Table of Contents

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 June 30, 2026
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)**

(617) 675-2739
(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 per share	**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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

The number of issued and outstanding shares of the registrant's Common Stock, $0.0001 par value per share, as of July 30, 2026, was 249,187,572.

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," "positioned," "potential," "predict," "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 developments 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 Part II, 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 if we are unable to continue to increase revenue and/or, if we pursue future business opportunities, we may not achieve cash flow positivity when expected or at all, and even if we do, we may not be able to sustain cash flow positivity quarter over quarter and year over year.

- We may 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 delay or limit our pursuit of other future business opportunities.
- 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. The inclusion of XPHOZAH in the ESRD PPS creates additional uncertainty as to the commercial opportunity for XPHOZAH.
- XPHOZAH became part of the ESRD PPS on January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is not available under Medicare Part D; this resulted in a negative and material impact on our XPHOZAH revenue in 2025; and the continued lack of Medicare Part D coverage for XPHOZAH will result in a materially lower pace of revenue growth as compared to expectations before XPHOZAH became part of the ESRD PPS.
- Current and future healthcare reform legislation, regulation or action by the current administration may increase the difficulty and cost for us to commercialize our approved products and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations.
- IBSRELA and/or XPHOZAH may cause undesirable side effects or have other properties that could limit the commercial success of the products.
- 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 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 titled “Risk Factors” and the other information set forth in this Quarterly Report on Form 10-Q, including our financial statements and the related notes, as well as in other documents that we file with the U.S. Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

NOTE REGARDING TRADEMARKS

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

ARDELYX, INC.
FORM 10-Q TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2026	December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 97,191	$ 67,999
Short-term investments	184,639	196,690
Accounts receivable	100,352	71,848
Inventory	25,858	17,735
Prepaid commercial manufacturing	14,697	14,479
Prepaid expenses and other current assets	19,189	13,566
Total current assets	441,926	382,317
Property and equipment, net	1,781	2,184
Inventory, non-current	113,127	105,372
Prepaid commercial manufacturing, non-current	8,494	—
Right-of-use assets	4,065	4,795
Other assets	6,501	6,936
Total assets	$ 575,894	$ 501,604
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 38,410	$ 19,235
Accrued compensation and benefits	14,564	19,108
Current portion of operating lease liability	1,545	1,479
Deferred revenue	6,738	1,206
Accrued expenses and other current liabilities	70,963	47,577
Total current liabilities	132,220	88,605
Operating lease liability, net of current portion	2,822	3,641
Long-term debt	251,823	202,834
Deferred revenue, non-current	13,699	13,699
Deferred royalty obligation related to the sale of future royalties	26,317	25,876
Total liabilities	426,881	334,655
Commitments and contingencies (Note 14)		
Stockholders' equity		
Common stock, $0.0001 par value per share; 500,000,000 shares authorized; 249,147,061 and 244,351,501 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	25	24
Additional paid-in capital	1,150,446	1,113,666
Accumulated deficit	(1,001,265)	(946,939)
Accumulated other comprehensive (loss) income	(193)	198
Total stockholders' equity	149,013	166,949
Total liabilities and stockholders' equity	$ 575,894	$ 501,604

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Revenues				
Product sales, net	$ 118,129	$ 90,077	$ 211,502	$ 157,891
Product supply revenue	1,976	6,185	2,330	6,439
Licensing revenue	96	20	147	5,040
Non-cash royalty revenue related to the sale of future royalties	676	1,380	1,371	2,406
Total revenues	120,877	97,662	215,350	171,776
Costs and operating expenses				
Cost of sales	5,759	12,403	10,570	24,706
Research and development	26,103	15,666	46,291	30,604
Selling, general and administrative	101,440	83,988	203,707	167,210
Total costs and operating expenses	133,302	112,057	260,568	222,520
Loss from operations	(12,425)	(14,395)	(45,218)	(50,744)
Interest expense	(4,957)	(4,356)	(10,556)	(8,547)
Non-cash interest expense related to the sale of future royalties	(1,267)	(2,219)	(2,584)	(4,290)
Other income, net	2,038	1,892	4,150	4,218
Loss before provision for income taxes	(16,611)	(19,078)	(54,208)	(59,363)
Provision for income taxes	110	1	118	860
Net loss	$ (16,721)	$ (19,079)	$ (54,326)	$ (60,223)
Net loss per share of common stock - basic and diluted	$ (0.07)	$ (0.08)	$ (0.22)	$ (0.25)
Shares used in computing net loss per share - basic and diluted	248,067,253	239,928,570	246,967,275	239,279,962
Comprehensive loss				
Net loss	$ (16,721)	$ (19,079)	$ (54,326)	$ (60,223)
Unrealized losses on available-for-sale securities	(69)	(56)	(391)	(95)
Comprehensive loss	$ (16,790)	$ (19,135)	$ (54,717)	$ (60,318)

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 share amounts)

Three Months Ended June 30, 2026

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance as of March 31, 2026	246,973,414	$ 25	$ 1,133,265	$ (984,544)	$ (124)	$ 148,622
Issuance of common stock for services	32,627	—	185	—	—	185
Issuance of common stock upon exercise of options	789,428	—	1,680	—	—	1,680
Issuance of common stock upon vesting of restricted stock units	1,351,592	—	—	—	—	—
Stock-based compensation	—	—	15,316	—	—	15,316
Unrealized losses on available-for-sale securities	—	—	—	—	(69)	(69)
Net loss	—	—	—	(16,721)	—	(16,721)
Balance as of June 30, 2026	249,147,061	$ 25	$ 1,150,446	$ (1,001,265)	$ (193)	$ 149,013

Six Months Ended June 30, 2026

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2025	244,351,501	$ 24	$ 1,113,666	$ (946,939)	$ 198	$ 166,949
Issuance of common stock under employee stock purchase plan	136,480	—	742	—	—	742
Issuance of common stock for services	32,627	—	185	—	—	185
Issuance of common stock upon exercise of options	1,889,734	1	6,379	—	—	6,380
Issuance of common stock upon vesting of restricted stock units	2,736,719	—	—	—	—	—
Stock-based compensation	—	—	29,474	—	—	29,474
Unrealized losses on available-for-sale securities	—	—	—	—	(391)	(391)
Net loss	—	—	—	(54,326)	—	(54,326)
Balance as of June 30, 2026	249,147,061	$ 25	$ 1,150,446	$ (1,001,265)	$ (193)	$ 149,013

	Three Months Ended June 30, 2025					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance as of March 31, 2025	239,201,256	$ 24	$ 1,072,118	$ (926,484)	$ 18	$ 145,676
Issuance of common stock for services	87,256	—	315	—	—	315
Issuance of common stock upon exercise of options	391,027	—	988	—	—	988
Issuance of common stock upon vesting of restricted stock units	1,085,977	—	—	—	—	—
Stock-based compensation	—	—	11,687	—	—	11,687
Unrealized losses on available-for-sale securities	—	—	—	—	(56)	(56)
Net loss	—	—	—	(19,079)	—	(19,079)
Balance as of June 30, 2025	240,765,516	$ 24	$ 1,085,108	$ (945,563)	$ (38)	$ 139,531

