

**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 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

(State or Other Jurisdiction of Incorporation or Organization)

400 Fifth Avenue , Suite 210 , Waltham , Massachusetts

(Address of Principal Executive Offices)

26-1303944

(I.R.S. Employer Identification No)

02451

(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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, was 235,428,183 .

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 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);
- 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 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 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.
 - 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 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.

	<u>PAGE</u>
 <u>PART I. FINANCIAL INFORMATION</u>	
Item 1. Financial Statements:	2
Condensed Balance Sheets (unaudited)	2
Condensed Statements of Operations and Comprehensive Loss (unaudited)	3
Condensed Statements of Changes in Stockholders' Equity (unaudited)	4
Condensed Statements of Cash Flows (unaudited)	6
Notes to Condensed Financial Statements (unaudited)	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3. Quantitative and Qualitative Disclosures About Market Risk	30
Item 4. Controls and Procedures	31
 <u>PART II. OTHER INFORMATION</u>	
Item 1. Legal Proceedings	32
Item 1A. Risk Factors	32
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	69
Item 3. Defaults Upon Senior Securities	70
Item 4. Mine Safety Disclosures	70
Item 5. Other Information	70
Item 6. Exhibits	71
Signatures	72

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
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 41,890	\$ 21,470
Short-term investments	144,071	162,829
Accounts receivable	37,241	22,031
Inventory	13,756	12,448
Prepaid commercial manufacturing	14,797	18,925
Prepaid expenses and other current assets	11,265	8,408
Total current assets	263,020	246,111
Inventory, non-current	69,676	37,039
Prepaid commercial manufacturing, non-current	—	4,235
Right-of-use assets	4,324	5,589
Property and equipment, net	1,016	1,009
Other assets	5,452	3,596
Total assets	\$ 343,488	\$ 297,579
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 10,881	\$ 11,138
Accrued compensation and benefits	10,458	12,597
Current portion of operating lease liability	3,550	4,435
Deferred revenue	10,829	7,182
Accrued expenses and other current liabilities	26,718	15,041
Total current liabilities	62,436	50,393
Operating lease liability, net of current portion	1,096	1,725
Long-term debt	100,249	49,822
Deferred revenue, non-current	9,613	8,644
Deferred royalty obligation related to the sale of future royalties	23,104	20,179
Total liabilities	196,498	130,763
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	23	23
Additional paid-in capital	1,036,244	1,012,773
Accumulated deficit	(889,176)	(846,204)
Accumulated other comprehensive (loss) income	(101)	224
Total stockholders' equity	146,990	166,816
Total liabilities and stockholders' equity	\$ 343,488	\$ 297,579

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Product sales, net	\$ 72,591	\$ 18,309	\$ 116,103	\$ 29,664
Product supply revenue	13	3,260	2,139	3,262
Licensing revenue	19	764	36	776
Non-cash royalty revenue related to the sale of future royalties	599	—	967	—
Total revenues	73,222	22,333	119,245	33,702
Cost of goods sold:				
Cost of product sales	1,405	492	2,418	864
Other cost of revenue	8,031	2,997	14,146	4,162
Total cost of goods sold	9,436	3,489	16,564	5,026
Operating expenses:				
Research and development	12,762	8,282	23,341	17,375
Selling, general and administrative	64,654	27,186	117,648	53,989
Total operating expenses	77,416	35,468	140,989	71,364
Loss from operations	(13,630)	(16,624)	(38,308)	(42,688)
Interest expense	(3,326)	(1,075)	(5,682)	(2,103)
Non-cash interest expense related to the sale of future royalties	(1,576)	(968)	(3,278)	(1,937)
Other income, net	2,145	1,546	4,484	2,848
Loss before provision for income taxes	(16,387)	(17,121)	(42,784)	(43,880)
Provision for income taxes	67	—	188	14
Net loss	\$ (16,454)	\$ (17,121)	\$ (42,972)	\$ (43,894)
Net loss per share of common stock - basic and diluted	\$ (0.07)	\$ (0.08)	\$ (0.18)	\$ (0.21)
Shares used in computing net loss per share - basic and diluted	234,571,192	214,951,127	233,818,576	211,009,029
Comprehensive loss:				
Net loss	\$ (16,454)	\$ (17,121)	\$ (42,972)	\$ (43,894)
Unrealized losses on available-for-sale securities	(81)	(190)	(325)	(156)
Comprehensive loss	\$ (16,535)	\$ (17,311)	\$ (43,297)	\$ (44,050)

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

Three Months Ended June 30, 2024						
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of March 31, 2024	233,959,744	\$ 23	\$ 1,023,610	\$ (872,722)	\$ (20)	\$ 150,891
Issuance of common stock for services	40,549	—	257	—	—	257
Issuance of common stock upon exercise of options	862,691	—	1,608	—	—	1,608
Issuance of common stock upon vesting of restricted stock units	538,414	—	—	—	—	—
Stock-based compensation	—	—	10,769	—	—	10,769
Unrealized losses on available-for-sale securities	—	—	—	—	(81)	(81)
Net loss	—	—	—	(16,454)	—	(16,454)
Balance as of June 30, 2024	<u>235,401,398</u>	<u>\$ 23</u>	<u>\$ 1,036,244</u>	<u>\$ (889,176)</u>	<u>\$ (101)</u>	<u>\$ 146,990</u>

