3,000 shares of Common Stock (subject to any adjustment pursuant to Section 5.2 hereof). The Administrator may, for future Offering Periods, increase or decrease, in its absolute discretion, the maximum number of shares of Common Stock that a Participant may purchase during such future Offering Periods. Each Option shall expire on the Exercise Date for the applicable Offering Period immediately after the automatic

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exercise of the Option in accordance with Section 4.3 hereof, unless such Option terminates earlier in accordance with Article 6 hereof.

IV.2 Option Price. The "Option Price" per share of Common Stock to be paid by a Participant upon exercise of the Participant's Option on the applicable Exercise Date for an Offering Period shall be equal to eighty five percent (85%) of the lesser of the Fair Market Value of a share of Common Stock on (a) the applicable Grant Date and (b) the applicable Exercise Date; *provided* that in no event shall the Option Price per share of Common Stock be less than the par value per share of the Common Stock.

IV.3 Purchase of Shares.

(a) On the applicable Exercise Date for an Offering Period, each Participant shall automatically and without any action on such Participant's part be deemed to have exercised his or her Option to purchase at the applicable per share Option Price the largest number of whole shares of Common Stock which can be purchased with the amount in the Participant's Plan Account. Any balance less than the per share Option Price that is remaining in the Participant's Plan Account (after exercise of such Participant's Option) as of the Exercise Date shall be carried forward to the next Offering Period, unless the Participant has elected to withdraw from the Plan pursuant to Section 6.1 hereof or, pursuant to Section 6.2 hereof, such Participant has ceased to be an Eligible Employee. Any balance not carried forward to the next Offering Period in accordance with the prior sentence promptly shall be refunded to the applicable Participant. For the avoidance of doubt, in no event shall an amount greater than or equal to the per share Option Price as of an Exercise Date be carried forward to the next Offering Period.

(b) As soon as practicable following the applicable Exercise Date, the number of shares of Common Stock purchased by such Participant pursuant to Section 4.3(a) hereof shall be delivered (either in share certificate or book entry form), in the Company's sole discretion, to either (i) the Participant or (ii) an account established in the Participant's name at a stock brokerage or other financial services firm designated by the Company. If the Company is required to obtain from any commission or agency authority to issue any such shares of Common Stock, the Company shall seek to obtain such authority. Inability of the Company to obtain from any such commission or agency authority which counsel "at will." This means it is for the Company deems necessary for the lawful issuance of any such shares shall relieve the Company from liability to any Participant except to refund to the Participant such Participant's Plan Account balance, without interest thereon.

IV.4 Transferability of Rights.

(a) An Option granted under the Plan shall not no specified term and may be transferable, other than terminated by will you or the applicable laws of descent and distribution, and is exercisable during the Participant's lifetime only by the Participant.No option or interest or right to the Option shall be available to pay off any debts, contracts or engagements of the Participant or his or her successors in interest or shall be subject to disposition by pledge, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by

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judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempt at disposition of the option shall have no effect.

ARTICLE V.
PROVISIONS RELATING TO COMMON STOCK

V.1 Common Stock Reserved. Subject to adjustment as provided in Section 5.2 hereof, the maximum number of shares of Common Stock that shall be made available for sale under the Plan is 5,940,132. Shares of Common Stock made available for sale under the Plan may be authorized but unissued shares, treasury shares of Common Stock, or reacquired shares reserved for issuance under the Plan.

V.2 Adjustments Upon Changes in Capitalization, Dissolution, Liquidation, Merger or Asset Sale.

(a) Changes in Capitalization. Subject to any required action by the stockholders of the Company the number of shares of Common Stock which have been authorized for issuance under the Plan but not yet placed under Option, as well as the price per share and the number of shares of Common Stock covered by each Option under the Plan which has not yet been exercised shall be proportionately adjusted for any increase or decrease in the number of issued shares of Common Stock resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the Common Stock, or any other increase or decrease in the number of shares of Common Stock effected without receipt of consideration by the Company; *provided*, *however*, that conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." Such adjustment shall be made by the Administrator, whose determination in that respect shall be final, binding and conclusive. Except as expressly provided herein, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number or price of shares of Common Stock subject to an Option.