	Six Months Ended June 30, 2025					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	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 for services	87,256	—	315	—	—	315
Issuance of common stock upon exercise of options	780,990	—	1,455	—	—	1,455
Issuance of common stock upon vesting of restricted stock units	1,658,711	—	—	—	—	—
Stock-based compensation	—	—	23,775	—	—	23,775
Unrealized losses on available-for-sale securities	—	—	—	—	(95)	(95)
Net loss	—	—	—	(60,223)	—	(60,223)
Balance as of June 30, 2025	240,765,516	$ 24	$ 1,085,108	$ (945,563)	$ (38)	$ 139,531

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

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

	Six Months Ended June 30,	
	2026	**2025**
Operating activities		
Net loss	$ (54,326)	$ (60,223)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	1,519	1,233
Non-cash lease expense	730	1,254
Stock-based compensation	29,474	23,775
Non-cash interest expense	3,150	4,425
Non-cash royalty revenue related to the sale of future royalties	(1,371)	(2,406)
Other, net	(1,088)	(2,083)
Changes in operating assets and liabilities		
Accounts receivable	(28,504)	(4,848)
Inventory	(15,878)	(32,075)
Prepaid commercial manufacturing	(8,712)	3,638
Prepaid expenses and other assets	(5,486)	(5,917)
Accounts payable	19,175	5,685
Accrued compensation and benefits	(4,544)	(3,126)
Operating lease liabilities	(753)	(1,268)
Accrued and other liabilities	22,446	7,480
Deferred revenue	5,532	657
Net cash used in operating activities	(38,636)	(63,799)
Investing activities		
Proceeds from maturities and redemptions of investments	94,510	93,110
Purchases of investments	(81,762)	(54,361)
Purchases of property and equipment	(82)	(975)
Net cash provided by investing activities	12,666	37,774
Financing activities		
Proceeds from Loan Agreement, net of costs	81,871	48,668
Repayment of Loan Agreement, including fees	(33,831)	—
Proceeds from issuance of common stock under equity incentive plans	7,122	2,470
Net cash provided by financing activities	55,162	51,138
Net increase in cash and cash equivalents	29,192	25,113
Cash and cash equivalents at beginning of period	67,999	64,932
Cash and cash equivalents at end of period	$ 97,191	$ 90,045
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 7,745	$ 6,280
Cash paid for income taxes	$ 101	$ 440
Supplemental disclosure of non-cash activities		
Right-of-use assets obtained in exchange for lease obligations	$ —	$ 3,880
Issuance of common stock for services	$ 185	$ 315

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 commercial-stage biopharmaceutical company focused on the development and commercialization of innovative medicines that meet significant unmet medical needs. We currently market two therapies from the active ingredient tenapanor, a sodium/hydrogen exchanger (NHE3) inhibitor that was discovered and developed by Ardelyx. NHE3 is an antiporter expressed on the apical surface of the small and large intestines. Tenapanor is a minimally absorbed, small molecule therapy. In addition, we are building a pipeline which is currently focused on expanding the commercial footprint of tenapanor.

Tenapanor, branded as IBSRELA®, is approved in the U.S. for the treatment of adults with irritable bowel syndrome with constipation (IBS-C). We are seeking to further expand the IBSRELA eligible patient population to include patients with chronic idiopathic constipation (CIC), and have initiated a Phase 3 clinical trial evaluating tenapanor in adults with CIC.

Tenapanor, branded as XPHOZAH®, is approved in the U.S. to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

We are also developing a next-generation NHE3 inhibitor, RDX10531, which is currently in IND-enabling studies and has demonstrated in preclinical models to have improved solubility and potency compared to tenapanor. We believe that RDX10531 can have application across multiple therapeutic areas.

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

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 on the condensed statements of operations and comprehensive loss to include the "cost of product sales" and the "other cost of revenue" captions within the "cost of sales" caption. Certain prior year amounts have also been reclassified to conform to the current year presentation in *Note 12. Segment Reporting*. These reclassifications had no effect on the previously reported results of operations.

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 2025 Form 10-K. The results for the three and six months ended June 30, 2026 are not necessarily indicative of results to be expected for the entire year ending December 31, 2026, 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. 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.

Concentration of Credit Risk

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. We are exposed to credit risks in the event of default by the counterparties to the extent of the amount recorded in our condensed balance sheets. Cash, cash equivalents and short-term investments are invested through banks and other financial institutions in the U.S.

Recent Accounting Pronouncements

Recent Accounting Pronouncement Not Yet Adopted

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 annual reporting periods, additional information about certain expenses in the financial statements. The new disclosure requirements are effective for the Company's annual periods beginning January 1, 2027, and interim periods beginning January 1, 2028, with early adoption permitted, and may be applied either prospectively or retrospectively. 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:

	June 30, 2026				December 31, 2025			
	Amortized	Gross Unrealized		Fair	Amortized	Gross Unrealized		Fair
(in thousands)	Cost	Gains	Losses	Value	Cost	Gains	Losses	Value
Cash and cash equivalents								
Cash	$ 7,086	$ —	$ —	$ 7,086	$ 18,569	$ —	$ —	$ 18,569
Money market funds	90,105	—	—	90,105	49,430	—	—	49,430
Total cash and cash equivalents	97,191	—	—	97,191	67,999	—	—	67,999
Short-term investments								
U.S. treasury securities	$ 88,142	$ —	$ (75)	$ 88,067	$ 95,052	$ 105	$ —	$ 95,157
Commercial paper	46,918	3	(66)	46,855	46,421	32	(3)	46,450
U.S. government-sponsored agency bonds	23,452	—	(30)	23,422	27,330	36	—	27,366
Corporate bonds	21,229	—	(23)	21,206	22,557	25	—	22,582
Yankee bonds	5,091	—	(2)	5,089	5,132	3	—	5,135
Total short-term investments	184,832	3	(196)	184,639	196,492	201	(3)	196,690
Total cash, cash equivalents and investments	$ 282,023	$ 3	$ (196)	$ 281,830	$ 264,491	$ 201	$ (3)	$ 264,689

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

Unrealized losses as of June 30, 2026 and December 31, 2025 were not material. All of the short-term available-for-sale securities held as of June 30, 2026 and December 31, 2025 had contractual maturities of less than one year, 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 June 30, 2026 and December 31, 2025.

See "Cash Equivalents" and "Short-Term Investments" captions of *Note 2. Summary of Significant Accounting Policies* of our 2025 Form 10-K for more information on our accounting policies for 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 based on unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access 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:

	June 30, 2026				December 31, 2025			
(in thousands)	**Total Fair Value**	**Level 1**	**Level 2**	**Level 3**	**Total Fair Value**	**Level 1**	**Level 2**	**Level 3**
Assets								
Money market funds	$ 90,105	$ 90,105	$ —	$ —	$ 49,430	$ 49,430	$ —	$ —
U.S. treasury securities	88,067	—	88,067	—	95,157	—	95,157	—
Commercial paper	46,855	—	46,855	—	46,450	—	46,450	—
U.S. government-sponsored agency bonds	23,422	—	23,422	—	27,366	—	27,366	—
Corporate bonds	21,206	—	21,206	—	22,582	—	22,582	—
Yankee bonds	5,089	—	5,089	—	5,135	—	5,135	—
Total	$ 274,744	$ 90,105	$ 184,639	$ —	$ 246,120	$ 49,430	$ 196,690	$ —

Fair Value of Debt

The outstanding principal under our Loan Agreement is subject to a variable interest rate based on the one-month SOFR, a readily observable market data (Level 2 input). Therefore, we believe the carrying amount of the term loan facility approximated its fair value as of June 30, 2026 and December 31, 2025. See *Note 8. Borrowing* for more information.

