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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2025
OR

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

For the transition period from to
Commission file number: 001-36485

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

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

(510) 745-1700
(Registrant's Telephone Number, Including Area Code)
N/A
(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001	**ARDX**	**The Nasdaq Global Market**

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

The number of issued and outstanding shares of the registrant's Common Stock, $0.0001 par value per share, as of April 24, 2025, was 239,255,212.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

Unless the context requires otherwise, in this Quarterly Report on Form 10-Q, the terms "Ardelyx," "Company," "we," "us," and "our" 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:

- 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, that could cause actual outcomes or results to differ materially from those expressed or implied by such forward-looking statements. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the "Item 1A. Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q. Except as required by law, we assume no obligation to update any forward-looking statement publicly, or to revise any forward-looking statement to reflect events or developments occurring after the date of this Quarterly Report on Form 10-Q, even if new information becomes available in the future. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in any such forward-looking statement.

SUMMARY OF PRINCIPAL RISKS ASSOCIATED WITH OUR BUSINESS

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

- We have incurred losses in each year since our inception, and we expect to continue to incur operating losses in the future as we incur additional expenses related to our ongoing operations and our pursuit of future business opportunities.
- We will require additional financing for the foreseeable future as we invest in the growth of IBSRELA and XPHOZAH in the U.S. and build a pipeline. The inability to access necessary capital when needed on acceptable terms, or at all, could force us to reduce our efforts to commercialize IBSRELA and/or XPHOZAH, or to delay or limit our pursuit of other future business opportunities.
- We have generated limited revenue from product sales and may never be profitable for a full fiscal year.
- We are substantially dependent on the successful commercialization of IBSRELA, and there is no guarantee that we will maintain sufficient market acceptance for IBSRELA, grow market share for IBSRELA, secure and maintain adequate coverage and reimbursement for IBSRELA, or generate sufficient revenue from product sales of IBSRELA.
- There is no guarantee that we will achieve sufficient market acceptance for XPHOZAH, or that we will be able to secure and maintain adequate coverage and reimbursement for XPHOZAH, or generate sufficient revenue from product sales of XPHOZAH.
- XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer 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 products.

- 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 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, 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. SEC. 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.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	(Unaudited) March 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 30,808	$ 64,932
Short-term investments	183,144	185,168
Accounts receivable	46,467	57,705
Inventory	23,776	21,173
Prepaid commercial manufacturing	13,848	16,378
Prepaid expenses and other current assets	14,649	11,096
Total current assets	312,692	356,452
Property and equipment, net	1,665	1,495
Inventory, non-current	82,099	70,011
Prepaid commercial manufacturing, non-current	3,246	—
Right-of-use assets	3,670	2,380
Other assets	6,822	5,416
Total assets	$ 410,194	$ 435,754
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 13,722	$ 16,000
Accrued compensation and benefits	7,168	14,940
Current portion of operating lease liability	1,302	1,562
Deferred revenue	10,913	10,686
Accrued expenses and other current liabilities	42,735	34,642
Total current liabilities	75,840	77,830
Operating lease liability, net of current portion	2,505	1,023
Long-term debt	151,301	150,853
Deferred revenue, non-current	8,350	7,232
Deferred royalty obligation related to the sale of future royalties	26,522	25,527
Total liabilities	264,518	262,465
Commitments and contingencies (Note 14)		
Stockholders' equity		
Common stock, $0.0001 par value; 500,000,000 shares authorized; 239,201,256 and 238,015,825 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	24	24
Additional paid-in capital	1,072,118	1,058,548
Accumulated deficit	(926,484)	(885,340)
Accumulated other comprehensive income	18	57
Total stockholders' equity	145,676	173,289
Total liabilities and stockholders' equity	$ 410,194	$ 435,754

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 March 31,	
	2025	**2024**
Revenues		
Product sales, net	$ 67,814	$ 43,512
Product supply revenue	254	2,126
Licensing revenue	5,020	17
Non-cash royalty revenue related to the sale of future royalties	1,026	368
Total revenues	74,114	46,023
Cost of goods sold		
Cost of product sales	2,340	1,013
Other cost of revenue	9,963	6,115
Total cost of goods sold	12,303	7,128
Operating expenses		
Research and development	14,938	10,579
Selling, general and administrative	83,222	52,994
Total operating expenses	98,160	63,573
Loss from operations	(36,349)	(24,678)
Interest expense	(4,191)	(2,356)
Non-cash interest expense related to the sale of future royalties	(2,071)	(1,702)
Other income, net	2,326	2,339
Loss before provision for income taxes	(40,285)	(26,397)
Provision for income taxes	859	121
Net loss	$ (41,144)	$ (26,518)
Net loss per share of common stock - basic and diluted	$ (0.17)	$ (0.11)
Shares used in computing net loss per share - basic and diluted	238,624,145	233,065,960
Comprehensive loss		
Net loss	$ (41,144)	$ (26,518)
Unrealized losses on available-for-sale securities	(39)	(244)
Comprehensive loss	$ (41,183)	$ (26,762)

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

ARDELYX, INC.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)
(in thousands, except shares)

	Three Months Ended March 31, 2025					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2024	238,015,825	$ 24	$ 1,058,548	$ (885,340)	$ 57	$ 173,289
Issuance of common stock under employee stock purchase plan	222,734	—	1,015	—	—	1,015
Issuance of common stock upon exercise of options	389,963	—	467	—	—	467
Issuance of common stock upon vesting of restricted stock units	572,734	—	—	—	—	—
Stock-based compensation	—	—	12,088	—	—	12,088
Unrealized losses on available-for-sale securities	—	—	—	—	(39)	(39)
Net loss	—	—	—	(41,144)	—	(41,144)
Balance as of March 31, 2025	239,201,256	$ 24	$ 1,072,118	$ (926,484)	$ 18	$ 145,676

	Three Months Ended March 31, 2024					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	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 upon exercise of options	701,578	—	2,183	—	—	2,183
Issuance of common stock upon vesting of restricted stock units	551,664	—	—	—	—	—
Stock-based compensation	—	—	7,616	—	—	7,616
Unrealized losses on available-for-sale securities	—	—	—	—	(244)	(244)
Net loss	—	—	—	(26,518)	—	(26,518)
Balance as of March 31, 2024	233,959,744	$ 23	$ 1,023,610	$ (872,722)	$ (20)	$ 150,891

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

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

	Three Months Ended March 31,	
	2025	**2024**
Operating activities		
Net loss	$ (41,144)	$ (26,518)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	602	435
Non-cash lease expense	923	948
Stock-based compensation	12,088	7,616
Non-cash interest expense	2,136	1,753
Non-cash royalty revenue related to the sale of future royalties	(1,026)	(368)
Other, net	(1,191)	(1,265)
Changes in operating assets and liabilities		
Accounts receivable	11,238	(6,131)
Inventory	(14,692)	(29,371)
Prepaid commercial manufacturing	(716)	13,406
Prepaid expenses and other assets	(5,022)	(5,450)
Accounts payable	(2,278)	6,139
Accrued compensation and benefits	(7,772)	(5,870)
Operating lease liabilities	(991)	(1,068)
Accrued and other liabilities	8,043	7,159
Deferred revenue	1,345	2,863
Net cash used in operating activities	(38,457)	(35,722)
Investing activities		
Proceeds from maturities and redemptions of investments	34,726	31,602
Purchases of investments	(31,550)	(34,024)
Purchases of property and equipment	(325)	(150)
Net cash provided by (used in) investing activities	2,851	(2,572)
Financing activities		
Proceeds from 2022 Loan Agreement, net of issuance costs	—	49,750
Proceeds from issuance of common stock under equity incentive and stock purchase plans	1,482	3,221
Net cash provided by financing activities	1,482	52,971
Net (decrease) increase in cash and cash equivalents	(34,124)	14,677
Cash and cash equivalents at beginning of period	64,932	21,470
Cash and cash equivalents at end of period	30,808	36,147
Supplementary disclosure of cash flow information		
Cash paid for interest	$ 2,454	$ 2,095
Cash paid for income taxes	$ 2	$ 1
Supplementary disclosure of non-cash activities		
Right-of-use assets obtained in exchange for lease obligations	$ 2,213	$ —

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

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

NOTE 1. NATURE OF OPERATIONS

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 IBS-C. Tenapanor, branded as XPHOZAH®, is approved 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.

We operate in one business segment, which is the development and commercialization of biopharmaceutical products. Refer to *Note 12. Segment Reporting* for further discussion on our segment reporting.

Basis of Presentation

These condensed financial statements have been prepared in accordance with U.S. GAAP and pursuant to the requirements of the 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 normal and recurring adjustments necessary to present fairly our financial position, results of operations, changes in stockholders' equity and cash flows for the interim periods presented. Certain prior year amounts have been reclassified to conform to the current year presentation.

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 2024 Form 10-K. The results for the 2025 first quarter are not necessarily indicative of results to be expected for the entire year ending December 31, 2025, or for any other interim period or future year.

Refer to the *Summary of Abbreviated Terms* at the end of this Quarterly Report on Form 10-Q for definitions of terms used throughout the document.

Use of Estimates

The preparation of financial statements requires management to make estimates, judgments and assumptions. The most significant assumptions are estimates used in our revenue gross-to-net accruals and other assumptions. 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.

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740) - *Improvements to Income Tax Disclosures*. 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. The Company is in the process of evaluating the impact of this new guidance on its disclosures.

In November 2024, the FASB issued ASU No. 2024-03, Income Statement (Topic 220) - *Reporting Comprehensive Income - Expense Disaggregation Disclosures, Disaggregation of Income Statement Expenses*, which requires public companies to disclose, in interim and reporting periods, additional information about certain expenses in the financial statements. ASU No. 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted and is effective on either a prospective basis or retrospective basis. The Company is in the process of evaluating the impact of this new guidance on its disclosures.

NOTE 2. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

The following table summarizes our cash, cash equivalents and short-term investments:

	March 31, 2025				December 31, 2024			
		Gross Unrealized				Gross Unrealized		
(in thousands)	Amortized Cost	Gains	Losses	Fair Value	Amortized Cost	Gains	Losses	Fair Value
Cash and cash equivalents								
Cash	$ 8,318	$ —	$ —	$ 8,318	$ 16,282	$ —	$ —	$ 16,282
Money market funds	22,490	—	—	22,490	48,650	—	—	48,650
Total cash and cash equivalents	30,808	—	—	30,808	64,932	—	—	64,932
Short-term investments								
U.S. treasury securities	$ 72,431	$ 43	$ (3)	$ 72,471	$ 79,720	$ 58	$ (5)	$ 79,773
U.S. government-sponsored agency bonds	41,852	4	(26)	41,830	45,960	29	(27)	45,962
Commercial paper	33,026	2	(3)	33,025	37,061	19	(15)	37,065
Corporate bonds	28,077	7	(2)	28,082	17,415	4	(6)	17,413
Asset-backed securities	5,752	—	(3)	5,749	2,983	2	—	2,985
Yankee bonds	1,988	—	(1)	1,987	1,972	—	(2)	1,970
Total short-term investments	183,126	56	(38)	183,144	185,111	112	(55)	185,168
Total cash, cash equivalents and investments	$ 213,934	$ 56	$ (38)	$ 213,952	$ 250,043	$ 112	$ (55)	$ 250,100

Realized gains or losses have not been significant and are included in other income, net, in the condensed statements of operations and comprehensive loss.

Unrealized losses as of March 31, 2025 and December 31, 2024 were not material. We determined that none of our available-for-sale securities were other-than-temporarily impaired as of March 31, 2025 and December 31, 2024, and no investment was in a continuous unrealized loss position for more than one year. Therefore, we believe that it is more likely than not that the investments will be held until maturity or a forecasted recovery of fair value.

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 March 31, 2025 and December 31, 2024.

See “Cash and Cash Equivalents” and “Short-Term Investments” captions of *Note 2. Summary of Significant Accounting Policies* of our 2024 Form 10-K for more information on our accounting policies for cash, cash equivalents and short-term investments.

NOTE 3. FAIR VALUE MEASUREMENTS

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 that are measured or disclosed on a recurring basis by level within the fair value hierarchy:

	March 31, 2025				December 31, 2024			
(in thousands)	Total Fair Value	Level 1	Level 2	Level 3	Total Fair Value	Level 1	Level 2	Level 3
Assets								
Money market funds	$ 22,490	$ 22,490	$ —	$ —	$ 48,650	$ 48,650	$ —	$ —
U.S. treasury securities	72,471	—	72,471	—	79,773	—	79,773	—
U.S. government-sponsored agency bonds	41,830	—	41,830	—	45,962	—	45,962	—
Commercial paper	33,025	—	33,025	—	37,065	—	37,065	—
Corporate bonds	28,082	—	28,082	—	17,413	—	17,413	—
Asset-backed securities	5,749	—	5,749	—	2,985	—	2,985	—
Yankee bonds	1,987	—	1,987	—	1,970	—	1,970	—
Total	$ 205,634	$ 22,490	$ 183,144	$ —	$ 233,818	$ 48,650	$ 185,168	$ —

Fair Value of Debt

The principal outstanding under our term loans is subject to a variable interest rate and therefore, we believe the carrying amount of the term loan approximates fair value as of March 31, 2025 and December 31, 2024. 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 March 31, 2025 and December 31, 2024 and is based on our current estimates of future royalties and commercialization milestones expected to be paid to us by 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 consisted of the following:

(in thousands)	March 31, 2025	December 31, 2024
Raw materials	$ 40,612	$ 30,792
Work in process	60,988	58,685
Finished goods	4,275	1,707
Total	$ 105,875	$ 91,184
Reported as		
Inventory	$ 23,776	$ 21,173
Inventory, non-current	82,099	70,011
Total	$ 105,875	$ 91,184

Prepaid commercial manufacturing with third-party CMOs not included in inventory was $17.1 million and $16.4 million as of March 31, 2025 and December 31, 2024, respectively. There was $3.2 million of prepayments expected to be converted into inventory after 12 months as of March 31, 2025, as compared to zero as of December 31, 2024.

NOTE 5. REVENUE

Disaggregation of total revenues by nature is as follows:

(in thousands)	Three Months Ended March 31, 2025	2024
Product sales, net	$ 67,814	$ 43,512
Licensing revenue	5,020	17
Non-cash royalty revenue related to the sale of future royalties	1,026	368
Product supply revenue	254	2,126
Total revenues	$ 74,114	$ 46,023

Product Sales, Net

Total product sales, net was as follows:

(in thousands)	Three Months Ended March 31, 2025	2024
Product sales, net		
IBSRELA	$ 44,403	$ 28,361
XPHOZAH	23,411	15,151
Total product sales, net	$ 67,814	$ 43,512

Product sales, net approximated 91.5% and 94.5% of total revenues in the 2025 and 2024 first quarters, respectively.