Six Months Ended June 30, 2024						
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2023	232,453,190	\$ 23	\$ 1,012,773	\$ (846,204)	\$ 224	\$ 166,816
Issuance of common stock under employee stock purchase plan	253,312	—	1,038	—	—	1,038
Issuance of common stock for services	40,549	—	257	—	—	257
Issuance of common stock upon exercise of options	1,564,269	—	3,791	—	—	3,791
Issuance of common stock upon vesting of restricted stock units	1,090,078	—	—	—	—	—
Stock-based compensation	—	—	18,385	—	—	18,385
Unrealized losses on available-for-sale securities	—	—	—	—	(325)	(325)
Net loss	—	—	—	(42,972)	—	(42,972)
Balance as of June 30, 2024	<u>235,401,398</u>	<u>\$ 23</u>	<u>\$ 1,036,244</u>	<u>\$ (889,176)</u>	<u>\$ (101)</u>	<u>\$ 146,990</u>

	Three Months Ended June 30, 2023					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of March 31, 2023	214,462,050	\$ 21	\$ 932,330	\$ (806,910)	\$ (20)	\$ 125,421
Issuance of common stock for services	86,095	—	337	—	—	337
Issuance of common stock upon exercise of options	62,993	—	149	—	—	149
Issuance of common stock upon vesting of restricted stock units	215,301	—	—	—	—	—
Issuance of common stock in at-the-market offerings	3,036,482	1	11,365	—	—	11,366
Stock-based compensation	—	—	3,199	—	—	3,199
Unrealized losses on available-for-sale securities	—	—	—	—	(190)	(190)
Net loss	—	—	—	(17,121)	—	(17,121)
Balance as of June 30, 2023	<u>217,862,921</u>	<u>\$ 22</u>	<u>\$ 947,380</u>	<u>\$ (824,031)</u>	<u>\$ (210)</u>	<u>\$ 123,161</u>

	Six Months Ended June 30, 2023					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2022	198,575,016	\$ 20	\$ 878,500	\$ (780,137)	\$ (54)	\$ 98,329
Issuance of common stock under employee stock purchase plan	165,969	—	138	—	—	138
Issuance of common stock for services	86,095	—	337	—	—	337
Issuance of common stock upon exercise of options	98,994	—	211	—	—	211
Issuance of common stock upon vesting of restricted stock units	423,074	—	—	—	—	—
Issuance of common stock in at-the-market offerings	18,513,773	2	62,083	—	—	62,085
Stock-based compensation	—	—	6,111	—	—	6,111
Unrealized losses on available-for-sale securities	—	—	—	—	(156)	(156)
Net loss	—	—	—	(43,894)	—	(43,894)
Balance as of June 30, 2023	<u>217,862,921</u>	<u>\$ 22</u>	<u>\$ 947,380</u>	<u>\$ (824,031)</u>	<u>\$ (210)</u>	<u>\$ 123,161</u>

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,	
	2024	2023
Operating activities		
Net loss	\$ (42,972)	\$ (43,894)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,004	639
Non-cash lease expense	1,953	1,821
Stock-based compensation	18,385	6,111
Non-cash interest expense	3,411	2,090
Non-cash royalty revenue related to the sale of future royalties	(967)	—
Other, net	(2,483)	(521)
Changes in operating assets and liabilities:		
Accounts receivable	(15,210)	(1,376)
Inventory	(33,945)	(19,566)
Prepaid commercial manufacturing	8,363	401
Prepaid expenses and other assets	(4,626)	817
Accounts payable	(257)	(5,565)
Accrued compensation and benefits	(2,139)	(668)
Operating lease liabilities	(2,200)	(1,892)
Accrued and other liabilities	11,947	110
Deferred revenue	4,616	1,961
Net cash used in operating activities	(55,120)	(59,532)
Investing activities		
Proceeds from maturities and redemptions of investments	78,112	19,250
Purchases of investments	(56,870)	(88,127)
Purchases of property and equipment	(281)	(107)
Net cash provided by (used in) investing activities	20,961	(68,984)
Financing activities		
Proceeds from 2022 Loan Agreement, net of issuance costs	49,750	—
Proceeds from issuance of common stock in at the market offering, net of issuance costs	—	62,085
Proceeds from issuance of common stock under equity incentive and stock purchase plans	4,829	349
Net cash provided by financing activities	54,579	62,434
Net increase (decrease) in cash and cash equivalents	20,420	(66,082)
Cash and cash equivalents at beginning of period	21,470	96,140
Cash and cash equivalents at end of period	\$ 41,890	\$ 30,058
Supplementary disclosure of cash flow information:		
Cash paid for interest	\$ 4,034	\$ 1,757
Cash paid for income taxes	\$ 272	\$ 19
Supplementary disclosure of non-cash activities:		
Right-of-use assets obtained in exchange for lease obligations	\$ 689	\$ —
Issuance of common stock for services	\$ 257	\$ 337

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

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

NOTE 1. ORGANIZATION AND BASIS OF PRESENTATION

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

	June 30, 2024			
	Amortized Cost	Gross Unrealized		Fair Value
		Gains	Losses	
Cash and cash equivalents:				
Cash	\$ 5,834	\$ —	\$ —	\$ 5,834
Money market funds	36,056	—	—	36,056
Total cash and cash equivalents	41,890	—	—	41,890
Short-term investments:				
U.S. government-sponsored agency bonds	\$ 98,350	\$ —	\$ (60)	\$ 98,290
Commercial paper	42,074	4	(44)	42,034
Asset-backed securities	3,748	—	(1)	3,747
Total short-term investments	144,172	4	(105)	144,071
Total cash, cash equivalents and investments	\$ 186,062	\$ 4	\$ (105)	\$ 185,961

	December 31, 2023			
	Amortized Cost	Gross Unrealized		Fair Value
		Gains	Losses	
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 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.