The carrying value of the deferred royalty obligation related to the sale of future royalties approximated its fair value as of June 30, 2026 and December 31, 2025, and is based on our current estimates of future royalties and commercialization milestones expected to be received by HCR over the life of the HCR Agreement. See *Note 7. Deferred Royalty Obligation Related to the Sale of Future Royalties* for more information.

NOTE 4. INVENTORY

Inventory consisted of the following:

(in thousands)	**June 30, 2026**	**December 31, 2025**
Raw materials	$ 38,554	$ 28,009
Work in process	87,037	88,259
Finished goods	13,394	6,839
Total	$ 138,985	$ 123,107
Reported as		
Inventory	$ 25,858	$ 17,735
Inventory, non-current	113,127	105,372
Total	$ 138,985	$ 123,107

Prepaid commercial manufacturing with third-party CMOs not included in inventory was $23.2 million and $14.5 million as of June 30, 2026 and December 31, 2025, respectively. There were $8.5 million prepayments expected to be converted into inventory after 12 months as of June 30, 2026, compared to none as of December 31, 2025.

NOTE 5. REVENUE

Disaggregation of total revenues by nature is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2026**	**2025**	**2026**	**2025**
Product sales, net	$ 118,129	$ 90,077	$ 211,502	$ 157,891
Product supply revenue	1,976	6,185	2,330	6,439
Licensing revenue	96	20	147	5,040
Non-cash royalty revenue related to the sale of future royalties	676	1,380	1,371	2,406
Total revenues	$ 120,877	$ 97,662	$ 215,350	$ 171,776

Product Sales, Net

Total product sales, net was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2026**	**2025**	**2026**	**2025**
Product sales, net				
IBSRELA	$ 86,243	$ 65,045	$ 156,317	$ 109,448
XPHOZAH	31,886	25,032	55,185	48,443
Total product sales, net	$ 118,129	$ 90,077	$ 211,502	$ 157,891
Product sales, net as a percentage of total revenues	97.7 %	92.2 %	98.2 %	91.9 %

Concentrations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Customers[(1)]				
BioRidge Pharma, LLC	76.3 %	61.1 %	80.3 %	62.2 %
Cencora, Inc.	16.0 %	20.5 %	16.5 %	19.5 %
McKesson Corporation	14.4 %	20.7 %	15.0 %	19.1 %
Cardinal Health, Inc.	14.4 %	23.4 %	13.7 %	22.8 %
Caremark, LLC	13.4 %	— %	12.8 %	— %

(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, 2025	$ 1,693	$ 34,456	$ 9,274	$ 45,423
Provisions[1]	17,983	70,766	25,383	114,132
Credits/payments	(16,957)	(58,732)	(24,495)	(100,184)
Balance as of June 30, 2026	$ 2,719	$ 46,490	$ 10,162	$ 59,371

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

NOTE 6. COLLABORATION AND LICENSING AGREEMENTS

We have out-licensed to external partners for the development and commercialization of tenapanor outside of the U.S. We recognize revenue from our collaboration partnerships 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 "Collaboration and Licensing Revenue" caption of *Note 2. Summary of Significant Accounting Policies* of our 2025 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 June 30,		Six Months Ended June 30,	
(in thousands)	2026	2025	2026	2025
Licensing revenue				
Fosun Pharma	$ 95	$ —	$ 115	$ 5,000
Knight	1	20	32	40
Total licensing revenue	$ 96	$ 20	$ 147	$ 5,040
Product supply revenue				
Fosun Pharma	$ 1,976	$ —	$ 2,328	$ —
Kyowa Kirin	—	6,185	2	6,185
Knight	—	—	—	254
Total supply revenue	$ 1,976	$ 6,185	$ 2,330	$ 6,439
Non-cash royalty revenue related to the sale of future royalties				
Kyowa Kirin	$ 676	$ 1,380	$ 1,371	$ 2,406

The following table presents changes in our current deferred revenue balances by collaboration partner:

	2026			2025		
(in thousands) ***Current***	Kyowa Kirin	Fosun Pharma	Total	Kyowa Kirin	Fosun Pharma	Total
Deferred revenue balance as of January 1,	$ —	$ 1,206	$ 1,206	$ 10,686	$ —	$ 10,686
Prepaid product supply	—	7,529	7,529	227	—	227
Product supply delivered	—	(1,997)	(1,997)	(4,633)	—	(4,633)
Reclassify amounts to be recognized in the next 12 months	—	—	—	—	—	—
Deferred revenue balance as of June 30,	$ —	$ 6,738	$ 6,738	$ 6,280	$ —	$ 6,280

The following table presents changes in our non-current deferred revenue balances by collaboration partner:

(in thousands)	2026			2025		
Non-current	**Kyowa Kirin**	**Fosun Pharma**	**Total**	**Kyowa Kirin**	**Fosun Pharma**	**Total**
Deferred revenue balance as of January 1,	$ 13,699	$ —	$ 13,699	$ 7,232	$ —	$ 7,232
Prepaid product supply	—	—	—	5,063	—	5,063
Product supply delivered	—	—	—	—	—	—
Reclassify amounts to be recognized in the next 12 months	—	—	—	—	—	—
Deferred revenue balance as of June 30,	$ 13,699	$ —	$ 13,699	$ 12,295	$ —	$ 12,295

Significant developments and updates related to our collaboration partnerships in the six months ended June 30, 2026 and 2025 are discussed below.

Fosun Pharma

In March 2026, Fosun Pharma reported the first commercial sales of tenapanor, marketed under the Chinese trade name Wan Ti Le, for patients with CKD on hemodialysis with hyperphosphatemia in China. Pursuant to the terms of the license and manufacturing services agreements with Fosun Pharma, we are eligible to receive reimbursement of cost plus a reasonable overhead for the supply of product and tiered royalties on net sales ranging from the mid-teens to 20%.

In February 2025, we announced the NDA approval by China's Center for Drug Evaluation of the NMPA for tenapanor in the control of serum phosphorus in adult patients with CKD on hemodialysis. This approval triggered a $5.0 million milestone to us, which was recorded as licensing revenue in our condensed statements of operations and comprehensive loss in the 2025 first quarter.

Knight - Former Collaboration Partner

Effective as of March 13, 2026, we entered into a termination agreement with Knight, pursuant to which we and Knight agreed to mutually terminate our exclusive license agreement for the development, commercialization and distribution of tenapanor in Canada for hyperphosphatemia and IBS-C. The decision was not related to any concerns regarding the safety, efficacy or quality of the product. Sales of IBSRELA in Canada were discontinued effective March 31, 2026. The termination did not have a material effect on our operations or financial results, and we do not expect it to adversely impact our operations or financial results in the future.

AstraZeneca

In connection with the AstraZeneca Termination Agreement, we recognized royalty expense as cost of sales in our condensed statements of operations and comprehensive loss of $3.8 million and $12.7 million in the three and six months ended June 30, 2025, respectively. As of the end of the 2025 second quarter, we had fully recognized the maximum $75.0 million royalty obligation, which had been fully remitted as of the end of the 2025 third quarter.