(b) Dissolution or Liquidation. In the event of the proposed dissolution or liquidation of the Company, the Offering Period then in progress shall be shortened by setting a new Exercise Date (the "New Exercise Date"), and shall terminate immediately prior to the consummation of such proposed dissolution or liquidation, unless provided otherwise by the Administrator. The New Exercise Date shall be before the date of the Company's proposed dissolution or liquidation. The Administrator shall notify each Participant in writing, at least ten (10) business days prior to the New Exercise Date, that the Exercise Date for the Participant's Option has been changed to the New Exercise Date and that the Participant's Option shall be exercised automatically on the New Exercise Date, unless prior to such date the Participant has withdrawn from the Offering Period as provided in Section 6.1 hereof.

(c) Merger or Asset Sale. In the event of a proposed sale of all or substantially all of the assets of the Company, or the merger of the Company with or into another corporation, each outstanding Option shall be assumed or an equivalent Option substituted by the successor corporation or a Parent or Subsidiary of the successor corporation. In the event that

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the successor corporation refuses to assume or substitute for the Option, any Offering Periods then in progress shall be shortened by setting a New Exercise Date and any Offering Periods then in progress shall end on the New Exercise Date. The New Exercise Date shall be before the date of the Company's proposed sale or merger. The Administrator shall notify each Participant in writing, at least ten (10) business days prior to the New Exercise Date, that the Exercise Date for the Participant's Option has been changed to the New Exercise Date and that the Participant's Option shall be exercised automatically on the New Exercise Date, unless prior to such date the Participant has withdrawn from the Offering Period as provided in Section 6.1 hereof.

V.3 Insufficient Shares. If the Administrator determines that, on a given Exercise Date, the number of shares of Common Stock with respect to which Options are to be exercised may exceed the number of shares of Common Stock remaining available for sale under the Plan on such Exercise Date, the Administrator shall make a pro rata allocation of the shares of Common Stock available for issuance on such Exercise Date in as uniform a manner as shall be practicable and as it shall determine in its sole discretion to be equitable among all Participants exercising Options to purchase Common Stock on such Exercise Date, and unless additional shares are authorized for issuance under the Plan, no further Offering Periods shall take place and the Plan shall terminate pursuant to Section 7.5 hereof. If an Offering Period is so terminated, then the balance of the amount

credited to the Participant's Plan Account which has not been applied to the purchase of shares of Common Stock shall be paid to such Participant in one lump sum in cash within thirty (30) days after such Exercise Date, without any interest thereon.

V.4 Rights as Stockholders. With respect to shares of Common Stock subject to an Option, a Participant shall not be deemed to be a stockholder of the Company and shall not have any of the rights or privileges of a stockholder. A Participant shall have the rights and privileges of a stockholder of the Company when, but not until, shares of Common Stock have been deposited in the designated brokerage account following exercise of his or her Option.

ARTICLE VI.
TERMINATION OF PARTICIPATION

VI.1 Cessation of Contributions; Voluntary Withdrawal.

(a) A Participant may cease payroll deductions during an Offering Period and elect to withdraw from the Plan by delivering written notice of such election to the Company in such form and at such time prior to the Exercise Date for such Offering Period as may be established by the Administrator (a "Withdrawal Election"). A Participant electing to withdraw from the Plan may elect to either (i) withdraw all of the funds then credited to the Participant's Plan Account as of the date on which the Withdrawal Election is received by the Company, in which case amounts credited to such Plan Account shall be returned to the Participant in one (1) lump-sum payment in cash within thirty (30) days after such election is received by the Company, without any interest thereon, and the Participant shall cease to participate in the Plan and the Participant's Option for such Offering Period shall terminate; or (ii) exercise the Option for the maximum number of whole shares of Common Stock on the applicable Exercise Date with any remaining Plan Account balance returned to the Participant in

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one (1) lump-sum payment in cash within thirty (30) days after such Exercise Date, without any interest thereon, and after such exercise cease to participate in the Plan.Upon receipt of a Withdrawal Election, the Participant's payroll deduction authorization and his or her Option to purchase under the Plan shall terminate.