All of the short-term available-for sale securities held as of June 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 to its fair value and establish that value as a new cost basis for the investment. Our unrealized losses as of June 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 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			
	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	\$ 36,056	\$ 36,056	\$ —	\$ —
U.S. government-sponsored agency bonds	98,290	—	98,290	—
Commercial paper	42,034	—	42,034	—
Asset-backed securities	3,747	—	3,747	—
Total	<u>\$ 180,127</u>	<u>\$ 36,056</u>	<u>\$ 144,071</u>	<u>\$ —</u>

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 asset-backed securities 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 conditions for payment of the 2022 Exit Fee were met and it was therefore valued at its full contractual amount as there were no unobservable inputs.

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 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 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 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 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 and December 31, 2023 consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Raw materials	\$ 25,915	\$ 22,920
Work in process	55,136	24,582
Finished goods	2,381	1,985
Total	<u>\$ 83,432</u>	<u>\$ 49,487</u>
Reported as:		
Inventory	\$ 13,756	\$ 12,448
Inventory, non-current	69,676	37,039
Total	<u>\$ 83,432</u>	<u>\$ 49,487</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Product sales, net:				
IBSRELA	\$ 35,445	\$ 18,309	\$ 63,806	\$ 29,664
XPHOZAH	37,146	—	52,297	—
Total product sales, net	72,591	18,309	116,103	29,664
Product supply revenue	13	3,260	2,139	3,262
Licensing revenue	19	764	36	776
Non-cash royalty revenue related to the sale of future royalties	599	—	967	—
Total revenues	<u>\$ 73,222</u>	<u>\$ 22,333</u>	<u>\$ 119,245</u>	<u>\$ 33,702</u>

Revenue from Customers who contributed greater than 10% of our total gross product revenue during the three and six months ended June 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,	
	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 %

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

	Discounts and Chargebacks	Rebates, Wholesaler and GPO Fees	Copay and Returns	Total
Balance as of December 31, 2023	\$ 478	\$ 4,234	\$ 3,916	\$ 8,628
Provisions	5,928	24,938	13,258	44,124
Credits/payments	(5,473)	(19,334)	(10,265)	(35,072)
Balance as of June 30, 2024	<u>\$ 933</u>	<u>\$ 9,838</u>	<u>\$ 6,909</u>	<u>\$ 17,680</u>

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. We may also be eligible to receive approximately ¥ 8.5 billion for commercialization milestones, or approximately \$ 52.8 million at the currency exchange rate on June 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.

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.

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 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 months ended June 30, 2024, we recognized \$ 0.6 million and \$ 1.0 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 months ended June 30, 2024, we recognized \$ 13 thousand and \$ 2.1 million, respectively, of product supply revenue pursuant to the 2017 Kyowa Kirin Agreement. During the three and six months ended June 30, 2023, we recognized \$ 3.3 million 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, 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.

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 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 months ended June 30, 2024 and 2023, we did not recognize a material amount of 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 at the currency exchange rate on June 30, 2024, of which \$ 0.7 million has been received and recognized as revenue as of June 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.

During the three and six months ended June 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, to date in aggregate, we have recognized \$ 40.2 million of the \$ 75.0 million, which has been recorded as other cost of revenue on our condensed statements of operations and comprehensive loss. During the three and six months ended June 30, 2024, we recognized \$ 7.9 million and \$ 12.6 million, respectively, as other cost of revenue related to the AstraZeneca Termination Agreement. During the three and six months ended June 30, 2023 we recognized \$ 1.9 million and \$ 3.0 million, respectively, as other cost of revenue related to the AstraZeneca Termination Agreement.

Deferred Revenue

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

	2024		2023	
	Current	Non-Current	Current	Non-Current
Balance at January 1,	\$ 7,182	\$ 8,644	\$ 4,211	\$ 9,025
Amounts invoiced as prepayments for product supply	731	5,213	816	3,478
Decrease for revenue recognized for product supply	(1,328)	—	(2,333)	—
Reclassify amounts to be recognized in the next twelve months	4,244	(4,244)	3,265	(3,265)
Balance at June 30,	\$ 10,829	\$ 9,613	\$ 5,959	\$ 9,238

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, our effective interest rate used to amortize the liability is 28.8 %. During the three and six months ended June 30, 2024, we recognized \$ 1.6 million and \$ 3.3 million, respectively, of non-cash interest expense related to the deferred royalty obligation. During the three and six months ended June 30, 2023, we recognized \$ 1.0 million and \$ 1.9 million, respectively, of non-cash interest expense related to the deferred royalty obligation. As of June 30, 2024, we have received \$ 0.4 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), 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). We concluded that the First Amendment and the Second Amendment were 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 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). 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 Third Amendment was a modification to the 2022 Original Loan Agreement.

Under the Third Amendment, the maturity date for the Four 2022 Loans is March 1, 2027. 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 %.

In addition, pursuant to the Third Amendment, the period under which we are permitted to make interest-only payments on the Four 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.

We were obligated to pay \$ 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. In addition, we will be obligated to pay 0.5 % of the aggregate original principal amount of the Term D 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 Loan, (2) if we request 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 the Term C Loan on or prior to the date immediately preceding the amortization date.