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

We and HCR have an agreement in which HCR paid $15.0 million in exchange for royalty and commercialization 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 2025 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.

Payments received from HCR are recorded as a deferred royalty obligation on our condensed balance sheets, which is being amortized as non-cash interest expense over the life of the HCR Agreement using the effective interest method. The deferred royalty obligation will be effectively repaid over the life of the HCR Agreement as we remit to HCR royalties and commercialization milestones paid to us by Kyowa Kirin. We periodically assess the estimated amounts and timing of future royalties and commercialization milestone payments from Kyowa Kirin and, to the extent that the amount or timing of such payments is materially different than our original estimates, we prospectively adjust the imputed interest rate and the related amortization of the deferred royalty obligation.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2026**	**2025**	**2026**	**2025**
Non-cash interest expense related to the sale of future royalties	$ (1,267)	$ (2,219)	$ (2,584)	$ (4,290)

($ in thousands)	**2026**	**2025**
Deferred royalty obligation balance as of January 1,	$ 25,876	$ 25,527
Non-cash interest expense related to the sale of future royalties	2,584	4,290
Royalty and commercialization milestone payments remitted to HCR	(2,143)	(2,056)
Deferred royalty obligation balance as of June 30,	$ 26,317	$ 27,761
Effective interest rate as of June 30,	19.6 %	33.5 %

NOTE 8. BORROWING

The following table presents our outstanding term loans under the Loan Agreement:

(in thousands)	**June 30, 2026**	**December 31, 2025**
Principal[(1)]		
Term A Loan	$ 14,371	$ 27,500
Term B Loan	11,758	22,500
Term C Loan	41,940	50,000
Term D Loan	50,000	50,000
Term E Loan	50,000	50,000
Term F Loan	50,000	—
Term H Loan	31,931	—
Total principal	250,000	200,000
Adjustments to principal value		
Unamortized discount and debt issuance costs	(3,021)	(1,127)
Accreted value of final fee	4,844	3,961
Total long-term debt	251,823	202,834
Less: Current portion of long-term debt	—	—
Long-term debt, net of current portion	$ 251,823	$ 202,834

(1) The outstanding term loans bear an interest rate at the sum of 4.55% plus the greater of (a) the one-month SOFR or (b) 3.50%, and mature on July 1, 2030.

On April 28, 2026, we entered into an amendment to our Loan Agreement (the Sixth Amendment), by and among us, as borrower, SLR, as collateral agent and the lenders party thereto. Pursuant to the Sixth Amendment, among other things, (i) a portion of $200.0 million in outstanding principal previously allocated among the Term A through C Loans (collectively, the Revised Loans) was refinanced with a new Term H Loan; (ii) the maturity date for the Revised Loans, the Term D Loan and the Term E Loan was extended from July 1, 2028 to July 1, 2030 (the New Maturity Date), which is the maturity date for each other term loan; (iii) the interest-only payment period for the Revised Loans, the Term D Loan and the Term E Loan was extended until the New Maturity Date, which is the interest-only payment period for each other term loan; (iv) the interest rate for each term loan will have a collectively reduced interest rate, at the sum of 4.55% plus the greater of (a) the one-month SOFR reference rate or (b) 3.50%; (v) we retained the option to draw the Term F and Term G Loans, each in the amount of $50.0 million, at our election by June 30, 2026 and December 20, 2026, respectively; and (vi) we amended certain negative covenants and other conditions to provide additional flexibility to us. We concluded that the Sixth Amendment was a modification to the Loan Agreement and we accounted for it accordingly.

On the closing date of the Sixth Amendment, we paid approximately $1.9 million in final fees and prepayment premium in connection with the partial repayment of the Term A through C Loans.

We are obligated to pay a final fee with respect to each of the outstanding amounts under each of the term loans, upon the earliest to occur of (i) the New Maturity Date, (ii) the acceleration of the applicable term loan or (iii) the prepayment, refinancing, substitution or replacement of the applicable term loan. This final fee is 4.95% for the Term A through E Loans, 3.45% for the Term F and Term G Loans and 2.50% for the Term H Loan. The total unaccreted final fee was $6.0 million and $5.9 million as of June 30, 2026 and December 31, 2025, respectively.

We may voluntarily prepay all amounts outstanding under the Revised Loans, the Term D Loan, the Term E Loan and the Term H Loan, subject to a prepayment premium of (i) three percent of the outstanding principal amount of the applicable term loan if prepaid on or after April 28, 2026 through and including April 28, 2027, (ii) two percent of the outstanding principal amount of the applicable term loan if prepaid on or after April 29, 2027 through and including April 28, 2028 or (iii) one percent of the outstanding principal amount of the applicable term loan if prepaid after April 28, 2028 and prior to July 1, 2030.

We may voluntarily prepay all amounts outstanding under the Term F and Term G Loans, subject to a prepayment premium of (i) two percent of the outstanding principal amount of the applicable term loan if prepaid on or after July 1, 2026 through and including June 30, 2027 or (ii) one percent of the outstanding principal amount of the applicable term loan if prepaid after June 30, 2027 and prior to July 1, 2030.

The Loan Agreement contains certain covenants, including a single financial covenant that the sum of our net product revenue, calculated on a trailing six-month basis, plus unrestricted cash and cash equivalents that are subject to a first-priority perfected lien in favor of SLR, shall be greater than or equal to 100% of the principal amount outstanding under the Loan Agreement. The outstanding term loans are secured by substantially all of our assets, except for our intellectual property and certain other customary exclusions. In addition, the Loan Agreement contains subjective clauses to accelerate the maturity of outstanding principal amount in the event that a material adverse change has occurred within our business, operations or financial condition.

On June 29, 2026, we received $50.0 million of funding as a result of our draw down of the Term F Loan. We elected to draw down the Term F Loan for general corporate purposes and to enhance flexibility to support our ongoing strategic initiatives, in line with our capital allocation strategy.

As of June 30, 2026, our total future payment obligation related to the outstanding term loans, excluding interest payments, was $260.8 million, which is due on July 1, 2030.