Concentrations

Gross product sales from Customers accounting for more than 10% of total revenues were as follows:

	Three Months Ended March 31, 2025	2024
Customers[1]		
BioRidge Pharma, LLC	63.8 %	64.6 %
Cardinal Health	22.2 %	19.2 %
Cencora (formerly AmerisourceBergen Drug Corporation)	18.2 %	21.6 %
McKesson Corporation	16.9 %	16.0 %

(1) The total of the above percentages exceeds 100% as the numerators used in the calculations represent gross product sales for each Customer, as opposed to product sales, net as presented in our condensed statements of operations and comprehensive loss.

GTN Adjustments

The activities and ending reserve balances for each significant category of GTN adjustments on product sales, net, which constitute variable consideration, were as follows:

(in thousands)	Discounts and Chargebacks	Rebates, Wholesaler and GPO Fees	Copay Assistance and Returns	Total
Balance as of December 31, 2024	$ 1,643	$ 14,475	$ 11,170	$ 27,288
Provisions[1]	4,143	18,835	5,940	28,918
Credits/payments	(4,681)	(18,405)	(8,334)	(31,420)
Balance as of March 31, 2025	$ 1,105	$ 14,905	$ 8,776	$ 24,786

(1) Provisions included approximately $3.8 million of favorable adjustment resulting from changes in prior periods' estimated product returns for XPHOZAH.

NOTE 6. COLLABORATION AND LICENSING AGREEMENTS

We out-license to external partners for the development of tenapanor and commercialization of tenapanor outside of the U.S. We recognize revenue from our agreements with Kyowa Kirin, Fosun Pharma and Knight as licensing revenue, product supply revenue or non-cash royalty revenue related to the sale of future royalties. See *Note 7. Collaboration and Licensing Agreements* and "Licensing Revenue Recognition" caption of *Note 2. Summary of Significant Accounting Policies* of our 2024 Form 10-K for more information on the nature, purpose, significant rights and obligations of the parties, as well as our accounting policies for such revenue streams.

The following table summarizes total revenues by collaboration partner:

	Three Months Ended March 31,	
(in thousands)	**2025**	**2024**
Licensing revenue		
Fosun Pharma	$ 5,000	$ —
Knight	20	17
Total licensing revenue	$ 5,020	$ 17
Product supply revenue		
Kyowa Kirin	—	2,126
Knight	254	—
Total supply revenue	$ 254	$ 2,126
Non-cash royalty revenue related to the sale of future royalties		
Kyowa Kirin	$ 1,026	$ 368

The following table presents changes in our current and non-current deferred revenue balances, which are all attributable to Kyowa Kirin:

	2025		2024	
(in thousands)	**Current**	**Non-Current**	**Current**	**Non-Current**
Deferred revenue balance as of January 1,	$ 10,686	$ 7,232	$ 7,182	$ 8,644
Prepaid product supply	227	1,118	732	3,459
Product supply delivered	—	—	(1,328)	—
Deferred revenue balance as of March 31,	$ 10,913	$ 8,350	$ 6,586	$ 12,103

Significant developments and updates related to our collaboration and licensing agreements in the 2025 and 2024 first quarters are discussed below.

Kyowa Kirin

In February 2024, Kyowa Kirin announced the launch of tenapanor, marketed as PHOZEVEL®, for patients with CKD with hyperphosphatemia in Japan. In the 2024 first quarter, we began to recognize non-cash royalty revenue related to the sale of future royalties, which was remitted to HCR in accordance with the HCR Agreement.

Fosun Pharma

In February 2025, we announced the approval of an NDA for tenapanor for the control of hyperphosphatemia in adult patients with CKD undergoing hemodialysis by China's Center for Drug Evaluation of the NMPA. This approval triggered a $5.0 million milestone to us under the terms of the Fosun Agreement, which was recorded as licensing revenue on our condensed statement of operations and comprehensive loss when earned during the 2025 first quarter and was received in April 2025.

AstraZeneca

In connection with the AstraZeneca Termination Agreement, we recognized royalty expense as other cost of revenue in our condensed statements of operations and comprehensive loss of $8.8 million and $4.7 million in the 2025 and 2024 first quarters, respectively. As of March 31, 2025, we have recognized $71.2 million of the total $75.0 million outstanding royalty obligation.

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

We and HCR have an agreement in which HCR agreed to pay up to $20.0 million in exchange for royalty payments and commercial milestone payments that we may receive under our Kyowa Kirin Agreement. See *Note 8. Deferred Royalty Obligation Related to the Sale of Future Royalties* of our 2024 Form 10-K for further discussion on the nature, purpose, significant rights and obligations of the parties, as well as our accounting policies regarding the HCR Agreement.

A summary of financial information related to the HCR Agreement is as follows:

	Three Months Ended March 31,	
($ in thousands)	**2025**	**2024**
Non-cash interest expense related to the sale of future royalties	$ (2,071)	$ (1,702)
Effective interest rate	32.5 %	33.7 %

(in thousands)	**2025**	**2024**
Deferred royalty obligation balance as of January 1,	$ 25,527	$ 20,179
Non-cash interest expense related to sale of future royalties	2,071	1,702
Royalty distributed to HCR	(1,076)	—
Deferred royalty obligation balance as of March 31,	$ 26,522	$ 21,881

NOTE 8. BORROWING

The following table presents our long-term borrowing under the 2022 Loan Agreement:

(in thousands)	**March 31, 2025**	**December 31, 2024**	**Interest rate**
Principal			
Term A Loan	$ 27,500	$ 27,500	7.95% + 0.022% + SOFR (subject to a floor of 1.0%)
Term B Loan	22,500	22,500	7.95% + 0.022% + SOFR (subject to a floor of 1.0%)
Term C Loan	50,000	50,000	4.25% + 0.022% + SOFR (subject to a floor of 4.7%)
Term D Loan	50,000	50,000	4.00% + 0.022% + SOFR (subject to a floor of 4.7%)
Total principal	150,000	150,000	
Adjustments to principal value			
Unamortized discount and debt issuance costs	(1,070)	(1,136)	
Accreted value of final fee	2,371	1,989	
Total long-term debt	151,301	150,853	
Less: Current portion of long-term debt	—	—	
Long-term debt, net of current portion	$ 151,301	$ 150,853	

The total unaccreted final fee was $5.1 million and $5.4 million as of March 31, 2025 and December 31, 2024, respectively.

As of March 31, 2025, our total future payment obligation related to the outstanding balance of the term loans, excluding interest payments, was $151.3 million, which is due on July 1, 2028.

There have been no changes to the principal, maturity, interest rates, interest payment terms and debt covenants since December 31, 2024. See *Note 9. Borrowing* of our 2024 Form 10-K for additional information regarding our 2022 Loan Agreement.

NOTE 9. LEASES

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

($ in thousands)		
Facilities	**March 31, 2025**	**December 31, 2024**
Right-of-use assets	$ 3,670	$ 2,380
Current portion of lease liabilities	1,302	1,562
Operating lease liability, net of current portion	2,505	1,023
Total lease liabilities	$ 3,807	$ 2,585
Weighted-average remaining term (in years)	2.8	1.8
Weighted-average discount rate	6.0 %	6.5 %

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

	Three Months Ended March 31,	
(in thousands)	**2025**	**2024**
Operating lease expense	$ 977	$ 1,046
Cash paid for operating leases	$ 1,047	$ 1,166

The following table summarizes our undiscounted cash payment obligations for our operating lease liabilities as of March 31, 2025:

(in thousands)	**Operating Leases**
Remainder of 2025	$ 1,145
2026	1,480
2027	1,043
2028	469
2029	21
Thereafter	—
Total undiscounted operating lease payments	4,158
Imputed interest expenses	(351)
Total operating lease liabilities	3,807
Less: Current portion of operating lease liability	(1,302)
Operating lease liability, net of current portion	$ 2,505

NOTE 10. STOCKHOLDERS' EQUITY

In January 2023, we filed a registration statement on Form S-3, which became effective in January 2023, 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. In the 2025 first quarter, we completed no sales pursuant to the 2023 Open Market Sales Agreement. As of March 31, 2025, we have completed sales pursuant to the 2023 Open Market Sales Agreement, resulting in the issuance of 16.8 million shares of our common stock and receipt of gross proceeds of $70.0 million at a weighted average sales price of approximately $4.17.

NOTE 11. EQUITY INCENTIVE PLANS

Stock-based Compensation Expense

Stock-based compensation expense recognized for stock options, RSUs and our ESPP is recorded as operating expenses in our condensed statements of operations and comprehensive loss, as follows:

	Three Months Ended March 31,	
(in thousands)	**2025**	**2024**
Selling, general and administrative	$ 8,484	$ 5,646
Research and development	3,604	1,970
Total	$ 12,088	$ 7,616

A summary of our total unrecognized stock-based compensation expense, net of estimated forfeitures, as of March 31, 2025 is as follows:

	Unrecognized Compensation Expense (in thousands)	Average Remaining Vesting Period (in years)
Stock option grants	$ 64,626	2.88
RSU grants	$ 79,520	3.30
ESPP	$ 304	0.42

Stock Options

A summary of our stock option activity and related information for the 2025 first quarter is as follows:

	Number of Shares (in thousands)	Weighted-Average Exercise Price per Share
Balance as of December 31, 2024	28,085	$ 5.63
Options granted	4,113	$ 5.21
Options exercised	(390)	$ 1.20
Options forfeited or canceled	(821)	$ 7.91
Balance as of March 31, 2025	30,987	$ 5.57
Exercisable as of March 31, 2025	15,715	$ 5.45

Restricted Stock Units

A summary of our RSUs activity and related information for the 2025 first quarter is as follows:

	Number of RSUs (in thousands)	Weighted-Average Grant Date Fair Value Per Share
Non-vested restricted stock units as of December 31, 2024	8,013	$ 6.59
Granted	7,093	$ 5.21
Vested	(573)	$ 6.04
Forfeited	(425)	$ 5.79
Non-vested restricted stock units as of March 31, 2025	14,108	$ 5.94

Employee Stock Purchase Plan

During the 2025 first quarter, we issued approximately 0.2 million shares of our common stock under the ESPP. The shares were purchased by employees at an average purchase price of $4.56 per share, resulting in proceeds to us of approximately $1.0 million.

Issuance of Common Stock for Services

During the 2025 first quarter, we issued no shares of our common stock to members of the board of directors who elected to receive stock in lieu of their cash fees under our Non-Employee Director Compensation Program.

NOTE 12. SEGMENT REPORTING

We operate in a single reportable segment. The CODM primarily uses aggregated net loss as reported on the condensed statements of operations and comprehensive loss to measure segment loss, supplemented by certain additional significant expense details reflected in the table below. There have been no changes in the determination of segmentation or the measurements used to determine reported segment loss discussed in our 2024 Form 10-K. See *Note 17. Segment Reporting* of our 2024 Form 10-K for more discussion on our segment reporting.

Detailed information regarding our single operating segment's significant revenues, expenses and operating loss is as follows:

	Three Months Ended March 31,	
(in thousands)	**2025**	**2024**
Revenues		
Product sales, net	$ 67,814	$ 43,512
Other revenues[1]	6,300	2,511
Total revenues	74,114	46,023
Less:		
Cost of product sales	2,340	1,013
Other cost of revenue	9,963	6,115
Total cost of goods sold	12,303	7,128
Research and development[2]	10,542	7,790
Selling expenses[2]	56,800	34,852
General and administrative expenses[2]	13,904	8,969
Stock-based compensation	12,088	7,616
Other segment expenses[3]	4,826	4,346
Total operating expenses	98,160	63,573
Consolidated loss from operations	(36,349)	(24,678)
Other reconciliation items[4]	(4,795)	(1,840)
Consolidated net loss	$ (41,144)	$ (26,518)

(1) *"Other revenues"* includes revenues from our collaboration partnerships, including licensing revenue, product supply revenue and non-cash royalty revenue related to the sale of future royalties.
(2) Research and development, selling and general administrative expenses herein do not include certain allocated items, such as stock-based compensation expenses.
(3) *"Other segment expenses"* primarily consists of allocated facilities, information technology and employee costs of approximately $4.7 million and $3.7 million for the 2025 and 2024 first quarters, respectively.
(4) *"Other reconciliation items"* includes interest expense, non-cash interest expense related to the sale of future royalties, provision for income taxes and other income, net.

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 effect of stock-based awards. 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, unvested restricted stock units and ESPP shares issuable pursuant to the current purchase period. As we had net losses for the 2025 and 2024 first quarters, all potential common shares were determined to be anti-dilutive during those periods.

The following table sets forth the computation of net loss per common share:

(in thousands, except per share amounts)	Three Months Ended March 31,	
Numerator	**2025**	**2024**
Net loss	$ (41,144)	$ (26,518)
Denominator		
Weighted average common shares outstanding - basic and diluted	238,624	233,066
Net loss per share of common stock - basic and diluted	$ (0.17)	$ (0.11)

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:

	Three Months Ended March 31,	
(in thousands)	**2025**	**2024**
Options to purchase common stock	29,129	26,681
Restricted stock units	10,370	7,024
ESPP shares issuable	213	227
Total	39,712	33,932

NOTE 14. COMMITMENTS AND CONTINGENCIES

On July 30 and August 12, 2021, two putative securities class action lawsuits were commenced in the U.S. District Court for the Northern District of California naming as defendants Ardelyx and two current officers captioned Strezsak v. Ardelyx, Inc., et al., Case No. 4:21-cv-05868-HSG, and Siegel v. Ardelyx, Inc., et al., Case No. 5:21-cv-06228-HSG (together, the Securities Class Actions). The complaints allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the Exchange Act), as amended, and Rule 10b-5 thereunder, by making false and misleading statements and omissions of material fact related to tenapanor. The plaintiffs seek damages and interest, and an award of costs, including attorneys' fees. On July 19, 2022, the court consolidated the two putative class actions and appointed a lead plaintiff and lead counsel. The lead plaintiff filed a second amended complaint under which the plaintiffs seek to represent all persons who purchased or otherwise acquired Ardelyx securities between March 6, 2020 and July 19, 2021. Defendants filed a motion to dismiss the amended complaint on June 2, 2023. On March 22, 2024, the court granted defendants' motion to dismiss. The court provided plaintiffs a third opportunity to amend and plaintiffs filed a third amended complaint on April 19, 2024. Defendants filed a motion to dismiss the third amended complaint on June 3, 2024. The case was dismissed with prejudice on September 12, 2024. On October 9, 2024, plaintiff appealed the District Court's dismissal of the case to the Ninth Circuit. While we believe the plaintiffs' claims are without merit, we reached a settlement in the case on February 21, 2025 for an immaterial amount and the case was voluntarily dismissed on March 5, 2025.