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

We may voluntarily prepay all amounts outstanding under the Four 2022 Loans, subject to a prepayment premium of (i) 3 % of the outstanding principal amount of the Four 2022 Loans if prepaid prior to or on October 17, 2024, (ii) 2 % of the outstanding principal amount of the Four 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 2022 Loans if prepaid after October 17, 2025 and prior to the maturity date. The Four 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, the 2022 Exit Fee will expire 10 years from the Closing Date.

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 2022 Term Loan balance 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 2022 Loan balance.

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 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 due to principal repayments beginning in January 2027. We have concluded that the provisions that could cause acceleration of the principal repayments are remote.

As of June 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)
Less: Unaccreted value of final fee		(3,654)
Long-term debt		100,249
Less: Current portion of long-term debt		—
Long-term debt, net of current portion	\$	100,249

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) 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 recorded as a derivative liability and included in accrued expenses and other current liabilities on the accompanying condensed balance sheets. During the three months ended June 30, 2024, we achieved the Revenue Milestone and therefore expect to pay the \$ 1.0 million 2022 Exit Fee to the Agent. As of June 30, 2024 and December 31, 2023, the estimated fair value of the 2022 Exit Fee was \$ 1.0 million and \$ 0.7 million, respectively.

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, 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 and were as follows for the six months ended June 30, 2024 and 2023 (in thousands):

	2024	2023
Fair value of exit fee derivative liabilities at January 1,	\$ 675	\$ 1,656
Changes in estimated fair value:		
2018 Exit Fee	—	78
2022 Exit Fee	325	3
Fair value of exit fee derivative liabilities at June 30,	<u>\$ 1,000</u>	<u>\$ 1,737</u>

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	June 30, 2024	December 31, 2023
Right-of-use assets	\$ 4,324	\$ 5,589
Current portion of lease liabilities	3,550	4,435
Operating lease liability, net of current portion	1,096	1,725
Total lease liabilities	<u>\$ 4,646</u>	<u>\$ 6,160</u>
Weighted-average remaining life (years)	1.4	1.6
Weighted-average discount rate	6.7 %	6.8 %

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating lease expense	\$ 1,091	\$ 1,064	\$ 2,137	\$ 2,128
Cash paid for operating lease	\$ 1,221	\$ 1,100	\$ 2,386	\$ 2,198

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

Remainder of 2024	\$ 2,487
2025	1,663
2026	604
2027	117
Thereafter	—
Total undiscounted operating lease payments	4,871
Imputed interest expenses	(225)
Total operating lease liabilities	4,646
Less: Current portion of operating lease liability	(3,550)
Operating lease liability, net of current portion	\$ 1,096

NOTE 11. STOCKHOLDERS' EQUITY

At-the-Market Offering Agreements

In July 2020, we filed a 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 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 months ended June 30, 2024 we completed no sales pursuant to the 2023 Open Market Sales Agreement. As of June 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, as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Selling, general and administrative	\$ 8,460	\$ 2,303	\$ 14,106	\$ 4,391
Research and development	2,309	896	4,279	1,720
Total	<u>\$ 10,769</u>	<u>\$ 3,199</u>	<u>\$ 18,385</u>	<u>\$ 6,111</u>

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

	Unrecognized Compensation Expense	Average Remaining Vesting Period (Years)
Stock option grants	\$ 59,511	2.9
RSU grants	\$ 50,934	3.2
ESPP	\$ 204	0.2

Stock Options

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

	Number of Shares	Weighted-Average Exercise Price per Share
Balance at December 31, 2023	22,168	\$ 4.20
Options granted	7,470	\$ 8.39
Options exercised	(1,564)	\$ 2.42
Options forfeited or canceled	(307)	\$ 4.87
Balance at June 30, 2024	<u>27,767</u>	<u>\$ 5.42</u>
Exercisable at June 30, 2024	<u>13,276</u>	<u>\$ 5.43</u>

Restricted Stock Units

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

	Number of RSUs	Weighted-Average Grant Date Fair Value Per Share
Non-vested restricted stock units at December 31, 2023	3,646	\$ 3.09
Granted	5,549	\$ 8.66
Vested	(1,090)	\$ 5.72
Forfeited	(139)	\$ 4.60
Non-vested restricted stock units at June 30, 2024	<u>7,966</u>	<u>\$ 6.58</u>

Employee Stock Purchase Plan

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

Basic net loss per share is calculated by dividing net 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 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 months ended June 30, 2024 and 2023, all potential common shares were determined to be anti-dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
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	<u>\$ (0.07)</u>	<u>\$ (0.08)</u>	<u>\$ (0.18)</u>	<u>\$ (0.21)</u>

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,	
	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	<u>35,957</u>	<u>23,945</u>	<u>34,944</u>	<u>23,471</u>

NOTE 14. CONTINGENCIES

On July 30 and August 12, 2021, two putative securities class action lawsuits were commenced in the U.S. District Court for the Northern District of California naming as defendants Ardelyx and two current officers captioned *Strezsak v. Ardelyx, Inc., et al.*, Case No. 4:21-cv-05868-HSG, and *Siegel v. Ardelyx, Inc., et al.*, Case No. 5:21-cv-06228-HSG (together, the Securities Class Actions). The complaints allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 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 on the motion to dismiss is currently set for October 3, 2024. 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 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. 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 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 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.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. As of June 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.