NOTE 9. LEASES

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

($ in thousands)		
Facilities	**June 30, 2026**	**December 31, 2025**
Right-of-use assets	$ 4,065	$ 4,795
Current portion of lease liabilities	$ 1,545	$ 1,479
Operating lease liability, net of current portion	2,822	3,641
Total lease liabilities	$ 4,367	$ 5,120
Weighted-average remaining term (in years)	2.7	3.1
Weighted-average discount rate	5.6 %	5.6 %

The following table presents the lease costs, which are included in our condensed statements of operations and comprehensive loss, and the supplemental cash flow information related to the leases:

	Three Months Ended June 30,		**Six Months Ended June 30,**	
(in thousands)	**2026**	**2025**	**2026**	**2025**
Operating lease expense	$ 432	$ 393	$ 864	$ 1,370
Cash paid for operating leases	$ 446	$ 340	$ 888	$ 1,387

The following table summarizes our undiscounted cash payment obligations for our operating lease liabilities as of June 30, 2026:

(in thousands)	Operating Leases
Remainder of 2026	$ 897
2027	1,836
2028	1,402
2029	575
Thereafter	—
Total undiscounted operating lease payments	4,710
Imputed interest expenses	(343)
Total operating lease liabilities	4,367
Less: Current portion of operating lease liability	(1,545)
Operating lease liability, net of current portion	$ 2,822

NOTE 10. STOCKHOLDERS' EQUITY

In November 2025, we filed an automatic shelf registration statement on Form S-3ASR, which became effective upon filing, containing (i) a base prospectus, which covers the offering, issuance and sale from time to time in one or more offerings of our common stock, preferred stock, debt securities, warrants and/or units; and (ii) a prospectus supplement for the offering, issuance and sale of up to a maximum aggregate offering price of $100.0 million of our common stock that may be issued and sold from time to time under the 2025 Open Market Sales Agreement, deemed to be "at-the-market offerings." Pursuant to the 2025 Open Market Sales Agreement, Jefferies, as sales agent, may receive a commission of up to three percent of the gross sales price for shares of our common stock sold under the 2025 Open Market Sales Agreement. As of June 30, 2026, there have been no sales of our common stock under the 2025 Open Market Sales Agreement.

NOTE 11. EQUITY INCENTIVE PLANS

Stock-Based Compensation Expense

Stock-based compensation expense for stock options, RSUs and our ESPP included in our condensed statements of operations and comprehensive loss was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2026	2025	2026	2025
Selling, general and administrative	$ 12,408	$ 9,273	$ 23,964	$ 17,757
Research and development	2,908	2,414	5,510	6,018
Total	$ 15,316	$ 11,687	$ 29,474	$ 23,775

A summary of our total unrecognized stock-based compensation expense, net of estimated forfeitures, as of June 30, 2026 is as follows:

	Unrecognized Compensation Expense (in thousands)	Average Remaining Vesting Period (in years)
Stock option grants	$ 52,092	2.6
RSU grants	$ 91,005	2.9
ESPP	$ 129	0.2

Stock Options

A summary of our stock option activity and related information for the six months ended June 30, 2026 is as follows:

	Number of Shares (in thousands)	Weighted-Average Exercise Price per Share
Outstanding as of December 31, 2025	28,977	$ 5.54
Granted	3,968	$ 7.29
Exercised	(1,890)	$ 3.38
Forfeited or cancelled	(1,780)	$ 8.12
Outstanding as of June 30, 2026	29,275	$ 5.76
Exercisable as of June 30, 2026	18,078	$ 5.44

Restricted Stock Units

A summary of our RSU activity and related information for the six months ended June 30, 2026 is as follows:

	Number of RSUs (in thousands)	Weighted-Average Grant Date Fair Value per Share
Unvested as of December 31, 2025	12,583	$ 5.71
Granted	6,858	$ 7.24
Vested	(2,769)	$ 6.09
Forfeited or cancelled	(1,353)	$ 6.32
Unvested as of June 30, 2026	15,319	$ 6.27

Employee Stock Purchase Plan

During the six months ended June 30, 2026, we issued approximately 0.1 million shares of our common stock under the ESPP. The shares were purchased by employees at an average purchase price of $5.44 per share, resulting in proceeds to us of approximately $0.7 million.

Issuance of Common Stock for Services

During the six months ended June 30, 2026, we issued approximately 33 thousand 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 Chief Executive Officer is our Chief Operating Decision Maker, who 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 2025 Form 10-K. See *Note 17. Segment Reporting* of our 2025 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 June 30,		Six Months Ended June 30,	
(in thousands)	**2026**	**2025**	**2026**	**2025**
Revenues				
Product sales, net	$ 118,129	$ 90,077	$ 211,502	$ 157,891
Other revenues[1]	2,748	7,585	3,848	13,885
Total revenues	120,877	97,662	215,350	171,776
Less				
Cost of product sales[2]	3,689	3,245	6,564	5,585
Other cost of revenue[3]	2,070	9,158	4,006	19,121
Research and development[4]	23,195	13,251	40,781	24,586
Selling[4]	66,949	57,952	134,344	114,752
General and administrative[4]	22,083	16,764	45,399	34,701
Stock-based compensation	15,316	11,687	29,474	23,775
Loss from operations	(12,425)	(14,395)	(45,218)	(50,744)
Other reconciliation items[5]	(4,296)	(4,684)	(9,108)	(9,479)
Net loss	$ (16,721)	$ (19,079)	$ (54,326)	$ (60,223)

(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) *Cost of product sales* includes the cost of commercial goods sold to our Customers, such as the cost of materials, third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process and indirect overhead costs.
(3) *Other cost of revenue* includes the cost of materials sold to our collaboration partners under product supply agreements, certain costs related to capacity expansion at current and future CMOs and payments due to AstraZeneca. As of the end of the 2025 second quarter, the maximum $75.0 million royalty obligation under the AstraZeneca Termination Agreement had been fully recognized.
(4) *Research and development, selling* and *general and administrative* expenses herein do not include stock-based compensation expenses.
(5) *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 six months ended June 30, 2026 and 2025, 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:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except per share amounts)	**2026**	**2025**	**2026**	**2025**
Numerator				
Net loss	$ (16,721)	$ (19,079)	$ (54,326)	$ (60,223)
Denominator				
Weighted average common shares outstanding - basic and diluted	248,067	239,929	246,967	239,280
Net loss per share of common stock - basic and diluted	$ (0.07)	$ (0.08)	$ (0.22)	$ (0.25)

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 June 30,		Six Months Ended June 30,	
(in thousands)	**2026**	**2025**	**2026**	**2025**
Options to purchase common stock	29,725	30,618	29,717	29,878
Restricted stock units	15,734	13,600	15,601	11,993
ESPP shares issuable	161	188	152	199
Total	45,620	44,406	45,470	42,070

NOTE 14. COMMITMENTS AND CONTINGENCIES

On December 7, 2021 and March 29, 2022, two verified shareholder 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 (together, the Go and Morris actions). The complaints alleged that the defendants' violations of Section 14(a) of the Exchange Act, breaches of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets led to personally making and/or caused 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 Exchange Act from two executive officers. On January 19, 2022 and April 27, 2022, the court granted the parties' stipulation to stay the Go and Morris actions, respectively, until resolution of the motion(s) to dismiss in the lawsuits 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). 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 actions and stayed the consolidated action pending resolution of the anticipated motion(s) to dismiss in the Securities Class Action. The Securities Class Actions were voluntarily dismissed on March 5, 2025. The court dismissed the Go and Morris actions on April 30, 2025.

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 on March 27, 2025. Both Appellees and Appellants filed a final brief on April 10, 2025. Oral argument in the case was heard on September 25, 2025. On June 26, 2026, the United States Court of Appeals affirmed the District Court's dismissal. We are not pursuing further litigation on this matter.

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, Michael Raab, and Justin Renz as defendants and alleges violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, related to 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. The 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. The 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. Plaintiffs filed a response on May 13, 2025. Defendants filed a reply in support of their motion to dismiss on June 23, 2025. A hearing on the motion to dismiss was held on September 25, 2025, and on December 24, 2025, the Court granted defendants' motion to dismiss and issued an order dismissing the case with prejudice. On January 21, 2026, Plaintiffs appealed the District Court's decisions to the United States Court of Appeals for the First Circuit. On March 26, 2026, the Court granted the Parties' stipulated voluntary dismissal of Plaintiffs' appeal.