On December 7, 2021 and March 29, 2022, two verified shareholders derivative lawsuits were filed in the U.S. District Court for the Northern District of California purportedly on behalf of Ardelyx against certain of Ardelyx's executive officers and members of our board of directors, captioned Go v. Raab, et al., Case No. 4:21-cv-09455-HSG, and Morris v. Raab, et al., Case No. 4:22-cv-01988-JSC. The complaints allege that the defendants' violations of Section 14(a) of the Securities Exchange Act of 1934, as amended, breaches of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets for personally making and/or causing Ardelyx to make materially false and misleading statements regarding the Company's business, operations and prospects. The complaint seeks contribution under Sections 10(b) and 21D of the Securities Exchange Act of 1934 from two executive officers. On January 19, and April 27, 2022, the court granted the parties' stipulation to stay the Go and Morris actions, respectively, until resolution of the anticipated motion(s) to dismiss in the Securities Class Actions. On October 25, 2022, the parties filed a stipulation to consolidate and stay the Go and Morris actions, and on October 27, 2022, the court consolidated the Go and Morris action and stayed the consolidated action pending resolution of the anticipated motion(s) to dismiss in the Securities Class Action. The Securities Class Action was voluntarily dismissed on March 5, 2025. We believe the plaintiffs' claims are without merit.

On July 17, 2024, in partnership with the AAKP and the NMQF, we filed a lawsuit in the U.S. District Court for the District of Columbia against CMS, claiming that CMS has violated its statutory and regulatory authority under MIPPA, which established the ESRD PPS bundled payment system for dialysis services in 2008. Specifically, the lawsuit claims that moving 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, are not administered by dialysis providers and cannot be taken during the delivery of maintenance dialysis. On November 8, 2024, the U.S. District Court for the District of Columbia granted defendants' Motion to Dismiss and denied plaintiffs Motion for Preliminary Injunction, or in the Alternative, for Expedited Summary Judgment. Following the District Court's denial of plaintiffs' Motion to Alter or Amend the Judgment, or in the Alternative, for an Injunction Pending Appeal, plaintiffs filed an Emergency Motion for an Administrative Stay and Injunction Pending Appeal, which was denied by the United States Court of Appeals for the District of Columbia Circuit. Appellants filed an initial brief in the appeal on February 4, 2025; Appellees filed an initial brief on March 6, 2025; and Appellants filed a reply brief March 27, 2025. Both Appellees and Appellants filed a final brief on April 10, 2025.

On August 16, 2024, a complaint was filed against us in the U.S. District Court of Massachusetts, captioned Yarborough v. Ardelyx, Inc., et al., No. 24-cv-12119 (D. Mass.). The complaint names the Company, Mike Raab, and Justin Renz as defendants and alleges violations of Sections 10(b) and 20(a) the Exchange Act and Rule 10b-5 promulgated thereunder, related to the our announcement on July 2, 2024 that it had chosen not to file an application for Transitional Drug Add-on Payment Adjustment for XPHOZAH (the "Yarborough Action"). The plaintiffs seek damages and interest, and an award of costs, including attorneys' fees. The Court appointed Tate Wood as lead plaintiff on October 30, 2024. Lead Plaintiff filed an amended complaint on January 13, 2025, in which he added Susan Rodriguez, Laura Williams and Elizabeth Grammer as additional defendants and removed Justin Renz as a defendant. Lead Plaintiff purports to bring claims on behalf of all those who acquired Ardelyx common stock between February 22, 2024 and July 1, 2024. Defendants filed a motion to dismiss the amended complaint on March 14, 2025. We believe the plaintiff's claims are without merit.

On September 6 and 13, 2024, certain Ardelyx shareholders filed two verified derivative complaints purportedly on behalf of the Company in the United States District Court for the District of Massachusetts alleging violations of Sections 10(b) and/or 14(a) of the Exchange Act, breaches of fiduciary duty, unjust enrichment, waste, and aiding and abetting breaches of fiduciary duty against certain members of our board of directors and management based on substantially the same factual allegations in the Yarborough Action. The complaints seek unspecified damages and corporate governance reforms, as well as costs and attorneys' fees. On September 25, 2024, the Court consolidated the two derivative actions into the case In re Ardelyx, Inc. Stockholder Derivative Litigation, Case No. 1:24-cv-12302-LTS (D. Mass.). On November 7, 2024, the Court stayed the consolidated derivative action pending resolution of any and all motion(s) to dismiss in the Yarborough Action. We believe the plaintiffs' claims are without merit.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. As of March 31, 2025, there is no litigation pending that would reasonably be expected to have a material adverse effect on our results of operations and financial condition.

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 2024 Form 10-K. 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.

EXECUTIVE SUMMARY

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 IBS-C. Tenapanor, branded as XPHOZAH®, is approved 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.

Refer to the *Summary of Abbreviated Terms* at the end of this Quarterly Report on Form 10-Q for definitions of terms used throughout the document.

We are committed to our mission of discovering, developing and commercializing first-in-class medicines that address unmet patient needs. Our principal strategy is to maintain our commercial momentum with our current products while identifying additional assets that leverage our core capabilities, including clinical, developmental and regulatory expertise and commercial excellence while maintaining a solid financial foundation, to support our future growth.

Our priorities include: (i) accelerating IBSRELA growth momentum; (ii) executing our XPHOZAH strategy to grow utilization; (iii) building a pipeline focused on areas of unmet patient need; and (iv) continuing to deliver strong commercial and financial performance.

In February 2025, we announced the approval of an NDA for tenapanor for the control of hyperphosphatemia in adult patients with CKD undergoing hemodialysis by China's Center for Drug Evaluation of the NMPA. This approval triggered a $5.0 million milestone to us under the terms of the Fosun Agreement, which was recorded as licensing revenue on our condensed statement of operations and comprehensive loss when earned during the 2025 first quarter and was received in April 2025.

RESULTS OF OPERATIONS

The results of operations for the 2025 first quarter are not necessarily indicative of results to be expected for the entire year ending December 31, 2025, or for any other interim period or future year. See Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," of our 2024 Form 10-K to enhance the understanding of our financial metrics below.

Revenue

Below is a summary of our total revenues:

	Three Months Ended March 31,		Change 2025 vs. 2024	
($ in thousands)	**2025**	**2024**	**$**	**%**
Product sales, net	$ 67,814	$ 43,512	$ 24,302	56 %
Product supply revenue	254	2,126	(1,872)	(88)%
Licensing revenue	5,020	17	5,003	(a)
Non-cash royalty revenue related to the sale of future royalties	1,026	368	658	179 %
Total revenues	$ 74,114	$ 46,023	$ 28,091	61 %

(a) Percent change is not meaningful.

Below is a summary of our product sales, net by product:

	Three Months Ended March 31,		Change 2025 vs. 2024	
($ in thousands)	**2025**	**2024**	**$**	**%**
Product sales, net				
IBSRELA	$ 44,403	$ 28,361	$ 16,042	57 %
XPHOZAH	23,411	15,151	8,260	55 %
Total product sales, net	$ 67,814	$ 43,512	$ 24,302	56 %

Product sales, net:

The increase in IBSRELA product sales, net in the 2025 first quarter was due to higher demand, reflecting continued increase in awareness and prescriber experience, and to a lesser extent, higher net price.

The increase in XPHOZAH product sales, net in the 2025 first quarter was due to higher demand since its commercial launch in November 2023, partially offset by lower net price due to unfavorable payor mix shifts associated with loss of XPHOZAH Medicare Part D reimbursement. As of January 1, 2025, the Centers of Medicare and Medicaid Services officially began the transition of oral only therapies, including XPHOZAH, into the End Stage Renal Disease Prospective Payment System. The increase in XPHOZAH product sales, net also reflected the release of $3.8 million of prior periods' estimated product returns for XPHOZAH, based on assumptions from actual returns history and other data supporting an expectation of minimal returns.

Product supply revenue:

Product supply revenue is primarily impacted by the timing of product supply shipments to our collaboration partners. The product supply revenue in the 2025 and 2024 first quarters was attributable to Knight and Kyowa Kirin, respectively, under our product supply agreements in support of non-U.S. launches.

Licensing revenue:

Licensing revenue is primarily impacted by the timing of regulatory and commercial milestone achievements from our collaboration partners, as well as sales-based royalties received from Knight. The licensing revenue in the 2025 first quarter was primarily attributable to the earning of a $5.0 million milestone under the terms of the Fosun Agreement upon approval of an NDA for tenapanor for the control of hyperphosphatemia in adult patients with CKD undergoing hemodialysis by China's Center for Drug Evaluation of the NMPA.

Non-cash royalty revenue:

The increase in non-cash royalty revenue in the 2025 first quarter was attributable to a full quarter of royalties from Kyowa Kirin for sales of PHOZEVEL in Japan, which was launched in February 2024, as compared to a partial quarter of royalties in the 2024 first quarter.

GTN Adjustments

Reconciliation of gross product sales to product sales, net by GTN adjustment category is as follows:

	Three Months Ended March 31,		Change 2025 vs. 2024	
($ in thousands)	**2025**	**2024**	**$**	**%**
Gross product sales	$ 96,732	$ 62,527	$ 34,205	55 %
GTN adjustments	(28,918)	(19,015)	$ (9,903)	52 %
Product sales, net	$ 67,814	$ 43,512	$ 24,302	56 %
GTN adjustment percentage	29.9 %	30.4 %		

The decrease in GTN adjustment percentage in the 2025 first quarter was primarily due to the favorable impact of a change in prior periods' estimate of expected returns of XPHOZAH, partially offset by unfavorable payor mix shifts.

The activities and ending reserve balances for each significant category of GTN adjustments on product sales, net, which constitute variable consideration, were as follows:

(in thousands)	Discounts and Chargebacks	Rebates, Wholesaler and GPO Fees	Copay Assistance and Returns	Total
Balance as of December 31, 2024	$ 1,643	$ 14,475	$ 11,170	$ 27,288
Provisions[1]	4,143	18,835	5,940	28,918
Credits/payments	(4,681)	(18,405)	(8,334)	(31,420)
Balance as of March 31, 2025	$ 1,105	$ 14,905	$ 8,776	$ 24,786

(1) Provisions included approximately $3.8 million of favorable adjustment resulting from changes in prior periods' estimated product returns for XPHOZAH.

Expenses

Below is a summary of our cost of goods sold, operating expenses, interest expense, non-cash interest expense related to the sale of future royalties and other income, net:

	Three Months Ended March 31,		Change 2025 vs. 2024	
($ in thousands)	**2025**	**2024**	**$**	**%**
Cost of product sales	$ 2,340	$ 1,013	$ 1,327	131 %
Other cost of revenue	9,963	6,115	3,848	63 %
Total cost of goods sold	$ 12,303	$ 7,128	$ 5,175	73 %
Research and development	$ 14,938	$ 10,579	$ 4,359	41 %
Selling, general and administrative	83,222	52,994	30,228	57 %
Total operating expenses	$ 98,160	$ 63,573	$ 34,587	54 %
Interest expense	$ (4,191)	$ (2,356)	$ (1,835)	78 %
Non-cash interest expense related to the sale of future royalties	$ (2,071)	$ (1,702)	$ (369)	22 %
Other income, net	$ 2,326	$ 2,339	$ (13)	(1)%

Cost of Goods Sold

Cost of product sales:

The increase in cost of product sales in the 2025 first quarter was due to higher product sales. A portion of the costs of IBSRELA and XPHOZAH units recognized as revenue during the 2025 and 2024 first quarters was expensed as research and development expenses in periods prior to the commencement of capitalization of inventory costs for each respective product. The cost associated with inventory sold but previously expensed as research and development was $0.7 million and $1.2 million for the 2025 and 2024 first quarters, respectively. The value of inventory on hand as of March 31, 2025 and December 31, 2024 that was previously expensed as research and development was approximately $14.8 million and $15.6 million, respectively.

Other cost of revenue:

The increase in other cost of revenue in the 2025 first quarter was primarily due to higher AstraZeneca royalties, driven by higher tenapanor product sales, net. Other cost of revenue related to the AstraZeneca Termination Agreement was $8.8 million and $4.7 million for the 2025 and 2024 first quarters, respectively. The remaining future royalty obligation to AstraZeneca was $3.8 million as of March 31, 2025.

Research and Development

Below is a summary of our research and development expenses:

	Three Months Ended March 31,		Change 2025 vs. 2024	
($ in thousands)	**2025**	**2024**	**$**	**%**
External R&D and other expenses	$ 4,202	$ 3,520	$ 682	19 %
Employee-related expenses	9,455	6,136	3,319	54 %
Facilities, equipment, depreciation and other expenses	1,281	923	358	39 %
Total research and development expenses	$ 14,938	$ 10,579	$ 4,359	41 %

The increase in R&D expenses in the 2025 first quarter was primarily driven by the increase in employee-related expenses, reflecting an increase in headcount to support medical engagement with scientific communities in the areas of gastroenterology and nephrology related to our marketed products. This increase included an incremental $1.6 million in stock-based compensation expense.

Selling, General and Administrative

The increase in selling, general and administrative expenses in the 2025 first quarter was primarily due to increased commercialization and administrative costs to support net sales growth of IBSRELA and XPHOZAH. The increase consisted of spending for disease awareness initiatives, patient affordability, access support and related patient awareness, as well as increased commercial infrastructure. In addition, the increase was attributable to increased headcount, including an incremental $2.8 million in stock-based compensation expense.

Interest Expense

The increase in interest expense in the 2025 first quarter was due to a higher loan balance resulting from the Term D Loan draw of $50.0 million in October 2024. In addition, the increase was attributable to a full quarter of interest expense related to the Term C Loan as compared to a partial quarter of interest expense in the 2024 first quarter.