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 approved by 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, we had an accumulated deficit of \$889.2 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 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 license fees, milestones and product supply revenue, funds from our loan agreement with SLR Investment Corp. (SLR), as amended on August 1, 2022, February 9, 2023 and October 17, 2023 (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, a first-in-class, U.S. FDA approved, sodium hydrogen exchange 3 (NHE3) inhibitor 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 a market-responsive commercial strategy and built a commercial organization highly experienced in launching 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, 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 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. 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. 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, received approval from the U.S. FDA to market XPHOZAH 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, 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); Sucroferri 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 Unicivce 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.

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) 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 million at the currency exchange rate on June 30, 2024, of which \$0.7 million has been received and recognized as revenue as of June 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. We may also be eligible to receive approximately ¥8.5 billion for commercialization milestones, or approximately \$52.8 million at the currency exchange rate on June 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, 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 months ended June 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 the inclusion of XPHOZAH, along with other oral ESRD-related drugs without an injectable or intravenous equivalent, in the ESRD PPS or 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 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, as well as payments due to AstraZeneca AB (AstraZeneca) based on sales of tenapanor. We capitalize 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 months ended June 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 months ended June 30, 2024 would have been \$1.2 million and \$2.4 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 months ended June 30, 2023 would have been \$2.0 million and \$2.4 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 and December 31, 2023, we had approximately \$19.6 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 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 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 months ended June 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	
	2024	2023	\$	%	2024	2023	\$	%
Product sales, net	\$ 72,591	\$ 18,309	\$ 54,282	296 %	\$ 116,103	\$ 29,664	\$ 86,439	291 %
Product supply revenue	13	3,260	(3,247)	(100)%	2,139	3,262	(1,123)	(34)%
Licensing revenue	19	764	(745)	(98)%	36	776	(740)	(95)%
Non-cash royalty revenue related to the sale of future royalties	599	—	599	(a)	967	—	967	(a)
Total revenues	<u>\$ 73,222</u>	<u>\$ 22,333</u>	<u>\$ 50,889</u>	228 %	<u>\$ 119,245</u>	<u>\$ 33,702</u>	<u>\$ 85,543</u>	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 %
XPHOZAH	37,146	—	37,146	(a)	52,297	—	52,297	(a)
Total product sales, net	<u>\$ 72,591</u>	<u>\$ 18,309</u>	<u>\$ 54,282</u>	296 %	<u>\$ 116,103</u>	<u>\$ 29,664</u>	<u>\$ 86,439</u>	291 %

(a) Percent change is not meaningful.

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

The decrease in licensing revenue during the three and six months ended June 30, 2024 as compared to the same periods in 2023 is primarily attributable to a one-time upfront payment we received from METiS Therapeutics Inc. during the prior year.

Non-cash royalty revenue during the three and six months ended June 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	
	2024	2023	\$	%	2024	2023	\$	%
Cost of product sales	\$ 1,405	\$ 492	\$ 913	186 %	\$ 2,418	\$ 864	\$ 1,554	180 %
Other cost of revenue	8,031	2,997	5,034	168 %	14,146	4,162	9,984	240 %
Total cost of goods sold	<u>\$ 9,436</u>	<u>\$ 3,489</u>	<u>\$ 5,947</u>	<u>170 %</u>	<u>\$ 16,564</u>	<u>\$ 5,026</u>	<u>\$ 11,538</u>	<u>230 %</u>

The increase to cost of product sales during the three and six months ended June 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 months ended June 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 cost of goods sold for decreased 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	
	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	<u>\$ 77,416</u>	<u>\$ 35,468</u>	<u>\$ 41,948</u>	<u>118 %</u>	<u>\$ 140,989</u>	<u>\$ 71,364</u>	<u>\$ 69,625</u>	<u>98 %</u>

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

The increase in our R&D expenses during the three and six months ended June 30, 2024 as compared to the same periods in 2023 is primarily the result of increased engagement with the scientific communities in the areas of gastroenterology and nephrology, 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 and \$2.6 million, respectively, during the three and six months ended June 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 months ended June 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 and \$9.7 million, respectively, during the three and six months ended June 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	
	2024	2023	\$	%	2024	2023	\$	%
Interest expense	\$ (3,326)	\$ (1,075)	\$ (2,251)	209 %	\$ (5,682)	\$ (2,103)	\$ (3,579)	170 %

The increase in interest expense during the three and six months ended June 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	
	2024	2023	\$	%	2024	2023	\$	%
Non-cash interest expense related to the sale of future royalties	\$ (1,576)	\$ (968)	\$ (608)	63 %	\$ (3,278)	\$ (1,937)	\$ (1,341)	69 %

The increase in non-cash interest expense related to the sales of future royalties during the three and six months ended June 30, 2024 as compared to the same periods in 2023 is due to a higher 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	
	2024	2023	\$	%	2024	2023	\$	%
Other income, net	\$ 2,145	\$ 1,546	\$ 599	39 %	\$ 4,484	\$ 2,848	\$ 1,636	57 %

The increase in other income, net during the three and six months ended June 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 %
Cash and cash equivalents	\$ 41,890	\$ 21,470	\$ 20,420	95 %
Short-term investments	144,071	162,829	(18,758)	(12) %
Total liquid funds	\$ 185,961	\$ 184,299	\$ 1,662	1 %

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

In January 2023, we filed a registration statement of 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 and 2023, we completed no sales pursuant to the 2023 Open Market Sales Agreement. As of June 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 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) 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 of committed capital by March 15, 2024 (the Term C Loan); (2) provides us with the option to draw up to an additional \$50.0 million of uncommitted capital, subject to approval by the 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.