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. On April 9, 2026, the Court dismissed the consolidated derivative action pursuant to the parties' stipulation of dismissal.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. As of June 30, 2026, 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 2025 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 titled "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 commercial-stage biopharmaceutical company focused on the development and commercialization of innovative medicines that meet significant unmet medical needs. We currently market two therapies from the active ingredient tenapanor, an NHE3 inhibitor that was discovered and developed by Ardelyx. NHE3 is an antiporter expressed on the apical surface of the small and large intestines. Tenapanor is a minimally absorbed, small molecule therapy. In addition, we are building a pipeline which is currently focused on expanding the commercial footprint of tenapanor.

We are committed to our mission of developing and commercializing innovative medicines that address unmet patient needs. Our principal strategy is to continue our commercial momentum with our current products while advancing and expanding a portfolio of important medicines for patients with unmet medical needs.

Our priorities include (i) driving significant IBSRELA growth, (ii) maintaining XPHOZAH commercial momentum, (iii) further advancing our pipeline and portfolio and (iv) maintaining a solid financial foundation to support our future growth.

Tenapanor, branded as IBSRELA®, is approved in the U.S. for the treatment of adults with IBS-C. We believe that IBSRELA can bring meaningful benefit to the approximately 13 million Americans who suffer from the symptoms of IBS-C, many of whom continue to experience symptoms despite intervention with other therapies. We are seeking to further expand the IBSRELA eligible patient population to include patients with CIC, and have initiated a Phase 3 clinical trial (ACCEL) evaluating tenapanor in adults with CIC. In January 2026, we dosed the first patient in ACCEL and have initiated all pre-identified sites. We expect to complete enrollment by the end of 2026 and to announce topline data in the second half of 2027. IBSRELA is also being evaluated in multiple pediatric clinical trials which could expand its use and potentially provide six months of additional patent life for tenapanor.

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 believe XPHOZAH can bring meaningful relief to adult CKD patients on dialysis, the vast majority of whom have elevated levels of serum phosphorus and are unable to achieve target serum phosphorus levels with phosphate binders alone. Continually elevated levels of serum phosphorus can result in severe cardiovascular health complications.

We are also developing a next-generation NHE3 inhibitor, RDX10531, which has demonstrated in preclinical models to have improved solubility and potency compared to tenapanor. RDX10531 is currently being tested in IND-enabling studies. If successful, RDX10531 has potential for broad applications across multiple therapeutic areas.

Effective April 28, 2026, we entered into the Sixth Amendment to our Loan Agreement with SLR as collateral agent and the lenders party thereto, resulting in better overall terms.

On June 26, 2026, the U.S. Court of Appeals for the District of Columbia Circuit affirmed the District Court's dismissal of our lawsuit against CMS related to CMS reimbursement classification of XPHOZAH. We are not pursuing further litigation on this matter.

On June 29, 2026, we received $50.0 million of funding as a result of our draw down of the Term F Loan. We elected to draw down the Term F Loan for general corporate purposes and to enhance flexibility to support our ongoing strategic initiatives, in line with our capital allocation strategy.

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.

RESULTS OF OPERATIONS

The results of operations for the three and six months ended June 30, 2026 are not necessarily indicative of results to be expected for the entire year ending December 31, 2026, 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 2025 Form 10-K to enhance the understanding of our financial metrics below.

Revenues

Below is a summary of our total revenues:

	Three Months Ended June 30,		Change 2026 vs. 2025		Six Months Ended June 30,		Change 2026 vs. 2025	
($ in thousands)	**2026**	**2025**	**$**	**%**	**2026**	**2025**	**$**	**%**
Product sales, net	$ 118,129	$ 90,077	$ 28,052	31 %	$ 211,502	$ 157,891	$ 53,611	34 %
Product supply revenue	1,976	6,185	(4,209)	(68)%	2,330	6,439	(4,109)	(64)%
Licensing revenue	96	20	76	380 %	147	5,040	(4,893)	(97)%
Non-cash royalty revenue related to the sale of future royalties	676	1,380	(704)	(51)%	1,371	2,406	(1,035)	(43)%
Total revenues	$ 120,877	$ 97,662	$ 23,215	24 %	$ 215,350	$ 171,776	$ 43,574	25 %

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

	Three Months Ended June 30,		Change 2026 vs. 2025		Six Months Ended June 30,		Change 2026 vs. 2025	
($ in thousands)	**2026**	**2025**	**$**	**%**	**2026**	**2025**	**$**	**%**
Product sales, net								
IBSRELA	$ 86,243	$ 65,045	$ 21,198	33 %	$ 156,317	$ 109,448	$ 46,869	43 %
XPHOZAH	31,886	25,032	6,854	27 %	55,185	48,443	6,742	14 %
Total product sales, net	$ 118,129	$ 90,077	$ 28,052	31 %	$ 211,502	$ 157,891	$ 53,611	34 %

Product sales, net:

The increase in IBSRELA product sales, net in the three and six months ended June 30, 2026 primarily reflected higher demand, driven by continued increase in awareness and prescriber experience, and to a lesser extent, higher net price.

The increase in XPHOZAH product sales, net in the three and six months ended June 30, 2026 primarily reflected higher demand and net price. XPHOZAH product sales, net in the six months ended June 30, 2025 included a $3.8 million favorable adjustment driven by a change in previously estimated product returns.

Product supply revenue:

Product supply revenue is primarily impacted by the timing of product supply shipments to our collaboration partners under our product supply agreements in support of the development and commercialization of our products ex-U.S. by our collaboration partners.

The product supply revenue was primarily attributable to Fosun Pharma in the three and six months ended June 30, 2026. In the three and six months ended June 30, 2025, the product supply revenue was primarily attributable to Kyowa Kirin.

Licensing revenue:

Licensing revenue is primarily impacted by the timing of regulatory and commercialization milestone achievements as well as sales-based royalties received from our collaboration partners.

The licensing revenue was primarily attributable to sales-based royalties received from Fosun Pharma in the three and six months ended June 30, 2026. The licensing revenue in the six months ended June 30, 2025 included a $5.0 million milestone earned in the 2025 first quarter under the terms of the Fosun Agreement, following the NDA approval by China's Center for Drug Evaluation of the NMPA for tenapanor in the control of serum phosphorus in adult patients with CKD on hemodialysis.

Non-cash royalty revenue:

The decrease in non-cash royalty revenue in the three and six months ended June 30, 2026 reflected lower royalties received from Kyowa Kirin for sales of PHOZEVEL in Japan.

GTN Adjustments

Reconciliation of gross product sales to product sales, net is as follows:

	Three Months Ended June 30,		Change 2026 vs. 2025		Six Months Ended June 30,		Change 2026 vs. 2025	
($ in thousands)	**2026**	**2025**	**$**	**%**	**2026**	**2025**	**$**	**%**
Gross product sales	$ 179,016	$ 131,187	$ 47,829	36 %	$ 325,634	$ 227,919	$ 97,715	43 %
GTN adjustments	(60,887)	(41,110)	(19,777)	48 %	(114,132)	(70,028)	(44,104)	63 %
Product sales, net	$ 118,129	$ 90,077	$ 28,052	31 %	$ 211,502	$ 157,891	$ 53,611	34 %
GTN adjustment percentage	34.0 %	31.3 %			35.0 %	30.7 %		

The increase in GTN adjustment percentage in the three and six months ended June 30, 2026 primarily reflected an unfavorable channel mix as well as Medicare and Medicaid Inflation Rebate charges.