(b) A participant's withdrawal from the Plan shall not have any effect upon his or her eligibility to participate in any similar plan which may hereafter be adopted by the Company or in succeeding Offering Periods which commence after the termination of the Offering Period from which the Participant withdraws.

(c) A Participant who ceases contributions to the Plan during any Offering Period shall not be permitted to resume contributions to the Plan during that Offering Period.

VI.2 Termination of Eligibility. Upon a Participant's ceasing to be an Eligible Employee, for any reason, such Participant's Option for the applicable Offering Period shall automatically terminate, he or she shall be deemed to have elected to withdraw from the Plan, and such Participant's Plan Account shall be paid to such Participant or, in the case of his or her death, to the person or persons entitled thereto pursuant to applicable law, within thirty (30) days after such cessation of being an Eligible Employee, without any interest thereon.

ARTICLE VII.
GENERAL PROVISIONS

VII.1 Administration.

(a) The Plan shall be administered by the Committee, which shall be composed of members of the Board. The Committee may delegate administrative tasks under the Plan to the services of an Agent and/or Employees to assist in the administration of the Plan, including establishing and maintaining an individual securities account under the Plan for each Participant.

(b) It shall be the duty of the Administrator to conduct the general administration of the Plan in accordance with the provisions of the Plan. The Administrator shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To establish Offering Periods;

(ii) To determine when and how Options shall be granted and the provisions and terms of each Offering Period (which need not be identical);

(iii) To select Designated Subsidiaries in accordance with Section 7.2 hereof; and

(iv) To construe and interpret the Plan, the terms of any Offering Period and the terms of the Options and to adopt such rules for the administration, interpretation, and application of the Plan as are consistent therewith and to interpret, amend or

revoke any such rules. The Administrator, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan, any Offering Period or any Option, in a manner and to the extent it shall deem necessary or expedient to make the Plan fully effect, subject to Section 423 of the Code and the Treasury Regulations thereunder.

(c) The Administrator may adopt rules or procedures relating to the operation and administration of the Plan to accommodate the specific requirements of local laws and procedures. Without limiting the generality of the foregoing, the Administrator is specifically authorized to adopt rules and procedures regarding handling of participation elections, payroll deductions, payment of interest, conversion of local currency, payroll tax, withholding procedures and handling of stock certificates which vary with local requirements. In its absolute discretion, the Board may at any time and from time to time exercise any and all rights and duties of the Administrator under the Plan.

(d) The Administrator may adopt sub-plans applicable to particular Designated Subsidiaries or locations, which sub-plans may be designed to be outside the scope of Section 423 of the Code. The rules of such sub-plans may take precedence over other provisions of this Plan, with the exception of Section 5.1 hereof, but unless otherwise superseded by the terms of such sub-plan, the provisions of this Plan shall govern the operation of such sub-plan.

(e) All expenses and liabilities incurred by the Administrator in connection with the administration of the Plan shall be borne by the Company. The Administrator may, with the approval of the Committee, employ attorneys, consultants, accountants, appraisers, brokers or other persons. The Administrator, the Company and its officers and directors shall be entitled to rely upon the advice, opinions or valuations of any such persons. All actions taken and all interpretations and determinations made by the Administrator in good faith shall be final and binding upon all Participants, the Company and all other interested persons. No member of the Board or Administrator shall be personally liable for any action, determination or interpretation made in good faith with respect to the Plan or the options, and all members of the Board or Administrator shall be fully protected by the Company in respect to any such action, determination, or interpretation.

VII.2 Designation of Subsidiary Corporations. The Board or Committee shall designate from among the Subsidiaries, as determined from time to time, the Subsidiary or Subsidiaries that shall constitute Designated Subsidiaries. The Board or Committee may designate a Subsidiary, or terminate the designation of a Subsidiary, without the approval of the stockholders of the Company.

VII.3 Reports. Individual accounts shall be maintained for each Participant in the Plan. Statements of Plan Accounts shall be given to Participants at least annually, which statements shall set forth the amounts of payroll deductions, the Option Price, the number of shares purchased and the remaining cash balance, if any.

VII.4 No Right to Employment. Nothing in the Plan shall be construed to give any person (including any Participant) the right to remain in the employ of the Company, a Parent or a Subsidiary or to affect the right of the Company, any Parent or any Subsidiary to

terminate the employment of any person (including any Participant) at any time, with or without cause which right is expressly reserved.