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 is \$889.2 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 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 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 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	
	2024	2023	\$	%
Net cash used in operating activities	\$ (55,120)	\$ (59,532)	\$ 4,412	(7)%
Net cash provided by (used in) investing activities	20,961	(68,984)	89,945	(130)%
Net cash provided by financing activities	54,579	62,434	(7,855)	(13)%
Net increase (decrease) in cash and cash equivalents	<u>\$ 20,420</u>	<u>\$ (66,082)</u>	<u>\$ 86,502</u>	<u>(131)%</u>

Cash Flows from Operating Activities

Net cash used in operating activities during the six months ended June 30, 2024 decreased by \$4.4 million as compared to the same period in 2023 primarily due to adjustments to reconcile net loss to net cash used in operating activities such as stock-based compensation, as well as changes in our operating assets and liabilities.

Cash Flows from Investing Activities

Net cash provided investing activities during the six months ended June 30, 2024 increased by \$89.9 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 months ended June 30, 2024 decreased by \$7.9 million as compared to the same period in 2023 primarily due to the receipt of \$62.1 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 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, we had cash, cash equivalents and short-term investments of \$186.0 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 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 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 million for the six months ended June 30, 2024. As of June 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, 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. 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, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the six months ended June 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 on the motion to dismiss is currently set for October 3, 2024. 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 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. 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 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.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. As of June 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.

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 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, we had an accumulated deficit of \$889.2 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 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 or judicial action is taken to further delay 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 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 XPHOZAH, 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.

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 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. 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 IBSRELA 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 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 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 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 in the future, we may not be able to sustain profitability in subsequent periods. 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 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 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 manner in which, XPHOZAH and other oral ESRD-related drugs without an injectable or intravenous equivalent are bundled into the ESRD PPS, including the length of any applicable TDAPA period, and the amount of the

add-on 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;

- 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 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 Medicare 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 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 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 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 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 XPHOZAH will continue to be paid for 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, 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 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 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, and on August 1, 2022, February 9, 2023 and October 17, 2023, we entered into amendments to the loan and security agreement (collectively, the 2022 Loan Agreement). The loan was funded in the amount of \$27.5 million on February 23, 2022 and additional amounts of \$22.5 million and \$50.0 million were drawn on October 19, 2023, and March 1, 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. 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.

We are permitted to make interest only payments on the loan facility through December 31, 2026, with principal repayments commencing on January 1, 2027. 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) 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 XPHOZAH. 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 the inclusion of oral only drugs in the ESRD PPS is not taken, XPHOZAH will become part of the ESRD PPS on January 1, 2025, and will no longer be covered under Medicare Part D, and as a result the revenue that we may generate on sales of XPHOZAH will be negatively and materially impacted*” above.

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

- the success or lack of success with regards to our commercialization of IBSRELA and XPHOZAH;
- results of regulatory inspections of our facilities or those of our CMOs, or specific label restrictions or patient populations for XPHOZAH's use, or changes or delays in the regulatory review process;
- announcements regarding whether XPHOZAH alone or with other oral only medications, will be included in the ESRD PPS, and the time and manner in which such transition is achieved;
- announcements relating to our current or future collaboration partnerships;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our product label, our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our approved products or our product candidates;
- the success of our testing and clinical trials;
- failure to meet any of our projected timelines or goals with regard to the commercialization of IBSRELA and XPHOZAH, 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, 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 , Chief Development 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 4, 2024	X		339,501	January 13, 2025
*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

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

By: /s/ Robert Felsch

Robert Felsch

Senior Vice President and Chief Accounting Officer

(Principal Accounting Officer)

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

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 “Plan”) is to promote the success and enhance the value of Ardelyx, Inc. (the “Company”) by linking the individual interests 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* and the Original 2014 Plan shall continue in effect in accordance with its terms.

ARTICLE 2.

DEFINITIONS AND CONSTRUCTION

Wherever the following terms are used in the Plan they shall have the meanings specified below, unless the context clearly indicates otherwise. The singular pronoun shall include the plural where the context so indicates.

2.1 “Administrator” 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 one or more persons pursuant to Section 12.6 hereof, or as to which 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.

2.2 “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 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, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within 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

(b) During any period of two consecutive years, individuals who, at 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 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

(c) The consummation by 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 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:

(i) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds 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 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 with respect to any portion of an Award that provides for 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 date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise 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.

2.9 "Code" shall mean the Internal Revenue Code of 1986, 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.

2.10 "Committee" shall mean 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 in Section 12.1 hereof.

2.11 "Common Stock" shall mean the common stock of the Company, par value \$0.0001 per share.

2.12 "Company" shall have the meaning set forth in Article 1 hereof.

2.13 “Consultant” shall mean any consultant or advisor engaged to provide services to the Company or any Affiliate who qualifies as a consultant or advisor under the applicable rules of the Securities and Exchange Commission for registration of shares on a Form S-8 Registration Statement or any successor Form thereto.

2.14 “Deferred Stock” shall mean a right to receive Shares awarded under Section 9.4 hereof.

2.15 “Deferred Stock Unit” shall mean a right to receive Shares awarded under Section 9.5 hereof.

2.16 “Director” shall mean a member of the Board, as constituted from time to time.

2.17 “Dividend Equivalent” shall mean a right to receive the equivalent value (in cash or Shares) of dividends paid on Shares, awarded under Section 9.2 hereof.