The increase in GTN adjustment percentage in the six months ended June 30, 2026 reflected a $3.8 million favorable adjustment recognized in the 2025 first quarter, which was driven by a change in previously estimated XPHOZAH product returns.

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, 2025	$ 1,693	$ 34,456	$ 9,274	$ 45,423
Provisions[1]	17,983	70,766	25,383	114,132
Credits/payments	(16,957)	(58,732)	(24,495)	(100,184)
Balance as of June 30, 2026	$ 2,719	$ 46,490	$ 10,162	$ 59,371

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

Costs and Expenses

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

	Three Months Ended June 30,		Change 2026 vs. 2025		Six Months Ended June 30,		Change 2026 vs. 2025	
($ in thousands)	**2026**	**2025**	**$**	**%**	**2026**	**2025**	**$**	**%**
Cost of sales	$ 5,759	$ 12,403	$ (6,644)	(54)%	$ 10,570	$ 24,706	$ (14,136)	(57)%
Research and development	26,103	15,666	10,437	67 %	46,291	30,604	15,687	51 %
Selling, general and administrative	101,440	83,988	17,452	21 %	203,707	167,210	36,497	22 %
Total costs and operating expenses	$ 133,302	$ 112,057	$ 21,245	19 %	$ 260,568	$ 222,520	$ 38,048	17 %
Interest expense	$ (4,957)	$ (4,356)	$ (601)	14 %	$ (10,556)	$ (8,547)	$ (2,009)	24 %
Non-cash interest expense related to the sale of future royalties	$ (1,267)	$ (2,219)	$ 952	(43)%	$ (2,584)	$ (4,290)	$ 1,706	(40)%
Other income, net	$ 2,038	$ 1,892	$ 146	8 %	$ 4,150	$ 4,218	$ (68)	(2)%

Cost of Sales

	Three Months Ended June 30,		Change 2026 vs. 2025		Six Months Ended June 30,		Change 2026 vs. 2025	
($ in thousands)	**2026**	**2025**	**$**	**%**	**2026**	**2025**	**$**	**%**
Cost of product sales	$ 3,689	$ 3,245	$ 444	14 %	$ 6,564	$ 5,585	$ 979	18 %
Other cost of revenue	2,070	9,158	(7,088)	(77)%	4,006	19,121	(15,115)	(79)%
Cost of sales	$ 5,759	$ 12,403	$ (6,644)	(54)%	$ 10,570	$ 24,706	$ (14,136)	(57)%

The increase in cost of product sales in the three and six months ended June 30, 2026 reflected higher product sales. A portion of the costs of IBSRELA and XPHOZAH units recognized as revenue during the three and six months ended June 30, 2026 was expensed as research and development expense 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 $0.3 million and $0.6 million for the three and six months ended June 30, 2026, and $1.0 million and $1.7 million for the three and six months ended June 30, 2025, respectively. The value of inventory on hand as of June 30, 2026 and December 31, 2025 that was previously expensed as research and development was approximately $8.0 million and $10.9 million, respectively.

The decrease in other cost of revenue in the three and six months ended June 30, 2026 primarily reflected the full recognition of the maximum $75.0 million royalty obligation under the AstraZeneca Termination Agreement as of the end of the 2025 second quarter and lower costs associated with product supply revenue. Other cost of revenue related to the AstraZeneca Termination Agreement was $3.8 million and $12.7 million for the three and six months ended June 30, 2025, respectively.

Research and Development

Below is a summary of our research and development expenses:

($ in thousands)	Three Months Ended June 30, 2026	Three Months Ended June 30, 2025	Change 2026 vs. 2025 $	Change 2026 vs. 2025 %	Six Months Ended June 30, 2026	Six Months Ended June 30, 2025	Change 2026 vs. 2025 $	Change 2026 vs. 2025 %
External R&D expenses	$ 13,942	$ 6,607	$ 7,335	111 %	$ 23,270	$ 10,809	$ 12,461	115 %
Employee-related expenses	10,808	7,997	2,811	35 %	20,678	17,452	3,226	18 %
Facility-related and other expenses	1,353	1,062	291	27 %	2,343	2,343	—	0 %
Total research and development expenses	$ 26,103	$ 15,666	$ 10,437	67 %	$ 46,291	$ 30,604	$ 15,687	51 %

External R&D expenses consist substantially of costs associated with our life cycle management initiatives for tenapanor, with more than half of these costs attributable to our CIC program for the three and six months ended June 30, 2026, respectively. External R&D expenses also include costs associated with early-stage, preclinical programs as well as unallocated program-specific costs, which were individually immaterial for the periods presented. We begin to track program-specific costs for early-stage, preclinical programs once they become material, which generally occurs following IND and when clinical-stage work has commenced. We do not track employee and facility-related expenses by program, as we typically use our employee and infrastructure resources across multiple R&D programs.

The increase in external R&D expenses in the three and six months ended June 30, 2026 reflected increased clinical trial activities, including Phase 3 clinical trials evaluating tenapanor in adults with CIC, as well as engagement with medical and scientific communities in the areas of gastroenterology and nephrology related to our marketed products.

The increase in employee-related expenses in the three and six months ended June 30, 2026 was primarily driven by increased headcount in connection with pipeline expansion activities as well as engagement with medical and scientific communities in the areas of gastroenterology and nephrology related to our marketed products.

Selling, General and Administrative

The increase in selling, general and administrative expenses in the three and six months ended June 30, 2026 primarily reflected increased commercialization and administrative costs to support net sales growth of IBSRELA, consisting of external spending for disease awareness initiatives, patient affordability, access support and related patient awareness, as well as increased commercial infrastructure costs. The increase was also attributable to increased headcount, including incremental stock-based compensation expenses of $3.1 million and $6.2 million in the three and six months ended June 30, 2026, respectively.

Interest Expense

The increase in interest expense in the three and six months ended June 30, 2026 primarily reflected a higher outstanding loan balance resulting from the Term E Loan draw at the end of June 2025, partially offset by the reduced interest rate under the term loans resulting from the Sixth Amendment to our Loan Agreement effective at the end of April 2026.

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

The decrease in non-cash interest expense related to the sale of future royalties in the three and six months ended June 30, 2026 primarily reflected the imputed interest accrued on the decreasing carrying value of the deferred royalty obligation and royalties received from Kyowa Kirin for sales of PHOZEVEL in Japan which were remitted to HCR.

Other Income, Net

Other income, net remained materially unchanged in the three and six months ended June 30, 2026 and primarily consisted of interest income earned on our cash, cash equivalents and short-term investments.