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

The increase in non-cash interest expense related to the sale of future royalties in the 2025 first quarter was due to the increasing outstanding balance of the deferred royalty obligation attributable to the imputed interest accrued on the outstanding balance, partially offset by royalties received from Kyowa Kirin related to the sale of PHOZEVEL, which were remitted to HCR.

Other Income, Net

Other income, net consists of interest income earned on our cash, cash equivalents and short-term investments as well as currency exchange gains and losses. In the 2024 first quarter, other income, net also included the periodic revaluation of our previously outstanding 2022 Exit Fee related to our 2022 Loan Agreement that was settled in October 2024.

LIQUIDITY AND CAPITAL RESOURCES

Below is a summary of our cash, cash equivalents and short-term investments:

($ in thousands)	**March 31, 2025**	**December 31, 2024**	**Change $**	**Change %**
Cash and cash equivalents	$ 30,808	$ 64,932	$ (34,124)	(53)%
Short-term investments	183,144	185,168	(2,024)	(1)%
Total liquid funds	$ 213,952	$ 250,100	$ (36,148)	(14)%

We regularly assess our cash position and our working capital needs to execute our strategy. Our primary uses of cash to date have been to fund research and development expenditures related to our development of tenapanor and to support the commercialization of our marketed products. We have funded our operations primarily from the sale of common stock, product sales, funds from our collaboration partnerships, funds from our loan agreements with SLR, as well as sale of future royalties to HCR. We expect that we will increasingly rely on cash generated from operations to fund our operating plan while maintaining financial flexibility from our ability to source cash from future equity sales and debt financing.

In January 2023, we filed a registration statement on Form S-3, which became effective in January 2023, 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. In the 2025 first quarter, we completed no sales pursuant to the 2023 Open Market Sales Agreement. As of March 31, 2025, we have completed sales pursuant to the 2023 Open Market Sales Agreement, resulting in the issuance of 16.8 million shares of our common stock and receipt of gross proceeds of $70.0 million at a weighted average sales price of approximately $4.17.

We have a loan and security agreement (as amended, the 2022 Loan Agreement) with SLR. The 2022 Loan Agreement provides a total of $200.0 million, of which $150.0 million has been drawn as of March 31, 2025 to support our ongoing operations and the commercial launches of IBSRELA and XPHOZAH. The borrowings under the 2022 Loan Agreement bear interest at SOFR plus a spread based on our public debt rating. We classify outstanding borrowings under the 2022 Loan Agreement as long-term based on the maturity date of the loan. All the term loans mature on July 1, 2028. See *Note 9. Borrowing* of our 2024 Form 10-K for further discussion.

We believe our available cash, cash equivalents and short-term investments as of March 31, 2025 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 as described in Part II, Item 1A, “Risk Factors,” of this Quarterly Report on Form 10-Q.

CASH FLOW ACTIVITIES

The following table summarizes our cash flows:

	Three Months Ended March 31,		Change 2025 vs. 2024	
($ in thousands)	**2025**	**2024**	**$**	**%**
Net cash used in operating activities	$ (38,457)	$ (35,722)	$ (2,735)	8 %
Net cash provided by (used in) investing activities	2,851	(2,572)	5,423	(211)%
Net cash provided by financing activities	1,482	52,971	(51,489)	(97)%
Net (decrease) increase in cash and cash equivalents	$ (34,124)	$ 14,677	$ (48,801)	(332)%

Cash Flows from Operating Activities

Net cash used in operating activities increased in the 2025 first quarter primarily due to higher expenses to support our commercial growth and higher payment to AstraZeneca under the AstraZeneca Termination Agreement. This increase was partially offset by cash inflows from higher product sales, net and timing of collection of our accounts receivable.

Cash Flows from Investing Activities

Net cash provided by investing activities increased in the 2025 first quarter primarily due to the timing of our investment maturities and purchases.

Cash Flows from Financing Activities

Net cash provided by financing activities decreased in the 2025 first quarter primarily due to the 2024 first quarter receipt of $49.8 million net of proceeds from the Term C Loan.

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. 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 March 31, 2025, we had cash, cash equivalents and short-term investments of $214.0 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, U.S. treasury securities, corporate bonds, Yankee bonds and asset-backed securities. The credit rating of our short-term investments must be rated A-1/P-1, or better by Standard and Poor's and Moody's Investors Service. Asset-backed securities must be rated AAA/Aaa. Money Market funds must be rated AAA/Aaa. Such interest-earning instruments carry a degree of interest rate risk. However, because our investments are high quality and short-term in duration, we believe that our exposure to interest rate risk is not significant and that a 10% movement in market interest rates would not have a significant impact on the total value of our portfolio, as noted above. We do not enter into investments for trading or speculative purposes.

We are subject to interest rate fluctuation exposure through our borrowings under the 2022 Loan Agreement, which bear interest at SOFR plus a spread based on our public debt rating. 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 $0.4 million for the 2025 first quarter. As of March 31, 2025, we had an aggregate principal amount of $150.0 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, Japanese yen 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. As of March 31, 2025, 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 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 March 31, 2025. 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 March 31, 2025, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the 2025 first quarter, 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

See information under the "Legal Proceedings and Claims" caption of *Note 14. Commitments and Contingencies* which we incorporated here by reference.

ITEM 1A. RISK FACTORS

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

Risks Related to our Financial Condition and Capital Requirements

We have incurred losses in each year since our inception, and we expect to continue to incur operating losses in the future as we 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 IBS-C in adult patients. In November 2023, we commenced the commercialization of XPHOZAH® (tenapanor) 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.

We have incurred losses in each year since our inception in October 2007, and we do not know whether or when we will become profitable. We continue to incur significant commercialization, development and additional expenses related to our ongoing operations and pursuit of future business opportunities. As of March 31, 2025, we had an accumulated deficit of $926.5 million.

We expect to continue to incur operating losses for the foreseeable future as we incur expenses related to our ongoing operations and our pursuit of future business opportunities.

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

Our prior losses, combined with any future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

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

We have substantial net operating loss and tax credit carryforwards for Federal and California income tax purposes. Such net operating losses and tax credits carryforwards may be reduced as a result of certain intercompany restructuring transactions. In addition, the future utilization of such net operating loss and tax credit carryforwards and credits may be subject to limitations, pursuant to Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. 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 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 growth of IBSRELA and XPHOZAH in the U.S. and build a pipeline. The inability to access necessary capital when needed on acceptable terms, or at all, could force us to reduce our efforts to commercialize IBSRELA and/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; investments to build a pipeline; 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 and/or XPHOZAH or otherwise delay or limit our pursuit of future business opportunities. 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;
- the extent to which access to XPHOZAH is impacted by the elimination of Medicare Part D coverage for XPHOZAH which occurred on January 1, 2025, and the extent to which this change will interfere with the shared decision-making between healthcare professionals and their patients, regardless of insurance coverage;
- the extent to which the elimination of separate payment for XPHOZAH for Medicare beneficiaries under Medicare Part D will influence the payment decisions of other payors and the extent to which payment for XPHOZAH will continue to be made as a pharmacy benefit for non-Medicare patients;
- the availability of adequate third-party reimbursement for IBSRELA;
- 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 extent to which IBSRELA and XPHOZAH are commercialized in other ex-U.S. territories;
- the cash requirements necessary to expand our business;
- 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, as amended to date.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to limit or reduce our commercialization of IBSRELA or XPOHZAH, delay or limit additional clinical trials for tenapanor, or delay or limit our pursuit of other future business opportunities.

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

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

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

- our ability to successfully commercialize ISBRELA and XPHOZAH and to increase market share for both products;
- maintaining sufficient market acceptance of IBSRELA as a viable treatment option for IBS-C;
- obtaining market acceptance of XPHOZAH;
- the extent to which access to XPHOZAH is impacted by the elimination of Medicare Part D coverage for XPHOZAH which occurred on January 1, 2025, and the extent to which this change will interfere with the shared decision-making between healthcare professionals and their patients, regardless of insurance coverage;

- the extent to which the elimination of separate payment for XPHOZAH for Medicare beneficiaries under Medicare Part D will influence the payment decisions of other payors and the extent to which payment for XPHOZAH will continue to be made as a pharmacy benefit for non-Medicare patients;
- our ability to obtain an adequate level of coverage and reimbursement for IBSRELA by third-party payors;
- 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. Beginning January 1, 2025, XPHOZAH, along with other oral ESRD related drugs without injectable or intravenous equivalents, are now included in the ESRD PPS, thereby eliminating coverage for XPHOZAH and these other ESRD related drugs under Medicare Part D as of such date. The inclusion of XPHOZAH in the ESRD PPS creates additional uncertainty as to the commercial opportunity for XPHOZAH. See "*—XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer 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*" 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 sales of IBSRELA or XPHOZAH. Even if we achieve profitability on a quarterly basis in the future, we may not be able to sustain profitability for a full fiscal year. Our failure to generate adequate revenue from product sales would likely depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations. A decline in the value of our common stock could cause our stockholders to lose all or part of their investment.

Principal Risks Related to Our Business

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

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

- the ability of the third-party manufacturers we contract with to provide an adequate (in amount and quality) supply of product to support the market demand for IBSRELA;
- our ability to obtain and sustain an adequate level of coverage and reimbursement for IBSRELA by third-party payors;
- the effectiveness of IBSRELA as a treatment for adult patients with IBS-C;
- whether IBSRELA will be subject to price negotiations under the IRA, and the timing and impact of those price negotiations on the revenue from product sales of IBSRELA;
- 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, or that we will be able to secure and maintain adequate coverage and reimbursement for XPHOZAH, or generate sufficient revenue from product sales of XPHOZAH. The inclusion of XPHOZAH in the ESRD PPS creates additional uncertainty as to the commercial opportunity for XPHOZAH.

We began selling XPHOZAH in the U.S. in November 2023. The overall commercial success of XPHOZAH will depend on a number of factors, including the following:

- the extent to which access to XPHOZAH is impacted by the elimination of Medicare Part D coverage for XPHOZAH which occurred on January 1, 2025, and the extent to which this change will interfere with the shared decision-making between healthcare professionals and their patients, regardless of insurance coverage;
- the extent to which the elimination of separate payment for XPHOZAH for Medicare beneficiaries under Medicare Part D will influence the payment decisions of other payors and the extent to which payment for XPHOZAH will continue to be made as a pharmacy benefit for non-Medicare patients;
- 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 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.

There is no guarantee that we will achieve sufficient market acceptance for XPHOZAH, or that we will be able to secure and maintain adequate coverage and reimbursement for XPHOZAH, or generate sufficient revenue from product sales of XPHOZAH. The inclusion of XPHOZAH in the ESRD PPS creates additional uncertainty as to the commercial opportunity for XPHOZAH. See "*—XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer 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*" below.

XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer 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 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 PPS 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. CMS included XPHOZAH in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer 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.

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 impacted by the elimination of Medicare Part D coverage for XPHOZAH which occurred on January 1, 2025, and the extent to which this change will interfere with the shared decision-making between healthcare professionals and their patients, regardless of insurance coverage; and
- the extent to which the elimination of separate payment for XPHOZAH for Medicare beneficiaries under Medicare Part D will influence the payment decisions of other payors and the extent to which payment for XPHOZAH will continue to be made as a pharmacy benefit for non-Medicare patients.

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

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 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., 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. Beginning January 1, 2025, XPHOZAH, along with other oral ESRD related drugs without injectable or intravenous equivalents, are now included in the ESRD PPS, thereby eliminating coverage for XPHOZAH and these other ESRD related drugs under Medicare Part D as of such date. See "*—XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer 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*" above.

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 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 cGMP requirements, 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 cGMP 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.

Further, we currently and may in the future rely on foreign CMOs and CROs. Such foreign CMOs and CROs may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies.

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

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 Lenders 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

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

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

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

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

In addition to the currently available phosphate binders, we are aware of at least four phosphate binders in development, including AP-301, developed by Alebund Pharmaceutical (Hong Kong) Limited and currently in Phase 3; VS-505, developed by Vidasym and currently in clinical development; TS-172, developed by Taisho Pharmaceuticals and currently in Phase 2; and OLC, developed by Unicycive Therapeutics, which has announced its plans to seek U.S. FDA approval via the 505(b)(2) pathway. OLC has demonstrated pharmacodynamic bioequivalence to Fosrenol. Additionally, Alebund is developing 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 our commercialization activities 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.

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.

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

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

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

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

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

Recruiting and retaining qualified scientific, sales and marketing, clinical, medical, business development, manufacturing, finance and administrative 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., 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 CCPA requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. 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, 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 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 FTC 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 GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the 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 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 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.

In addition, we use AI Technologies in our business. The regulatory framework for AI Technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of AI Technologies. As a result, 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 market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations.

It is possible that new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expand resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

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 Fosun Pharma for commercialization of tenapanor for hyperphosphatemia and IBS-C in China and related territories; in Canada with Knight for commercialization of tenapanor for IBS-C and hyperphosphatemia; and with 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.

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 IRBs 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 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 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 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 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.

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;
- changes in laws or policies governing the terms of foreign trade, and in particular increased trade restrictions, tariffs or taxes on imports or exports from or to countries where we manufacture or, sell, or our partners sell, our products to may affect the prices of and demand for our products;
- 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.

Changes in U.S. and international trade policies may adversely impact our business and operating results.

We currently rely on foreign third-party manufacturers. The U.S. government and persons involved in the current administration have made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies. The extent and duration of any tariffs and the resulting impact on general economic conditions and on our business are uncertain and depend on various factors, such as negotiations between the United States and other countries, the response of such countries, exemptions or exclusions that may be granted, and the availability and cost of alternative sources of supply of materials we purchase from companies in other countries targeted with tariffs.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect the demand for IBSRELA and XPHOZAH, and import or export of API and finished product. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

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, other sales practices, as well as the design and implementation of our patient assistance programs, 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 and the design and implementation of patient assistance programs 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, other sales practices, as well as the design and implementation of patient assistance programs, 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 FFDCA, 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 U.S. FDA or other regulations relating to the promotion of our products and/or the design and implementation of our patient assistance programs, 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. Before the Marketing Authorization is granted, the European Medicines Agency 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, including the False Claims Act, 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 Act;
- 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 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 MDRP 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, which was replaced by a new manufacturer discount program on January 1, 2025 (as discussed below), in which manufacturers were required 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, beginning January 1, 2025, XPHOZAH, along with other oral ESRD related drugs without injectable or intravenous equivalents, are now included in the ESRD PPS, thereby eliminating coverage under Medicare Part D as of such date. See "*—XPHOZAH is now included in the ESRD PPS, effective January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is no longer 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*" 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 AMP.