2.18 “DRO” shall mean a “domestic relations order” as defined by the Code or Title I of the Employee Retirement Income Security Act of 1974, as amended from time to time, or the rules thereunder.

2.19 “Effective Date” shall have the meaning set forth in Section 13.1.

2.20 “Eligible Individual” shall mean any person who is an Employee, a Consultant or a Non-Employee Director, as determined by the Administrator.

2.21 “Employee” shall mean any officer or other employee (as determined in accordance with Section 3401(c) of the Code and the Treasury Regulations thereunder) of the Company or any Affiliate.

2.22 “Equity Restructuring” shall mean a nonreciprocal transaction between 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 be the closing sales price for a Share as quoted on such exchange or system for such date or, if there is no closing

sales price for a Share 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 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.

2.34 “Parent” shall mean any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities ending with the Company if each of the entities other than the Company 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.

2.35 “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 any other transferee specifically approved by the Administrator, after taking into account Applicable Law.

2.38 “Plan” 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.

2.42 “Restricted Stock Unit” shall mean a contractual right awarded under Article 8 hereof to receive in the future a Share or the Fair Market Value of a Share 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 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.

2.48 "Stock Payment" shall mean (a) a payment in the form 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.

2.49 "Subsidiary" shall mean any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning 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, including, without limitation, the question of whether a Termination of Service resulted from a discharge for cause and all questions of whether particular leaves of absence constitute a Termination of Service; provided, however, that, with respect to Incentive Stock Options, unless the Administrator otherwise provides in the terms of the Program, the Award Agreement or otherwise, a leave of absence, change in status from an employee to an independent contractor or other change in the employee-employer relationship shall constitute a Termination of Service only if, and to the extent that, such leave of

absence, change in status or other change interrupts employment for the purposes of Section 422(a)(2) of the Code and the then applicable regulations and revenue rulings under said Section.

- For purposes of the Plan, a Holder's employee-employer relationship or consultancy relations shall be deemed to be terminated 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 subject to awards under the Prior Plan that, on or after the Effective Date, terminate, expire or lapse for any reason without 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

thereof; and (iv) Shares purchased on the open market by the Company with the cash proceeds from the exercise of 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) 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 Award Agreement. Each Award shall be evidenced by an Award Agreement that sets forth the terms, conditions and limitations for such Award, which may include the term of the Award, the provisions 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 the applicable provisions of Section 422 of the Code.

4.3 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan, 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 set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including Rule 16b-3 of the Exchange Act and any amendments thereto) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

4.4 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, shall have the power and authority to: (a) determine which Affiliates shall be covered by the Plan; (b) determine which Eligible Individuals outside the United States are eligible to participate in the Plan; (c) modify the terms and conditions of any Award granted to Eligible Individuals outside the United States to comply with applicable foreign laws or listing requirements of any such foreign securities exchange; (d) establish subplans and modify exercise procedures and other terms and procedures, to the extent such actions may be necessary or advisable (any such subplans and/or modifications shall be attached to the Plan as appendices); provided, however, that no such subplans and/or modifications shall increase 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 of any such foreign securities exchange. Notwithstanding the foregoing, the Administrator may not take any actions hereunder, and no Awards shall be granted, that would violate the Code, the Exchange Act, the Securities Act, any other securities law or governing statute, the rules of

the securities exchange or automated quotation system on which the Shares are listed, quoted or traded or any other Applicable Law. For purposes of the Plan, all references to foreign laws, rules, regulations or taxes shall be references to 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 (the “Non-Employee Director Equity Compensation Policy”), subject to the limitations 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/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 by the Administrator from time to time in its discretion.

4.7 Stand-Alone and Tandem Awards. 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 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. To the extent that the aggregate fair market value of stock with respect to which “incentive stock options” (within the meaning of Section 422 of the Code, but without regard to Section 422(d) of the Code) are exercisable for the first time by a Holder during any calendar year under the Plan, and all other plans of the Company 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. The rule set forth in the preceding sentence shall be applied by taking Options and other “incentive stock options” into account in the order in which they were granted and the Fair Market Value of stock shall be determined as of the time 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 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 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 of the date such Substitute Award is granted) of the shares subject to the Substitute Award, over (b) 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.

5.7 Substitution of Stock Appreciation Rights. The Administrator may provide in the applicable Program or the Award Agreement evidencing the grant of an Option that the Administrator, in its sole discretion, shall have the right 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 delivery of all of the following 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 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.

6.3 Notification Regarding Disposition. 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, 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 for each issuance of Restricted Stock to the extent required by Applicable Law.

7.2 Rights as Stockholders. Subject to Section 7.4 hereof, 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 set forth in Section 7.3 hereof.

7.3 Restrictions. All shares of Restricted Stock (including any shares received by Holders thereof with respect to shares of Restricted Stock as a result of stock dividends, stock splits or any other form of recapitalization) shall, in the terms of the applicable Program or in each individual Award Agreement, be subject to such restrictions and vesting requirements as 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 with the Company, Company or Affiliate performance, individual performance or other criteria selected by the Administrator. By action taken after the Restricted Stock is issued, the Administrator may, on such terms and conditions as it may determine to be appropriate, accelerate the vesting of such Restricted Stock by removing any or all of the restrictions imposed by the terms of the Program and/or the Award Agreement. Restricted Stock may not be sold or encumbered until all restrictions are

terminated or expire. In addition, notwithstanding anything to the contrary herein, with respect to a share of Restricted Stock, dividends which are paid prior to vesting shall only be paid out to the Participant to the extent the share of Restricted Stock vests.