VII.5 Amendment and Termination of the Plan.

(a) This Plan shall be effective on the date it is adopted by the Board (the "Effective Date"), *provided*, that the stockholders of the Company approve the Plan within twelve (12) months following the effective date.

(b) The Board may, in its sole discretion, amend, suspend or terminate the Plan at any time and from time to time; *provided*, *however*, that without approval of the Company's stockholders given within twelve (12) months before or after action by the Board, the Plan may not be amended to increase the maximum number of shares of Common Stock notice. In addition, subject to the Plan or change the designation or class of Eligible Employees; and *provided*, *further* that without approval 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 stockholders, standard form of employee nondisclosure and assignment agreement, and to provide the Plan may not Company with documents establishing your identity and right to work in the United States. Those documents must be amended in any manner that would cause provided to the Plan to no longer be an "employee stock purchase plan" Company within the meaning three business days of Section 423(b) of the Code. your employment start date.

(c)

In the event of any dispute or claim relating to or arising out of your employment relationship with the Administrator determines that Company, this agreement, or the ongoing operation termination of your employment with the Plan may result in unfavorable financial accounting consequences, the Administrator may, to the extent permitted under Section 423 of the Code, in its discretion and, to the extent necessary or desirable, modify or amend the Plan to reduce or eliminate such accounting consequence including, Company for any reason (including, but not limited to:

(i) altering 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 Option Price 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 any Offering Period including an Offering Period underway the Resolution of Employment Disputes then in effect, which are available online at the time of the change in Option Price;

(ii) shortening any Offering Period so that the Offering Period ends on a new Exercise Date, including an Offering Period underway AAA's website at the time of the Administrator action; www.adr.org. You and

(iii) allocating shares of Common Stock.

Such modifications or amendments shall not require stockholder approval or the consent of any Participant.

(d) Upon termination of the Plan, the balance in each Participant's Plan Account shall be refunded as soon as practicable after such termination, without any interest thereon.

VII.6 Use of Funds; No Interest Paid. All funds received by the Company by reason of purchase of Common Stock under hereby waive your respective rights to have any such disputes or claims tried before a judge or jury.

This agreement, the Plan shall be included in Severance Agreement and the general funds of non-disclosure, stock option and RSU agreements referred to above constitute the entire agreement between you and the Company free of any trust or other restriction and may be used for any corporate purpose. No interest shall be paid to any Participant or credited under the Plan.

VII.7 Term; Approval by Stockholders. No Option may be granted during any period of suspension of the Plan or after termination of the Plan. The Plan shall be submitted for

the approval of the Company's stockholders within twelve (12) months after the date of the Board's initial adoption of the Plan. Options may be granted prior to such stockholder approval; *provided*, *however*, that such Options shall not be exercisable prior to the time when the Plan is approved by the stockholders; *provided*, *further* that if such approval has not been obtained by the end of said twelve (12)-month period, all Options previously granted under the Plan shall thereupon terminate and be canceled and become null and void without being exercised.

VII.8 Effect Upon Other Plans. The adoption of the Plan shall not affect any other compensation or incentive plans in effect for the Company, any Parent or any Subsidiary. Nothing in the Plan shall be construed to limit the right of the Company, any Parent or any Subsidiary (a) to establish any other forms of incentives or compensation for Employees of the Company or any Parent or any Subsidiary, or (b) to grant or assume Options otherwise than under the Plan in connection with any proper corporate purpose, including, but not by way of limitation, the grant or assumption of options in connection with the acquisition, by purchase, lease, merger, consolidation or otherwise, of the business, stock or assets of any corporation, firm or association.

VII.9 Conformity to Securities Laws. Notwithstanding any other provision of the Plan, the Plan and the participation in the Plan by any individual who is then subject to Section 16 of the Exchange Act shall be subject to any additional limitations set forth in any applicable exemption rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by applicable law, the Plan shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

VII.10 Notice of Disposition of Shares. Each Participant shall give the Company prompt notice of any disposition or other transfer of any shares of Common Stock, acquired pursuant to the exercise of an Option, if such disposition or transfer is made (a) within two (2) years after the applicable Grant Date or (b) within one (1) year after the transfer of such shares of Common Stock to such Participant upon exercise of such Option. The Company may direct that any certificates evidencing shares acquired pursuant to the Plan refer to such requirement.