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 IRA was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare which will start to take effect 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 (which began on January 1, 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 HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject

to negotiation. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program, although the 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 MDRP 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.

We participate in the 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 AMP and the best price 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 best price, 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 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 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. VA/FSS pricing program. Under the VA/FSS program, we are obligated to report the Non-FAMP 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 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 an NCE. The U.S. FDA is prohibited during those five years from approving an 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 under the American Inventors Protection Act for delays by the USPTO 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 under the Hatch-Waxman Act and together with patent term adjustment 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 EU Patent Package regulations were passed with the goal of providing a single pan-European Unitary Patent and a new 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 EU 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.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We seek to protect our confidential proprietary information, in part, by entering into confidentiality agreements and invention assignment agreements with parties who have access to them, including our employees, consultants, scientific advisors, contractors, CROs, contract manufacturers, collaborators and other third parties, that are designed to protect our proprietary information. However, we cannot be certain that such agreements have been entered into with all relevant parties that may have or have had access to our trade secrets or proprietary technology, and we cannot be certain 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 and other confidential proprietary technology, or independently develop substantially equivalent information and techniques. For example, any of these parties with whom we have entered into such confidentiality or invention assignment agreements may breach the agreements and disclose our proprietary information, including trade secrets, and we may not be able to obtain adequate remedies for such breaches. We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know, whether the steps we have taken to protect our intellectual property will be effective.

Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. We may not be able to obtain adequate remedies in the event of such unauthorized use. Enforcing a claim that a

party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Trade secrets will also over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic institutions to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets and proprietary information, our agreements may contain certain limited publication rights. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are incorporated (inadvertently or not) into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of such information may be greatly reduced and our competitive position, business, financial condition, results of operations and prospects would be harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive, cancelled or determined to be infringing on other marks. We may not be able to protect or preserve our rights to these trademarks and trade names or may be forced to stop using those names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations and prospects.

Moreover, any name we have proposed to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

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 coverage and reimbursement for XPHOZAH alone or with other oral ESRD related drugs without injectable or intravenous equivalents;
- announcements relating to our current or future collaboration partnerships;
- announcements of therapeutic innovations or new products or strategic transactions by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our product label, our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our approved products or our product candidates;
- the success of our testing and clinical trials;
- failure to meet any of our projected timelines or goals with regard to the commercialization of IBSRELA and XPOHZAH, or the clinical development and commercialization of any of our product candidates;
- the success of our efforts to acquire or license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- the success of our efforts to obtain adequate intellectual property protection for our product candidates;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;

- U.S. FDA or other U.S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the U.S.;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- sales of debt securities and sales or licensing of assets;
- general economic and market conditions and overall fluctuations in the U.S. equity markets; and
- the loss of any of our key scientific or management personnel.

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

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

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

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

We are no longer a "smaller reporting company," and, as a result, we are or will be required to comply with various disclosure and compliance requirements that did not previously apply to us. Compliance with these additional requirements increases our legal and financial compliance costs and causes management and other personnel to divert attention from operational and other business matters to these additional public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to delisting proceedings by the Nasdaq Global Market, or sanctions or investigations by the 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 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 was closed by the California Department of Financial Protection and Innovation, which appointed the U.S. Federal Deposit Insurance Corporation 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 future business opportunities. Additionally, the terms of our 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, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES

Unregistered Sales of Equity Securities

None.

Use of Proceeds

Not applicable.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Trading Plans

During the 2025 first quarter, no director or Section 16 officer adopted or terminated any Rule 10b5-1 plans or non-Rule 10b5-1 trading arrangements.

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	06/24/2024	3.1	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	8-K	06/20/2023	3.1	
3.3	Amended and Restated Bylaws.	8-K	06/24/2014	3.2	
10.1#	Second Amended and Restated Executive Employment Agreement, dated April 29, 2025, by and between Ardelyx, Inc. and Michael Raab.				X
10.2#	Form of Amended and Restated Change in Control and Severance Agreement for Executive Officers Other Than CEO.				X
10.3#	Fourth Amended and Restated Non-Employee Director Compensation Program.				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 March 31, 2025 and December 31, 2024, (ii) Condensed Statements of Operations and Comprehensive Loss for the three months ended March 31, 2025 and 2024, (iii) Condensed Statements of Changes in Stockholders' Equity for the three months ended March 31, 2025 and 2024, (iv) Condensed Statements of Cash Flows for the three months ended March 31, 2025 and 2024, 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.

SIGNATURE

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: May 1, 2025

By: /s/ Joseph Reilly

Joseph Reilly
Senior Vice President and Chief Accounting Officer
(Principal Accounting Officer)

SUMMARY OF ABBREVIATED TERMS

Throughout this Quarterly Report on Form 10-Q, we have used terms which are defined below:

340B Program	Public Health Service's 340B Drug Pricing Program	GTN	gross-to-net
AAKP	American Association of Kidney Patients	HCR	HealthCare Royalty Partners IV, L.P.
ACA	Affordable Care Act	HCR Agreement	Royalty and Sales Milestone Interest Acquisition Agreement
AI Technologies	Artificial intelligence, machine learning and certain automated decision-making technologies	HHS	Department of Health and Human Services
AMP	average manufacturer price	HIPAA	Health Insurance Portability and Accountability Act of 1996, as amended, and regulations promulgated thereunder
ANDA	abbreviated New Drug Application	HRSA	Health Resources and Services Administration
2024 Form 10-K	Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on February 20, 2025	IBS-C	irritable bowel syndrome with constipation
API	active pharmaceutical ingredient	IND	Investigational New Drug
AstraZeneca	AstraZeneca AB	IRA	Inflation Reduction Act of 2022
ASU	Accounting Standards Update	IRB	institutional review board
CCPA	California Consumer Privacy Act, as amended by the California Privacy Rights Act	Jefferies	Jefferies, LLC
cGMP	current Good Manufacturing Practice	Kyowa Kirin	Kyowa Kirin Co., Ltd.
CKD	chronic kidney disease	Knight	Knight Therapeutics, Inc.
CME	Chicago Mercantile Exchange	MDRP	Medicaid Drug Rebate Program
CMO	contract manufacturing organization	METiS	METiS Therapeutics, Inc.
CMS	Centers for Medicare & Medicaid Services	MHLW	Ministry of Health, Labour and Welfare
CRO	contract research organization	MIPPA	Medicare Improvements for Patients and Providers Act
CODM	Chief Operating Decision Maker	OLC	Oxylanthanum Carbonate
Customers	collectively, major wholesalers, specialty pharmacies and GPOs (IBSRELA) and specialty wholesaler (XPHOZAH)	NCE	new chemical entity
DPF	EU-US Data Privacy Framework	NDA	New Drug Application
EEA	European Economic Area	NH3	sodium hydrogen exchange 3
ESPP	Employee Stock Purchase Plan	NMPA	National Medical Products Administration
ESRD	End-Stage Renal Disease	NOL	net operating loss
ESRD PPS	End-Stage Renal Disease Prospective Payment System	NMQF	National Minority Quality Forum
EU Patent Package	European Patent Package	Non-FAMP	Non-Federal Average Manufacturer Price
Exchange Act	the Securities Exchange Act of 1934, as amended	R&D	research and development
FASB	Financial Accounting Standards Board	REMS	Risk Evaluation and Mitigation Strategy
FDA	Food and Drug Administration	RSU	restricted stock units
FFDCA	Federal Food, Drug, and Cosmetic Act	SLR	SLR Investment Corp.
Fosun Pharma	Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd.	SEC	Securities and Exchange Commission
FSS	Federal Supply Schedule	SOFR	Secured Overnight Financing Rate
FTC	Federal Trade Commission	TDAPA	Transitional Drug Add-on Payment Adjustment
GAAP	generally accepted accounting principles	UPC	European Unified Patent Court
GCP	Good Clinical Practice	U.S.	United States
GDPR	European Union General Data Protection Regulation	USPTO	U.S. Patent and Trademark Office
GLP	Good Laboratory Practice	VA	Department of Veterans Affairs
GPO	group purchasing organization		

SECOND AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This Second Amended and Restated Executive Employment Agreement (the "**Agreement**") is entered into as of April 29, 2025 (the "**Effective Date**"), by and between Michael Raab ("**Executive**") and Ardelyx, Inc. (the "**Company**").

WHEREAS, the Company and Executive entered into that certain Amended and Restated Executive Employment Agreement dated as of June 6, 2014 setting forth the terms of Executive's employment by the Company as its Chief Executive Officer (the "**Prior Agreement**");

WHEREAS, Executive is currently employed by Company as its President and Chief Executive Officer, and Company desires to have the continued benefit of Executive's employment in such capacity, and Executive desires to continue to serve in such capacity, pursuant to the terms and conditions set forth in this Agreement; and

WHEREAS, Company and Executive intend that the Prior Agreement be superseded in all respects by this Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, it is hereby agreed by and between the parties hereto as follows:

ARTICLE I
DEFINITIONS

For purposes of the Agreement, the following terms are defined as follows:

1.1. "**Board**" means the Board of Directors of the Company.

1.2. "**Cause**" means any of the following events described below:

(a) Executive's theft, dishonesty or falsification of any employment or Company records that is non-trivial in nature;

(b) malicious or reckless disclosure of the Company's confidential or proprietary information or any material breach by Executive of his obligations under the Confidential Information Agreement;

(c) the conviction of the Executive of a felony (excluding motor vehicle violations) or the commission of gross negligence or willful misconduct, where a majority of the non-employee members of the Board reasonably determines that such act or misconduct has (i) seriously undermined the ability of the Board or management of the Company to entrust Executive with important matters or otherwise work effectively with Executive, (ii) substantially contributed to the Company's loss of significant revenues or business opportunities, or (iii) significantly and detrimentally affected the business or reputation of the Company or any of its subsidiaries; and/or

(d) the willful failure or refusal by Executive to follow the reasonable and lawful directives of the Board, provided such willful failure or refusal continues after Executive's receipt of reasonable notice in writing of such failure or refusal and a reasonable opportunity of not less than 30 days to correct the problem.

For the purpose of this Agreement, no act, or failure to act, shall be considered "willful" unless undertaken by Executive with an absence of good faith that this act, or failure to act, was in the best interests of the Company.

1.3. "**Change in Control**" shall have the meaning set forth in the Company's 2014 Equity Incentive Award Plan, as it may be amended from time to time, provided that such event must also constitute a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5).

1.4. "**COBRA**" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

1.5. "**Code**" means the Internal Revenue Code of 1986, as amended.

1.6. "**Company**" means Ardelyx, Inc. or any successor thereto.

1.7. "**Confidential Information Agreement**" means the Proprietary Information and Inventions Assignment Agreement entered into between Executive and the Company.

1.8. "**Covered Termination**" means (a) an Involuntary Termination Without Cause or (b) a voluntary termination for Good Reason, provided that the termination constitutes a Separation from Service.

1.9. "**Good Reason**" means Executive's resignation as a result of a Good Reason Condition. In order to resign for Good Reason, Executive must provide written notice to the Company of the existence of the Good Reason Condition within thirty (30) days of the initial existence of such Good Reason Condition. Upon receipt of such notice of the Good Reason Condition, the Company will be provided with a period of thirty (30) days during which it may remedy the Good Reason Condition and not be required to provide for the payments and benefits described in Section 4 as a result of such proposed resignation due to the Good Reason Condition specified in the notice. If the Good Reason Condition is not remedied within the period specified in the preceding sentence, Executive may resign for Good Reason based on the Good Reason Condition specified in the notice, provided that such resignation must occur within sixty (60) days after the initial existence of such Good Reason Condition.

1.10. "**Good Reason Condition**" means that any of the following are undertaken without Executive's express written consent:

(a) a material diminution in Executive's authority, duties, or responsibilities which substantially reduces the nature or character of Executive's position with the Company;

(b) a reduction by the Company of Executive's Base Salary (as defined in Section 3.1 below) as in effect immediately prior to such reduction (disregarding any reduction in base salary that would give rise to Executive's right to a resignation for Good Reason);

(c) a relocation of Executive's principal office to a location more than fifty (50) miles from the location of Executive's principal office as of immediately prior to such relocation, except for required travel by Executive on the Company's business; or

(d) any material breach by the Company of any provision of this Agreement which the Company does not cure within 30 days following written notice thereof from Executive.

1.11. "**Involuntary Termination Without Cause**" means Executive's dismissal or discharge by the Company other than for Cause. The termination of Executive's employment as a result of Executive's death or inability to perform the essential functions of his job due to disability will not be deemed to be an Involuntary Termination Without Cause.

1.12. "**Separation from Service**" means Executive's termination of employment or service constitutes a "separation from service" within the meaning of Treasury Regulation Section 1.409A-1(h).

ARTICLE II
EMPLOYMENT BY THE COMPANY

2.1. Position and Duties. Subject to terms set forth herein, Executive shall continue to serve in an executive capacity and shall continue to perform such duties as are customarily associated with the positions of President and Chief Executive Officer and such other duties as are assigned to Executive by the Board. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention (except for vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies or as otherwise set forth in this Agreement) to the business of the Company. As of the Effective Date, Executive shall continue to serve as a member of the Board.

2.2. Employment at Will. Both the Company and Executive shall have the right to terminate Executive's employment with the Company at any time, with or without Cause, and without prior notice. If Executive's employment with the Company is terminated, Executive will be eligible to receive severance benefits to the extent provided in this Agreement.

2.3. Employment Policies. The employment relationship between the parties shall also be governed by the general employment policies and practices of the Company, including those relating to protection of confidential information and assignment of inventions, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

ARTICLE III
COMPENSATION

3.1. Base Salary. As of the Effective Date, Executive shall receive for services to be rendered hereunder an annual base salary of $797,000 ("**Base Salary**"), payable on the regular payroll dates of the Company, subject to increase in the sole discretion of the Board.

3.2. Annual Bonus. As of the Effective Date, Executive is eligible to receive an annual performance bonus targeted at seventy-five percent (75%) of Base Salary, on such terms and conditions determined by the Board or a committee of the Board (the "**Annual Bonus**"). Annual Bonus payments for 2014, as well as for future years, will be determined in the discretion of the Board or a committee of the Board and will be (a) subject to achievement of any applicable bonus objectives and/or conditions determined by the Board or a committee of the Board, and (b) payable to Executive during the year following the end of the applicable calendar year at the same time as bonuses for other Company executives are paid.