7.4 Repurchase or Forfeiture of Restricted Stock Except as otherwise determined by the Administrator at the time of the grant of the Award or thereafter, if no price was paid by the Holder for the Restricted Stock, upon a Termination of Service during the applicable restriction period, the Holder's rights in unvested Restricted Stock then subject to restrictions shall lapse, and such Restricted Stock shall be surrendered to the Company 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 shall have the right to repurchase from the Holder the unvested Restricted Stock then subject to restrictions at a cash price per share equal to the price paid by the Holder for such Restricted Stock or such other amount as may be specified in the Program or the Award Agreement. Notwithstanding the foregoing, the Administrator in its sole discretion may provide that in the event 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 the purchase price, if any, to be paid by the Holder to the Company with respect to any Restricted 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.

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 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 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 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 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 (3^d) month following the end of calendar year in which the Restricted Stock Unit vests; or (b) the fifteenth (15th) day of the third (3^d) 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, in the sole discretion of the Administrator, an amount in cash equal to the Fair Market Value 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 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 and the Award Agreement.

8.8 Dividend Equivalents. Subject to 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 Awards.

(a) 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. The Administrator is authorized to make Stock Payments to any Eligible Individual. The number 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 will not be issued until those conditions have been satisfied. Unless otherwise provided by the Administrator, a Holder of a Stock Payment shall have no rights as a Company stockholder with respect to such Stock Payment until such time as the Stock Payment has vested and the Shares underlying the Award have been issued to the Holder. Stock

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 Deferred Stock. The Administrator is authorized to grant Deferred Stock to any Eligible Individual. The number of shares 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.

9.5 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.

9.6 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

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

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 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 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

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

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, 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 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 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 12.1 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 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 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

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.

(e) The Administrator may, in its sole discretion, include such further provisions 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) 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) The 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.

(h) In 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 of the Common Stock including any Equity Restructuring, for reasons of administrative convenience, the Company in its sole discretion may refuse to permit the exercise of any Award during a period of thirty (30) days prior to the consummation of any such transaction.

13.3 Approval of Plan by Stockholders. 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 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 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.

13.4 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. In the event that the Company establishes, for itself or using the services of a third party, an automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, then the paperless documentation, granting or exercise of Awards by a Holder may be permitted through the use of such an automated system.

13.6 Effect of Plan upon Other Compensation Plans. The adoption 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 under the Plan 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 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

awarded hereunder shall be deemed amended to the extent necessary to conform to such Applicable Law.

13.8 Titles and Headings, References to Sections of the Code or Exchange Act The titles and headings of the Sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control. References to sections of the Code or the Exchange Act shall include any amendment or successor thereto.

13.9 Governing Law. The Plan and any agreements hereunder shall be administered, interpreted and enforced under the internal laws of the State of Delaware without regard to conflicts of laws thereof or of any other jurisdiction.

13.10 Section 409A. To the extent that the Administrator determines that any Award granted under the Plan is subject to Section 409A of the Code, the Program pursuant to which such Award is granted and the Award Agreement evidencing such Award shall incorporate the terms and conditions required by Section 409A of the Code. To the extent applicable, the Plan, the Program and any Award Agreements shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Effective Date. Notwithstanding any provision of the Plan to the contrary, in the event that following the Effective Date the Administrator determines that any Award may be 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), 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 with respect to the Award, or (b) comply with the requirements of Section 409A of the Code and related Department of Treasury guidance and thereby avoid the application of any penalty taxes under such Section.

13.11 No Rights to Awards. No Eligible Individual or other person shall have 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 or any other persons uniformly.

13.12 Unfunded Status of Awards. The Plan is intended to be an “unfunded” plan for incentive compensation. With respect to any payments not yet made to a Holder pursuant to an Award, nothing contained in the Plan or any Program or Award Agreement shall give the Holder any rights that are greater than those of a general creditor of the Company or any Affiliate.

13.13 Indemnification. To the extent allowable pursuant to Applicable Law, each member of the Committee or of the Board and any officer or other employee to whom authority to administer any component of the Plan is delegated shall be indemnified and held harmless by the Company from any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by such member in connection with or resulting from any claim, action, suit, or

proceeding 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, as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

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.

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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 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

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

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

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

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 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 be transferable, other than by will 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

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

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

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 subject to the Plan or change the designation or class of Eligible Employees; and *provided, further* that without approval of the Company's stockholders, the Plan may not be amended in any manner that would cause the Plan to no longer be an "employee stock purchase plan" within the meaning of Section 423(b) of the Code.

(c) In the event the Administrator determines that the ongoing operation of 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, but not limited to:

(i) altering the Option Price for any Offering Period including an Offering Period underway 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 at the time of the Administrator action; 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 the Plan shall be included in the general funds of 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 the terms and conditions provided herein, the Board or the Committee may require that a Participant make such reasonable covenants, 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 and the rules of any securities exchange or automated quotation system on which the shares of Common Stock are listed, quoted, or traded. The Committee 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 a window-period limitation, as may be imposed in the sole discretion of the Committee.

(d) Notwithstanding any other provision of the Plan, unless otherwise determined by the Committee or required by any applicable law, rule or regulation, 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).

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.

* * * * *

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

By: /s/ Michael Raab

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

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

By:

/s/ Justin Renz

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

**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, 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

By: /s/ Michael Raab

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

Date: August 1, 2024

By: /s/ Justin Renz

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