VII.11 Tax Withholding. The Company or any Parent or any Subsidiary shall be entitled to require payment in cash or deduction from other compensation payable to each Participant of any sums required by federal, state or local tax law to be withheld with respect to any purchase of shares of Common Stock under the Plan or any sale of such shares.

VII.12 Governing Law. The Plan and all rights and obligations thereunder shall be construed and enforced in accordance with the laws of the State of Delaware.

VII.13 Notices. All notices or other communications by a participant to the Company under or in connection with the Plan shall be deemed to have been duly given when received in the form specified by the Company at the location, or by the person, designated by the Company for the receipt thereof.

VII.14 Conditions To Issuance of Shares.

(a) Notwithstanding anything herein to the contrary, the Company shall not be required to issue or deliver any certificates or make any book entries evidencing shares of Common Stock pursuant to the exercise of an Option by a Participant, unless and until the Board or the Committee has determined, with advice of counsel, that the issuance of such shares of Common Stock is in compliance with all applicable laws, regulations of governmental authorities and, if applicable, the requirements of any securities exchange or automated quotation system on which the shares of Common Stock are listed or traded, and the shares of Common Stock are covered by an effective registration statement or applicable exemption from registration. In addition to regarding the terms and conditions provided herein, the Board of your employment, and they supersede all prior or the Committee may require that a Participant make such reasonable covenants, contemporaneous negotiations, representations or agreements and representations as the Board or the Committee, in its discretion, deems advisable in order to comply with any such laws, regulations, or requirements.

(b) All certificates for shares of Common Stock delivered pursuant to the Plan and all shares of Common Stock issued pursuant to book entry procedures are subject to any stop-transfer orders and other restrictions as the Committee deems necessary or advisable to comply with federal, state, or foreign securities or other laws, rules and regulations between you and the rules Company. The provisions of any securities exchange or automated quotation system on which the shares of Common Stock are listed, quoted, or traded. The Committee this

agreement regarding “at will” employment and arbitration may place legends on any certificate or book entry evidencing shares of Common Stock to reference restrictions applicable to the shares of Common Stock.

(c) The Committee shall have the right to require any Participant to comply with any timing or other restrictions with respect to the settlement, distribution or exercise of any Option, including only be modified by a window-period limitation, as may be imposed in the sole discretion document signed by you and an authorized representative of the Committee.Company.

(d) Notwithstanding any other provision Please sign and date this letter on the spaces provided below to acknowledge your acceptance of the Plan, unless otherwise determined by terms of this agreement on or before Monday, July 29, 2024.

Eric, we look forward to having you join the Committee or required by any applicable law, rule or regulation, 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 may, in lieu of delivering to any Participant certificates evidencing shares of Common Stock issued in connection with any Option, record the issuance of shares of Common Stock in the books of the Company (or, as applicable, its transfer agent or stock plan administrator). is at-will.

Date: July 26, 2024 /s/ Eric Foster

VII.15 Equal Rights and Privileges. Except with respect to sub-plans designed to be outside the scope of Section 423 of the Code, all Eligible Employees of the Company (or of any Designated Subsidiary) shall have equal rights and privileges under this Plan to the extent required under Section 423 of the Code or the regulations promulgated thereunder so that this Plan qualifies as an “employee stock purchase plan” within the meaning of Section 423 of the Code or the Treasury Regulations thereunder. Any provision of this Plan that is inconsistent with Section 423 of the Code or the Treasury Regulations thereunder shall, without further act or amendment by the Company or the Board, be reformed to comply with the equal rights and privileges requirement of Section 423 of the Code or the Treasury Regulations thereunder.

****** 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: August 1, 2024 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: August 1, 2024 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 June 30, 2024 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: August 1, 2024 October 31, 2024

By: /s/ Michael Raab

Michael Raab
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 1, 2024 October 31, 2024

By: /s/ Justin Renz

Justin Renz
Chief Financial & Operations Officer
(Principal Financial Officer)

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