3.3. Standard Company Benefits. Executive shall continue to be entitled to all rights and benefits for which Executive is eligible under the terms and conditions of the standard Company benefits and compensation practices that may be in effect from time to time and are provided by the Company to its executive employees generally.

3.4. Equity Awards. Executive shall continue to be eligible to be granted additional equity awards in accordance with the Company's policies as in effect from time to time.

ARTICLE IV
SEVERANCE AND CHANGE IN CONTROL BENEFITS

4.1. Severance Benefits. Upon Executive's termination of employment, Executive shall receive any accrued but unpaid Base Salary and other accrued and unpaid compensation, including any Annual Bonus that has been earned with respect to a prior year, but remains unpaid as of the date of the termination. If the termination is due to a Covered Termination, provided that Executive first returns all Company property in his possession and, within sixty (60) days following the Covered Termination, executes and does not revoke an effective general release of all claims against the Company and its affiliates in a form reasonably acceptable to the Company (a "**Release of Claims**"), Executive shall also be entitled to receive the following severance benefits described in this Section 4.1.

(a) Covered Termination Not Related to a Change in Control. If Executive's employment terminates due to a Covered Termination which occurs more than three (3) months prior to a Change in Control or more than twelve (12) months after a Change in Control, Executive shall receive the following:

(i) An amount equal to eighteen (18) months of Executive's Base Salary payable in substantially equal installments in accordance with the Company's normal payroll policies, less applicable withholdings, with such installments to commence as soon as administratively practicable following the date the Release of Claims is not subject to revocation and, in any event, within sixty (60) days following the date of the Covered Termination.

(ii) If Executive elects to receive continued healthcare coverage pursuant to the provisions of COBRA, the Company shall directly pay, or reimburse Executive for, the premium for Executive and Executive's covered dependents through the earlier of (i) the eighteen (18-) month anniversary of the date of Executive's termination of employment and (ii) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s). Notwithstanding the foregoing, (i) if any plan pursuant to which such

benefits are provided is not, or ceases prior to the expiration of the period of continuation coverage to be, exempt from the application of Section 409A of the Code under Treasury Regulation Section 1.409A-1(a)(5), or (ii) the Company is otherwise unable to continue to cover Executive under its group health plans without penalty under applicable law (including without limitation, Section 2716 of the Public Health Service Act), then, in either case, an amount equal to each remaining Company subsidy shall thereafter be paid to Executive in substantially equal monthly installments. After the Company ceases to pay premiums pursuant to this Section 4.1(a)(ii), Executive may, if eligible, elect to continue healthcare coverage at Executive's expense in accordance the provisions of COBRA.

(iii) Each outstanding time-based equity award, including, without limitation, each time-based stock option, restricted stock unit award and restricted stock award, held by Executive shall automatically become vested and, if applicable, exercisable and any forfeiture restrictions or rights of repurchase thereon shall immediately lapse, in each case, with respect to that number of shares that would have vested and, if applicable, become exercisable in the eighteen (18) months immediately following Executive's Covered Termination had Executive's employment continued during such eighteen (18) month period. Each outstanding performance-based equity award, including, without limitation, each performance-based stock option, restricted stock unit award and restricted stock award, held by Executive shall be treated as set forth in the agreement evidencing such performance-based equity award or, in the absence of treatment in the applicable agreement evidencing the performance-based equity award, automatically become vested and, if applicable, exercisable and any forfeiture restrictions or rights of repurchase thereon shall immediately lapse, in each case, with respect to that number of shares that would have vested and, if applicable, become exercisable in the eighteen (18) months immediately following Executive's Covered Termination had Executive's employment continued during such eighteen (18) month period and achievement of the applicable performance goals was at target. To the extent vested after

giving effect to the acceleration provided in the preceding sentences, each stock option held by Executive shall remain exercisable until the earlier of the original expiration date for such stock option or the first anniversary of Executive's Covered Termination.

(b) Covered Termination Related to a Change in Control. If Executive's employment terminates due to a Covered Termination that occurs within three (3) months prior to a Change in Control or during the twelve (12) month period after a Change in Control, Executive shall receive the following:

(i) Executive shall be entitled to receive an amount equal to 2.0 multiplied by the sum of: (i) Executive's Base Salary and (ii) Executive's target Annual Bonus for the fiscal year of Executive's termination, in each case, at the rate in effect immediately prior to Executive's termination of employment (or, if higher, immediately prior to the Change in Control) payable in a cash lump sum, less applicable withholdings, as soon as administratively practicable following the date the Release of Claims is not subject to revocation and, in any event, within sixty (60) days following the date of the Covered Termination.

(ii) If Executive elects to receive continued healthcare coverage pursuant to the provisions of COBRA, the Company shall directly pay, or reimburse Executive for, the premium for Executive and Executive's covered dependents through the earlier of (i) the twenty-four (24) month anniversary of the date of Executive's termination of employment and (ii) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s). Notwithstanding the foregoing, (i) if any plan pursuant to which such benefits are provided is not, or ceases prior to the expiration of the period of continuation coverage to be, exempt from the application of Section 409A of the Code under Treasury Regulation Section 1.409A-1(a)(5), or (ii) the Company is otherwise unable to continue to cover Executive under its group health plans without penalty under applicable law (including without limitation, Section 2716 of the Public Health Service Act), then, in either case, an amount equal to each remaining Company subsidy shall thereafter be paid to Executive in substantially equal monthly installments. After the Company ceases to pay premiums pursuant to this Section 4.1(b)(ii), Executive may, if eligible, elect to continue healthcare coverage at Executive's expense in accordance the provisions of COBRA.

(iii) Each outstanding time-based equity award, including, without limitation, each time-based stock option, restricted stock unit award and restricted stock award, held by Executive shall automatically become vested and, if applicable, exercisable and any forfeiture restrictions or rights of repurchase thereon shall immediately lapse, in each case, with respect to one hundred percent (100%) of the shares subject thereto. Each outstanding performance-based equity award, including, without limitation, each performance-based stock option, restricted stock unit award and restricted stock award, held by Executive shall be treated as set forth in the agreement evidencing such performance-based equity award or, in the absence of treatment in the applicable agreement evidencing the performance-based equity award, automatically become vested and, if applicable, exercisable and any forfeiture restrictions or rights of repurchase thereon shall immediately lapse, in each case, with respect to one hundred percent (100%) of the shares subject thereto based on achievement of any performance goals target. To the extent vested after giving effect to the acceleration provided in the preceding sentences, each stock option held by Executive shall remain exercisable until the earlier of the original expiration date for such stock option or the first anniversary of Executive's Covered Termination.

4.2. 280G Provisions. Notwithstanding anything in this Agreement to the contrary, if any payment or distribution Executive would receive pursuant to this Agreement or otherwise ("**Payment**") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then such Payment shall either be (i) delivered in full, or (ii) delivered as to such lesser extent which would result in no portion of such Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Executive on an after-tax basis, of the largest payment, notwithstanding that all or some portion the Payment may be taxable under Section 4999 of the Code. The accounting firm engaged by the Company for general audit purposes as of

the day prior to the effective date of the Change in Control shall perform the foregoing calculations. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The accounting firm shall provide its calculations to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to a Payment is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive. Any reduction in payments and/or benefits pursuant to this Section 4.2 will occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits payable to Executive.

4.3. Section 409A.

(a) Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed at the time of his Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code which would subject Executive to a tax obligation under Section 409A of the Code, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of the Executive's Separation from Service or (ii) the date of Executive's death. Upon the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 4.3(a) shall be paid in a lump sum to Executive, and any remaining payments due under the Agreement shall be paid as otherwise provided herein.

(b) Any reimbursements payable to Executive pursuant to the Agreement shall be paid to Executive no later than 30 days after Executive provides the Company with a written request for reimbursement, and to the extent that any such reimbursements are deemed to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (i) such amounts shall be paid or reimbursed to Executive promptly, but in no event later than December 31 of the year following the year in which the expense is incurred, (ii) the amount of any such payments eligible for reimbursement in one year shall not affect the payments or expenses that are eligible for payment or reimbursement in any other taxable year, and (iii) Executive's right to such payments or reimbursement shall not be subject to liquidation or exchange for any other benefit.

(c) For purposes of Section 409A of the Code (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive installment payments under the Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment.

4.4. Mitigation. Executive shall not be required to mitigate damages or the amount of any payment provided under this Agreement by seeking other employment or otherwise, nor shall the amount of any payment provided for under this Agreement be reduced by any compensation earned by Executive as a result of employment by another employer or by any retirement benefits received by Executive after the date of the Covered Termination, or otherwise.

ARTICLE V
PROPRIETARY INFORMATION OBLIGATIONS

5.1. Agreement. Executive agrees to continue to abide by the Confidential Information Agreement.

5.2. Remedies. Executive's duties under the Confidential Information Agreement shall survive termination of Executive's employment with the Company and the termination of this Agreement. Executive acknowledges

that a remedy at law for any breach or threatened breach by Executive of the provisions of the Confidential Information Agreement, as well as Executive's obligations pursuant to Section 6.2 and Article 7 below, would be inadequate, and Executive therefore agrees that the Company shall be entitled to seek injunctive relief in case of any such breach or threatened breach.

ARTICLE VI
OUTSIDE ACTIVITIES

6.1. Other Activities.

(a) Except as otherwise provided in Section 6.1(b), Executive shall not, during the term of this Agreement undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor, unless he obtains the prior written consent of the Board.

(b) Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder. In addition, Executive shall be allowed to serve as a member of the board of directors of up to two (2) other for profit entities at any time during the term of this Agreement, which service shall not materially interfere with the performance of Executive's duties hereunder; provided, however, that the Board, in its discretion, may require that Executive resign from one or both of such director positions if it determines that such resignation(s) would be in the best interests of the Company.

6.2. Competition/Investments. During the term of Executive's employment by the Company, except on behalf of the Company, Executive shall not directly or indirectly, whether as an officer, director, stockholder, partner, proprietor, associate, representative, consultant, or in any capacity whatsoever engage in, become financially interested in, be employed by or have any business connection with any other person, corporation, firm, partnership or other entity whatsoever which were known by Executive to compete directly with the Company, throughout the world, in any line of business engaged in (or planned to be engaged in) by the Company; provided, however, that anything above to the contrary notwithstanding, Executive may own, as a passive investor, securities of any competitor corporation, so long as Executive's direct holdings in any one such corporation shall not in the aggregate constitute more than 1% of the voting stock of such corporation.

ARTICLE VII
NONINTERFERENCE

In addition to Executive's obligations under the Confidential Information Agreement, Executive shall not for a period of two (2) years following Executive's termination of employment for any reason, either on Executive's own account or jointly with or as a manager, agent, officer, employee, consultant, partner, joint venturer, owner or stockholder or otherwise on behalf of any other person, firm or corporation, directly or indirectly solicit or attempt to solicit away from the Company any of its officers or employees or offer employment to any person who is an officer or employee of the Company; *provided, however*, that a general advertisement to which an employee of the Company responds shall in no event be deemed to result in a breach of this Article 7. Executive also agrees not to harass or disparage the Company or its employees, clients, directors or agents or divert or attempt to divert any actual or potential business of the Company. The provisions of this Article 7 shall survive the termination or expiration of the applicable Executive's employment with the Company and shall be fully enforceable thereafter. If it is determined by a court of competent jurisdiction in any state that any restriction in this Article 7 is excessive in duration or scope or is unreasonable or unenforceable under the laws of that state, it is the intention of the parties that such restriction may be modified or amended by the court to render it enforceable to the maximum extent permitted by the law of that state.

ARTICLE VIII
GENERAL PROVISIONS

8.1. Notices. Any notices provided hereunder must be in writing and shall be deemed effective upon the earlier of personal delivery (including personal delivery by facsimile) or the third day after mailing by first class mail, to the Company at its primary office location and to Executive at Executive's address as listed on the Company payroll.

8.2. Tax Withholding. Executive acknowledges that all amounts and benefits payable under this Agreement are subject to deduction and withholding to the extent required by applicable law.

8.3. Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provisions had never been contained herein.

8.4. Waiver. If either party should waive any breach of any provisions of this Agreement, they shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

8.5. Complete Agreement. This Agreement, collectively with the Confidential Information Agreement and the agreements evidencing Executive's equity awards, constitutes the entire agreement between Executive and the Company and is the complete, final, and exclusive embodiment of their agreement with regard to this subject matter, and will supersede all prior agreements, understandings, discussions, negotiations and undertakings, whether written or oral, between the parties with respect to the subject matter hereof, including without limitation, the Prior Agreement. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein or therein, and cannot be modified or amended except in a writing signed by an officer of the Company and Executive.

8.6. Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

8.7. Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

8.8. Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign his rights or delegate his duties or obligations hereunder without the prior written consent of the Company.

8.9. Arbitration. Unless otherwise prohibited by law or specified below, all disputes, claims and causes of action, in law or equity, arising from or relating to this Agreement or its enforcement, performance, breach, or interpretation shall be resolved solely and exclusively by

final and binding arbitration held in Alameda County, California through Judicial Arbitration & Mediation Services/Endispute ("**JAMS**") in conformity with the then-existing JAMS employment arbitration rules and California law, a copy of which can be found at https://www.jamsadr.com/rules-employment-arbitration/english. The arbitrator shall: (a) provide adequate discovery for the resolution of the dispute; and (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the

award. However, nothing in this section is intended to prevent either party from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. The Company shall bear the costs of any such arbitration.

8.10. Executive Acknowledgement. Executive acknowledges that (a) he has consulted with or has had the opportunity to consult with independent counsel of his own choice concerning this Agreement, and has been advised to do so by the Company, and (b) that he has read and understands the Agreement, is fully aware of its legal effect, and has entered into it freely based on his own judgment.

8.11. Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the law of the State of California without regard to the conflicts of law provisions thereof.

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

ARDELYX, INC.

By: /s/ DAVID MOTT
DAVID MOTT

Title: Chairman of the Board of Directors

Accepted and Agreed:

/s/ MICHAEL RAAB
MICHAEL RAAB

ARDELYX, INC.

[THIRD] [AMENDED AND RESTATED] CHANGE IN CONTROL SEVERANCE AGREEMENT

This [Third] [Amended and Restated] Change in Control Severance Agreement (the "Agreement") is made and entered into [Date] (the "Effective Date") by and between [Executive Name] (the "Executive") and Ardelyx, Inc. (the "Company"). [This Agreement amends and restates in its entirety that certain [Second] [Amended and Restated] Change in Control Severance Agreement by and between Executive and the Company effective as of [Date] (the "Prior Agreement")].

R E C I T A L S

A. It is expected that the Company from time to time will consider the possibility of an acquisition by another company or other change in control. The Board of Directors of the Company (the "Board") recognizes that such consideration as well as the possibility of an involuntary termination or reduction in responsibility can be a distraction to Executive and can cause Executive to consider alternative employment opportunities. The Board has determined that it is in the best interests of the Company and its stockholders to assure that the Company will have the continued dedication and objectivity of Executive, notwithstanding the possibility, threat or occurrence of such an event.

B. The Board believes that it is in the best interests of the Company and its stockholders to provide Executive with an incentive to continue Executive's employment and to motivate Executive to maximize the value of the Company upon a Change in Control (as defined below) for the benefit of its stockholders.

C. The Board believes that it is imperative to provide Executive with severance benefits upon certain terminations of Executive's service to the Company that enhance Executive's financial security and provide incentive and encouragement to Executive to remain with the Company notwithstanding the possibility of such an event.

D. Certain capitalized terms used in this Agreement are defined in Section 7 below.

The parties hereto agree as follows:

1. Term of Agreement. This Agreement shall become effective as of the Effective Date and terminate upon the date that all obligations of the parties hereto with respect to this Agreement have been satisfied.

2. At-Will Employment. The Company and Executive acknowledge that Executive's employment is and shall continue to be "at-will," as defined under applicable law. If Executive's

employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, awards or compensation other than as provided by this Agreement.

3. Covered Termination Other Than During a Change in Control Period. If Executive experiences a Covered Termination other than during a Change in Control Period, and if Executive delivers to the Company a general release of all claims against the Company and its affiliates in a form acceptable to the Company (a "Release of Claims") that becomes effective and irrevocable within sixty (60) days, or such shorter period of time specified by the Company, following such Covered Termination, then in addition to any accrued but unpaid salary, bonus, vacation and expense reimbursement payable in accordance with applicable law, the Company shall provide Executive with the following:

(a) Severance. Executive shall be entitled to receive an amount equal to twelve (12) months of Executive's Base Salary payable in substantially equal installments in accordance with the Company's normal payroll policies, less applicable withholdings, with such installments to commence as soon as administratively practicable following the date the Release of Claims is not subject to revocation and, in any event, within sixty (60) days following the date of the Covered Termination.

(b) Equity Awards. Each outstanding time-based equity award, including, without limitation, each time-based stock option, restricted stock unit award and restricted stock award, held by Executive shall automatically become vested and, if applicable, exercisable, and any forfeiture restrictions or rights of repurchase thereon shall immediately lapse, in each case, with respect to that number of shares that would have vested, and if applicable, become exercisable, in the Acceleration Determination Period had Executive's employment continued during the entire Acceleration Determination Period. Each outstanding performance-based equity award, including, without limitation, each performance-based stock option, restricted stock unit award and restricted stock award, held by Executive shall be treated as set forth in the agreement evidencing such performance-based equity award or, in the absence of treatment in the applicable agreement evidencing the performance-based equity award, automatically become vested and, if applicable, exercisable, and any forfeiture restrictions or rights of repurchase thereon shall immediately lapse, in each case, with respect to that number of shares that would have vested and, if applicable, become exercisable in the Acceleration Determination Period had Executive's employment continued during such Acceleration Determination Period and achievement of the applicable performance goals was at target.

(c) Continued Healthcare. If Executive elects to receive continued healthcare coverage pursuant to the provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company shall directly pay, or reimburse Executive for, the premium for Executive and Executive's covered dependents through the earlier of (i) the twelve (12) month anniversary of the date of Executive's termination of employment and (ii) the date Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s). Notwithstanding the foregoing, (i) if any plan pursuant to which such benefits are provided is not, or ceases prior to the expiration of the period of continuation coverage to be,

exempt from the application of Section 409A of the Code under Treasury Regulation Section 1.409A-1(a)(5), or (ii) the Company is otherwise unable to continue to cover Executive under its group health plans without penalty under applicable law (including without limitation, Section 2716 of the Public Health Service Act), then, in either case, an amount equal to each remaining Company subsidy shall thereafter be paid to Executive in substantially equal monthly installments. After the Company ceases to pay premiums pursuant to this Section 3(c), Executive may, if eligible, elect to continue healthcare coverage at Executive's expense in accordance the provisions of COBRA.

4. Covered Termination During a Change in Control Period. If Executive experiences a Covered Termination during a Change in Control Period, and if Executive delivers to the Company a Release of Claims that becomes effective and irrevocable within sixty (60) days, or such shorter period of time specified by the Company, following such Covered Termination, then in addition to any accrued but unpaid salary, bonus, vacation and expense reimbursement payable in accordance with applicable law, the Company shall provide Executive with the following:

(a) Severance. Executive shall be entitled to receive an amount equal to 1.5 multiplied by the sum of: (i) Executive's Base Salary and (ii) Executive's target annual bonus for the fiscal year of Executive's termination, in each case, at the rate in effect immediately prior to Executive's termination of employment (or, if higher, immediately prior to the Change in Control) payable in a cash lump sum, less applicable withholdings, as soon as administratively practicable following the date the Release of Claims is not subject to revocation and, in any event, within sixty (60) days following the date of the Covered Termination.

(b) Equity Awards. Each outstanding time-based equity award, including, without limitation, each time-based stock option, restricted stock unit award and restricted stock award, held by Executive shall automatically become vested and, if applicable, exercisable and any forfeiture restrictions or rights of repurchase thereon shall immediately lapse, in each case, with respect to one hundred percent (100%) of the shares subject thereto. Each outstanding performance-based equity award, including, without limitation, each performance-based stock option, restricted stock unit award and restricted stock award, held by Executive shall be treated as set forth in the agreement evidencing such performance-based equity award or, in the absence of treatment in the applicable agreement evidencing the performance-based equity award, automatically become vested and, if applicable, exercisable and any forfeiture restrictions or rights of repurchase thereon shall immediately lapse, in each case, with respect to one hundred percent (100%) of the shares subject thereto based on achievement of any performance goals at target. To the extent vested after giving effect to the acceleration provided in the preceding sentences, each stock option held by Executive shall remain exercisable until the earlier of the original expiration date for such stock option or the first anniversary of Executive's Covered Termination.

(c) Continued Healthcare. If Executive elects to receive continued healthcare coverage pursuant to the provisions of COBRA, the Company shall directly pay, or reimburse Executive for, the premium for Executive and Executive's covered dependents through the earlier of (i) the 18 month anniversary of the date of Executive's termination of employment and (ii) the date

Executive and Executive's covered dependents, if any, become eligible for healthcare coverage under another employer's plan(s). Notwithstanding the foregoing, (i) if any plan pursuant to which such benefits are provided is not, or ceases prior to the expiration of the period of continuation coverage to be, exempt from the application of Section 409A of the Code under Treasury Regulation Section 1.409A-1(a)(5), or (ii) the Company is otherwise unable to continue to cover Executive under its group health plans without penalty under applicable law (including without limitation, Section 2716 of the Public Health Service Act), then, in either case, an amount equal to each remaining Company subsidy shall thereafter be paid to Executive in substantially equal monthly installments. After the Company ceases to pay premiums pursuant to this Section 4(c), Executive may, if eligible, elect to continue healthcare coverage at Executive's expense in accordance the provisions of COBRA.

5. Other Terminations. If Executive's service with the Company is terminated by the Company or by Executive for any or no reason other than as a Covered Termination, then Executive shall not be entitled to any benefits hereunder other than accrued but unpaid salary, bonus, vacation and expense reimbursement in accordance with applicable law and to elect any continued healthcare coverage as may be required under COBRA or similar state law.

6. Limitation on Payments. Notwithstanding anything in this Agreement to the contrary, if any payment or distribution Executive would receive pursuant to this Agreement or otherwise ("Payment") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment shall either be (i) delivered in full, or (ii) delivered as to such lesser extent which would result in no portion of such Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Executive on an after-tax basis, of the largest payment, notwithstanding that all or some portion the Payment may be taxable under Section 4999 of the Code. The accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The accounting firm shall provide its calculations to the Company and Executive within fifteen (15) calendar days after the date on which Executive's right to a Payment is triggered (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Executive. Any reduction in payments and/or benefits pursuant to this Section 6 will occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits payable to Executive.

7. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) Acceleration Determination Period. Acceleration Determination Period means that number of months following Executive's Covered Termination derived from the application of the following formula: three months for each twelve months of service to the Company; provided that the Acceleration Determination Period shall never exceed twelve (12) months.

(b) Base Salary. "Base Salary" means Executive's annual base salary in effect immediately prior to Executive's termination (disregarding any reduction in base salary that would give rise to Executive's right to a Voluntary Resignation for Good Reason).

(c) Cause. "Cause" means (i) Executive's theft, dishonesty or falsification of any employment or Company records that is non-trivial in nature; (ii) Executive's malicious or reckless disclosure of the Company's confidential or proprietary information or any material breach by Executive of his or her obligations under the Confidential Information Agreement (as defined below); (iii) the conviction of the Executive of a felony (excluding motor vehicle violations) or the commission of gross negligence or willful misconduct, where a majority of the non-employee members of the Board reasonably determines that such act or misconduct has (A) seriously undermined the ability of the Board or management of the Company to entrust Executive with important matters or otherwise work effectively with Executive, (B) substantially contributed to the Company's loss of significant revenues or business opportunities, or (C) significantly and detrimentally affected the business or reputation of the Company or any of its subsidiaries; and/or (iv) the willful failure or refusal by Executive to follow the reasonable and lawful directives of the Board or Executive's direct supervisor, provided such willful failure or refusal continues after Executive's receipt of reasonable notice in writing of such failure or refusal and a reasonable opportunity of not less than 30 days to correct the problem. For the purpose of this Agreement, no act, or failure to act, shall be considered "willful" unless undertaken by Executive with an absence of good faith that this act, or failure to act, was in the best interests of the Company.

(d) Change in Control. "Change in Control" shall have the meaning set forth in the Company's 2014 Equity Incentive Award Plan, as it may be amended from time to time, provided that such event must also constitute a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5).

(e) Change in Control Period. "Change in Control Period" means the period of time beginning three (3) months prior to and ending twelve (12) months following a Change in Control.

(f) Covered Termination. "Covered Termination" means (a) an Involuntary Termination Without Cause or (b) a Voluntary Resignation for Good Reason, provided that such termination or resignation constitutes a Separation from Service.

(g) Good Reason Condition. "Good Reason Condition" means that any of the following are undertaken without Executive's express written consent: (i) a material diminution in Executive's authority, duties, or responsibilities which substantially reduces the nature or character

of Executive's position with the Company; (ii) a material reduction by the Company of Executive's base salary as in effect immediately prior to such reduction; (iii) a relocation of Executive's principal office to a location more than fifty (50) miles from the location of Executive's principal office as of immediately prior to such relocation, except for required travel by Executive on the Company's business; or (iv) any material breach by the Company of any provision of Executive's employment agreement or offer letter agreement which the Company does not cure within 30 days following written notice thereof from Executive.

(h) Involuntary Termination Without Cause. "Involuntary Termination Without Cause" means Executive's dismissal or discharge by the Company other than for Cause. The termination of Executive's employment as a result of Executive's death or inability to perform the essential functions of his job due to disability will not be deemed to be an Involuntary Termination Without Cause.

(i) Separation from Service. "Separation from Service" means Executive's termination of employment or service constitutes a "separation from service" within the meaning of Treasury Regulation Section 1.409A-1(h).

(j) Voluntary Resignation for Good Reason. "Voluntary Resignation for Good Reason" means Executive's resignation as a result of a Good Reason Condition in accordance with this subsection (i). In order for a resignation to constitute a Voluntary Resignation for Good Reason, Executive must provide written notice to the Company of the existence of the Good Reason Condition within thirty (30) days of the initial existence of such Good Reason Condition. Upon receipt of such notice of the Good Reason Condition, the Company will be provided with a period of thirty (30) days during which it may remedy the Good Reason Condition and not be required to provide for the payments and benefits described in Sections 3 or 4 as a result of such proposed resignation due to the Good Reason Condition specified in the notice. If the Good Reason Condition is not remedied within the period specified in the preceding sentence, Executive may resign for Good Reason based on the Good Reason Condition specified in the notice, provided that such resignation must occur within sixty (60) days after the initial existence of such Good Reason Condition.

8. Successors.

(a) Company's Successors. Any successor to the Company (whether direct or indirect and whether by purchase, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets shall assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets which executes and delivers the assumption agreement described in this Section 8(a) or which becomes bound by the terms of this Agreement by operation of law.

(b) Executive's Successors. The terms of this Agreement and all rights of Executive hereunder shall inure to the benefit of, and be enforceable by, Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

9. Notices. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or one day following mailing via Federal Express or similar overnight courier service. In the case of Executive, mailed notices shall be addressed to Executive at Executive's home address that the Company has on file for Executive. In the case of the Company, mailed notices shall be addressed to its primary office location, and all notices shall be directed to the attention of its Chief Financial Officer.

10. Confidentiality; Non-Solicitation.

(a) Confidentiality. While Executive is employed by the Company, and thereafter, Executive shall not directly or indirectly disclose or make available to any person, firm, corporation, association or other entity for any reason or purpose whatsoever, any Confidential Information (as defined below). Upon termination of Executive's employment with the Company, all Confidential Information in Executive's possession that is in written or other tangible form (together with all copies or duplicates thereof, including computer files) shall be returned to the Company and shall not be retained by Executive or furnished to any third party, in any form except as provided herein; *provided, however*, that Executive shall not be obligated to treat as confidential, or return to the Company copies of any Confidential Information that (i) was publicly known at the time of disclosure to Executive, (ii) becomes publicly known or available thereafter other than by any means in violation of this Agreement or any other duty owed to the Company by any person or entity, or (iii) is lawfully disclosed to Executive by a third party. For purposes of this Agreement, the term "Confidential Information" shall mean information disclosed to Executive or known by Executive as a consequence of or through his or her relationship with the Company, about the customers, employees, business methods, public relations methods, organization, procedures or finances, including, without limitation, information of or relating to customer lists, of the Company and its affiliates. In addition, Executive shall continue to be subject to the Proprietary Information and Inventions Assignment Agreement entered into between Executive and the Company (the "Confidential Information Agreement").

(b) Non-Solicitation. In addition to Executive's obligations under the Confidential Information Agreement, Executive shall not for a period of two (2) years following Executive's termination of employment for any reason, either on Executive's own account or jointly with or as a manager, agent, officer, employee, consultant, partner, joint venturer, owner or stockholder or otherwise on behalf of any other person, firm or corporation, directly or indirectly solicit or attempt to solicit away from the Company any of its officers or employees or offer employment to any person who is an officer or employee of the Company; *provided, however*, that a general advertisement to which an employee of the Company responds shall in no event be deemed to result in a breach of this Section 10(b). Executive also agrees not to harass or disparage the

Company or its employees, clients, directors or agents or divert or attempt to divert any actual or potential business of the Company.

(c) Survival of Provisions. The provisions of this Section 10 shall survive the termination or expiration of the applicable Executive's employment with the Company and shall be fully enforceable thereafter. If it is determined by a court of competent jurisdiction in any state that any restriction in this Section 10 is excessive in duration or scope or is unreasonable or unenforceable under the laws of that state, it is the intention of the parties that such restriction may be modified or amended by the court to render it enforceable to the maximum extent permitted by the law of that state.

11. Dispute Resolution. To ensure the timely and economical resolution of disputes that arise in connection with this Agreement, Executive and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance or interpretation of this Agreement, Executive's employment, or the termination of Executive's employment, shall be resolved to the fullest extent permitted by law by final, binding and confidential arbitration, by a single arbitrator, in Middlesex County, Massachusetts, conducted by Judicial Arbitration and Mediation Services, Inc. ("JAMS") under the applicable JAMS employment rules. **By agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding**. The arbitrator shall: (i) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (ii) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award. The arbitrator shall be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS' arbitration fees in excess of the amount of court fees that would be required if the dispute were decided in a court of law. Nothing in this Agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Notwithstanding the foregoing, Executive and the Company each have the right to resolve any issue or dispute over intellectual property rights by Court action instead of arbitration.

12. Miscellaneous Provisions.

(a) Section 409A.

(i) Separation from Service. Notwithstanding any provision to the contrary in this Agreement, no amount deemed deferred compensation subject to Section 409A of the Code shall be payable pursuant to Section 3 unless Executive's termination of employment constitutes a Separation from Service and, except as provided under Section 12(a)(ii) of this Agreement, any such amount shall not be paid, or in the case of installments, commence payment, until the sixtieth (60^{th}) day following Executive's Separation from Service. Any installment payments that would have been made to Executive during the sixty (60) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to

Executive on the sixtieth (60th) day following Executive's Separation from Service and the remaining payments shall be made as provided in this Agreement.

(ii) Specified Employee. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed at the time of his separation from service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (a) the expiration of the six (6)-month period measured from the date of the Executive's Separation from Service or (b) the date of Executive's death. Upon the first business day following the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 12(a)(ii) shall be paid in a lump sum to Executive, and any remaining payments due under this Agreement shall be paid as otherwise provided herein.

(iii) Expense Reimbursements. To the extent that any reimbursements payable pursuant to this Agreement are subject to the provisions of Section 409A of the Code, any such reimbursements payable to Executive pursuant to this Agreement shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(iv) Installments. For purposes of Section 409A of the Code (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment.

(b) Waiver. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Whole Agreement. This Agreement, collectively with the Confidential Information Agreement and the agreements evidencing Executive's equity awards, represent the entire understanding of the parties hereto with respect to the subject matter hereof.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the Commonwealth of Massachusetts.

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(f) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

(*Signature page follows*)

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year set forth below.

ARDELYX, INC.

By: _____

Title: President and CEO

EXECUTIVE

_____

[Name]

ARDELYX, INC.
FOURTH AMENDED AND RESTATED
NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Non-employee members of the board of directors (the "***Board***") of Ardelyx, Inc. (the "***Company***") shall be eligible to receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this "***Program***"), which was adopted pursuant to the Board's resolutions on May 23, 2014, and amended pursuant to the Board's resolutions on March 3, 2017, March 14, 2019, March 11, 2021, June 15, 2022, December 5, 2023, January 9, 2025 and April 28, 2025. The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who may be eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. This Program, as amended and restated herein, shall become effective on April 28, 2025 (the "***Effective Date***").

1. Cash Compensation.

(a) Annual Retainers. Each Non-Employee Director shall be eligible to receive an annual retainer of $50,000 for service on the Board.

(b) Additional Annual Retainers. In addition, a Non-Employee Director shall receive the following annual retainers:

(i) Chairman of the Board. A Non-Employee Director serving as Chairman of the Board shall receive an additional annual retainer of $37,500 for such service.

(ii) Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of $20,000 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson) shall receive an additional annual retainer of $10,000 for such service.

(iii) Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson) shall receive an additional annual retainer of $7,500 for such service.

(iv) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $10,000 for such service. A Non-Employee Director serving as a member of the Nominating and Corporate Governance Committee (other than the Chairperson) shall receive an additional annual retainer of $5,000 for such service.

(c) Payment of Retainers. The annual retainers described in Sections 1(a) and 1(b) (the "***Annual Retainers***") shall be paid by the Company in a single cash lump sum immediately following the Effective Date and on the date of each annual meeting of the Company's stockholders after the Effective Date. In the event a Non-Employee Director is initially elected or appointed to the Board or a committee thereunder on a date other than the date of an annual meeting of the Company's stockholders, the Annual Retainers paid to such Non-Employee Director shall be paid on the date of election or appointment, prorated to reflect the number of months (rounded up to the next whole month) remaining until the next annual meeting of the Company's stockholders.

(d) Election to Receive Restricted Stock Units in Lieu of Annual Retainers. Non-Employee Directors shall have the ability to elect to receive the Annual Retainers in an award of restricted stock units (a "***Retainer RSU Award***") in lieu of cash pursuant to an election form provided by the Company for such purpose. In the event that a Non-Employee Director timely makes an election to receive the Annual Retainers in a Retainer RSU Award in lieu of cash, on the annual meeting of the Company's stockholders, he or she will automatically be granted that number of fully vested restricted stock units calculated by dividing the aggregate amount of the Annual Retainers by the Fair Market Value (as defined in the Equity Plan (as defined below)) of a share of Company common stock on the date of grant, rounded down to the nearest whole restricted stock unit. The Retainer RSU Awards shall be granted under and shall be subject to the terms and provisions of the Company's Amended and Restated 2014 Equity Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (such plan, as may be amended from time to time, the "***Equity Plan***"). In the event of any inconsistency between the Equity Plan and this Program, the terms of this Program shall control.

(i) Election Method. Each Retainer RSU Election must be submitted to the Company in the form and manner specified by the Board. Non-Employee Directors must complete and deliver the election form to the Company no later than 15 days prior to the next annual meeting of the Company's stockholders, provided, that in the event the Board determines to permit the deferral of Retainer RSU Awards pursuant to Section 2(c), then the election to receive a Retainer RSU Award in lieu of cash must comply with the following timing requirements:

A. Initial Retainer RSU Election. Each Non-Employee Director as of the date deferrals of restricted stock units are first permitted pursuant to Section 2(c) and each individual who first becomes a Non-Employee Director after the date such

deferrals are first permitted may make a Retainer RSU Election with respect to the Annual Retainer scheduled to be paid after the Effective Date and in the same calendar year as such date or such individual first becomes a Non-Employee Director (the "***Initial Retainer RSU Election***"). The Initial Retainer RSU Election must be submitted to the Company before the thirtieth day after deferrals of restricted stock units are first permitted or on or before the date that the individual first becomes a Non-Employee Director (the "***Initial Election Deadline***"), and the Initial Retainer RSU Election shall become final and irrevocable as of the Initial Election Deadline.

B. Annual Retainer RSU Election. No later than December 31 of each calendar year, or such earlier deadline as may be established by the Board, in its discretion (the "***Annual Election Deadline***"), each individual who is a Non-Employee Director as of immediately before the Annual Election Deadline may make a Retainer RSU Election with respect to the Annual Retainer relating to services to be performed in the following calendar year (the "***Annual Retainer RSU Election***"). The Annual Retainer RSU Election must be submitted to the Company on or before the applicable Annual Election Deadline and shall become final and irrevocable for the subsequent calendar year as of the applicable Annual Election Deadline.

2. Equity Compensation. Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Equity Plan and shall be granted subject to the execution and delivery of award agreements, including attached exhibits, in substantially the forms previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan. In the event of any inconsistency between the Equity Plan and this Program, the terms of this Program shall control.

(a) Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall be eligible to receive, on the date of such initial election or appointment, an equity grant comprised of an option to purchase shares of the Company's common stock (the "***Initial Option Award***") and an award of restricted stock units (the "***Initial RSU Award***" and together with the Initial Option Award, the "***Initial Awards***") with the split of the Initial Option Award and Initial RSU Award determined by the Board such that the aggregate grant date Fair Market Value of the Initial Awards is $450,000, but with a maximum number of shares of 200,000 shares of the Company's common stock. No Non-Employee Director shall be granted more than one Initial Award.

(b) Subsequent Awards. A Non-Employee Director who (i) has been serving on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted, on the date of such annual meeting, an equity grant comprised of an option to purchase shares of the Company's common stock (the "***Subsequent Option Award***") and an award of restricted stock units (the "***Subsequent RSU Award***" and together with the Subsequent Option Award, the "***Subsequent Awards***") with

the split of the Subsequent Option Award and Subsequent RSU Award determined by the Board such that the aggregate grant date Fair Market Value of the Subsequent Awards is $300,000, but covering a maximum of 100,000 shares of the Company's common stock. For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive Initial Awards in connection with such election, and shall not receive any Subsequent Awards on the date of such meeting as well.

(c) Election to Defer Issuances of Restricted Stock Units. The Board may, in its discretion, provide each Non-Employee Director with the opportunity to defer the issuance of the shares underlying the Retainer RSU Awards, Initial RSU Awards, and Subsequent RSU Awards, that would otherwise be issued to the Non-Employee Director in connection with the vesting or grant of the restricted stock units until the earliest of a fixed date properly elected by the Non-Employee Director, the Non-Employee Director's Termination of Service or a Change in Control (each as defined in the Equity Plan). Any such deferral election ("***Deferral Election***") shall be subject to such rules, conditions and procedures as shall be determined by the Board, in its sole discretion, which rules, conditions and procedures shall at all times comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended from time to time, unless otherwise specifically determined by the Board. If an individual elects to defer the delivery of the shares underlying the Retainer RSU Awards, Initial RSU Awards, and Subsequent RSU Awards, settlement of the deferred restricted stock units shall be made in accordance with the terms of the Deferral Election.

(i) Election Method. Each Deferral Election must be submitted to the Company in the form and manner specified by the Board. Deferral Elections must comply with the following timing requirements:

A. Initial Deferral Election. During the thirty-day period immediately following the date the Board first determines to permit deferrals under this Program each Non-Employee Director and, solely in respect of each individual who first becomes a Non-Employee Director after the Effective Date, such Non-Employee Director may make a Deferral Election with respect to the Non-Employee Director's Initial RSU Award, Subsequent RSU Awards and Retainer RSU Awards that otherwise would be granted after the date of such election and in the same calendar year as the date deferrals are first permitted or such individual first becomes a Non-Employee Director (the "***Initial Deferral Election***"). The Initial Deferral Election must be submitted to the Company on or before the Initial Election Deadline, and the Initial Deferral Election shall become final and irrevocable as of the Initial Election Deadline.

B. Annual Deferral Election. No later than the Annual Election Deadline, each individual who is a Non-Employee Director as of immediately before the Annual Election Deadline may make a Deferral Election with respect to the Subsequent RSU Award and Retainer RSU Awards to be granted in the following calendar year (the "***Annual Deferral Election***"). The Annual Deferral Election must be submitted to the Company on or before the applicable Annual Election Deadline and shall become final and irrevocable for the subsequent calendar year as of the applicable Annual Election Deadline.

(d) Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section 2(a) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section 2(b) above.

(e) Terms of Awards Granted to Non-Employee Directors.

(i) Purchase Price. The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value of a share of common stock on the date the option is granted.

(ii) Vesting. Each Initial Option Award shall vest and become exercisable with respect to 1/36th of the shares subject to the Initial Option Award on each monthly anniversary of the date of grant, subject to the Non-Employee Director continuing in service on the Board through each such vesting date. Each Initial RSU Award shall vest with respect to 1/12th of the shares on each designated Company quarterly vest date following the date of grant, subject to the Non-Employee Director continuing in service on the Board through each such vesting date. Each Subsequent Option Award shall vest and become exercisable with respect to 1/12th of the shares subject to the Subsequent Option Award on each monthly anniversary of the date of grant, which vesting will accelerate in full immediately prior to the next annual meeting of the Company's stockholders after the date of grant to the extent unvested as of such date, subject to the Non-Employee Director continuing in service on the Board through each such vesting date. Each Subsequent RSU Award shall vest with respect to 1/4th of the shares on each designated Company quarterly vest date following the date of grant, subject to the Non-Employee Director continuing in service on the Board through each such vesting date. Unless as otherwise specified herein, no portion of an Initial Award or Subsequent Award which is unvested and/or unexercisable at the time of a Non-Employee Director's termination of service on the Board shall become vested and/or exercisable thereafter. All of a Non-Employee Director's Initial Awards and Subsequent Awards, and any other stock options or other equity-based awards outstanding and held by the Non-Employee Director, shall vest in full immediately prior to the occurrence of a Change in Control, to the extent outstanding at such time.

(iii) Term. The term of each stock option granted to a Non-Employee Director shall be ten (10) years from the date the option is granted.

(iv) Equity Plan. In the event of any inconsistency between the Equity Plan and this Program, the terms of this Program shall control.

3. Reimbursements. The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of his or her duties to the Company in accordance

with the Company's applicable expense reimbursement policies and procedures as in effect from time to time.

* * * * *

Exhibit 31.1

CERTIFICATION

I, Michael Raab, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 1, 2025

By: /s/ Michael Raab

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

Exhibit 31.2

CERTIFICATION

I, Justin Renz, certify that:

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

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 1, 2025

By: /s/ Justin Renz

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

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Ardelyx, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2025, 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 and 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: May 1, 2025

By: /s/ Michael Raab

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

Date: May 1, 2025

By: /s/ Justin Renz

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