LIQUIDITY AND CAPITAL RESOURCES

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

($ in thousands)	June 30, 2026	December 31, 2025	Change $	Change %
Cash and cash equivalents	$ 97,191	$ 67,999	$ 29,192	43 %
Short-term investments	184,639	196,690	(12,051)	(6)%
Total liquid funds	$ 281,830	$ 264,689	$ 17,141	6 %

We regularly assess our cash position and our working capital needs to execute our strategy. We have historically funded our operations primarily from product sales, sales of our common stock, funds from our loan agreements with SLR, funds from our collaboration partnerships, as well as the sale of future royalties and commercialization milestones to HCR. We expect that we will increasingly rely on cash generated from our commercial operations to fund our operating plan while maintaining financial flexibility to source cash from future equity sales and debt financing. Our capital allocation strategy includes (i) accelerating IBSRELA growth, (ii) investing in our current pipeline and (iii) maintaining financial strength.

Sources of Liquidity

In November 2025, we filed an automatic shelf registration statement on Form S-3ASR, which became effective upon filing, containing (i) a base prospectus, which covers the offering, issuance and sale from time to time in one or more offerings of our common stock, preferred stock, debt securities, warrants and/or units; and (ii) a prospectus supplement for the offering, issuance and sale of up to a maximum aggregate offering price of $100.0 million of our common stock that may be issued and sold from time to time under the 2025 Open Market Sales Agreement, deemed to be "at-the-market offerings." Pursuant to the 2025 Open Market Sales Agreement, Jefferies, as sales agent, may receive a commission of up to three percent of the gross sales price for shares of our common stock sold under the 2025 Open Market Sales Agreement. As of June 30, 2026, there have been no sales of our common stock under the 2025 Open Market Sales Agreement.

We have a loan and security agreement with SLR (the Loan Agreement). The Loan Agreement provides a total of $300.0 million, of which $250.0 million has been drawn and is outstanding as of June 30, 2026. The additional borrowing of $50.0 million pursuant to the Term G Loan is available at our election to draw through December 20, 2026. See *Note 8. Borrowing* for further information on our long-term debt.

Cash Flow Activities

The following table summarizes our cash flows:

	Six Months Ended June 30,		Change 2026 vs. 2025	
($ in thousands)	2026	2025	$	%
Net cash used in operating activities	$ (38,636)	$ (63,799)	$ 25,163	(39)%
Net cash provided by investing activities	12,666	37,774	(25,108)	(66)%
Net cash provided by financing activities	55,162	51,138	4,024	8 %
Net increase in cash and cash equivalents	$ 29,192	$ 25,113	$ 4,079	16 %

Cash Flows from Operating Activities

Cash flows from operating activities represent the cash receipts and payments related to all of our activities other than investing and financing activities. Net operating cash flow is derived by adjusting our net loss for non-cash operating items and changes in operating assets and liabilities resulting from timing differences between the cash receipts and payments and when the transactions are recognized in our result of operations. As a result, changes in net operating cash flow reflect, among other things, the timing of (i) cash collections from our Customers and (ii) payments made in the normal course of business such as payments to suppliers, including our CMOs, CROs and government agencies.

Net cash used in operating activities decreased in the six months ended June 30, 2026, primarily due to the timing of our payments and inventory purchases, partially offset by the timing of cash collections from our Customers.

Cash Flows from Investing Activities

Cash flows from investing activities include cash used for capital expenditures and purchases of short-term investments as well as net proceeds from asset dispositions and maturities of short-term investments.

Net cash provided by investing activities decreased in the six months ended June 30, 2026, primarily reflecting higher short-term investment purchases.

Cash Flows from Financing Activities

Cash flows from financing activities include net proceeds associated with our Loan Agreement, sales of our common stock with respect to the "at-the-market offering" programs and issuances of our common stock under our equity incentive plans.

Net cash provided by financing activities included the receipts of the Term F Loan and the Term E Loan in the six months ended June 30, 2026 and 2025, respectively. Net cash provided by financing activities increased in the six months ended June 30, 2026, primarily due to higher proceeds received from the issuance of common stock under our equity incentive plans.

Funding Requirements

Based on our current operating model, we believe our available cash, cash equivalents and short-term investments as of June 30, 2026 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.

Contract Obligations and Commitments

As of June 30, 2026, our total future payment obligation related to the outstanding term loans, excluding interest payments, was $260.8 million, which is due on July 1, 2030. See *Note 8. Borrowing* for further information on our long-term debt.

We have entered into various operating leases for our offices. As of June 30, 2026, our total undiscounted obligation for operating leases was $4.7 million, with maturities ranging up through July 2029. See *Note 9. Leases* for further information on our operating leases.

We enter into a variety of contracts in the normal course of business. These contracts generally allow us to terminate on notice, reschedule or adjust our requirements based on our business needs prior to the delivery of goods or performance of services.

Critical Accounting Policies and Estimates

Our preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect reported amounts and related disclosures. We have discussed those policies and estimates that we believe are critical and require the use of significant judgment in their application in our 2025 Form 10-K. We have made no material changes to our critical accounting policies or the methodologies or assumptions that we apply under them during the six months ended June 30, 2026.

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 June 30, 2026, we had cash, cash equivalents and short-term investments of $281.8 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 and Yankee bonds. 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. 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.

The outstanding principal under our Loan Agreement is subject to a variable interest rate, which fluctuates with changes in the one-month SOFR reference rate as published by the CME Term SOFR Administrator on the CME Term SOFR Administrator's Website. A hypothetical increase in the one-month SOFR of 100 basis points above the current one-month SOFR rate would not have had a material effect on our result of operations for the six months ended June 30, 2026. As of June 30, 2026, we had an aggregate principal amount of $250.0 million outstanding pursuant to our 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 June 30, 2026, 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 June 30, 2026. 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 this evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2026, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the three months ended June 30, 2026, 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 in *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 if we are unable to continue to increase revenue and/or, if we pursue future business opportunities, we may not achieve cash flow positivity when expected or at all, and even if we do, we may not be able to sustain cash flow positivity quarter over quarter and year over year.

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. We continue to incur commercialization, development and additional expenses related to our ongoing operations and pursuit of future business opportunities. As of June 30, 2026, we had an accumulated deficit of $1.0 billion. 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.

If we are unable to continue to increase revenue for IBSRELA and XPHOZAH, and/or if we elect to pursue future business opportunities to strengthen our pipeline, we may not achieve cash flow positivity when expected or at all, and even if we do, we may not be able to sustain cash flow positivity quarter over quarter and year over year.

Our ability to achieve and sustain cash flow positivity quarter over quarter and year over year depends heavily on our ability to successfully commercialize IBSRELA and XPHOZAH and on the decisions we may make to expand our pipeline through internal investment and/or acquiring external assets. In addition, our cash flow positivity may be impacted by the costs of our ongoing development efforts, including our Phase 3 clinical trial evaluating tenapanor in CIC and our RDX10531 development program.

Our ability to successfully commercialize IBSRELA and XPHOZAH and continue to grow revenue received for both products depends on many factors, including but not limited to:

- 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 and any other regulatory action 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;
- the extent to which the actions of the current administration may result in downward pressure on the price that we receive for IBSRELA and XPHOZAH;

- 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, including competing therapies that currently exist or that could be successfully developed and approved;
- 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, and therefore, our ability to achieve and sustain cash flow positivity 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. On January 1, 2025, XPHOZAH, along with other oral drugs for ESRD patients on dialysis without injectable or intravenous equivalents, became part of the ESRD PPS and coverage for XPHOZAH and these other oral drugs under Medicare Part D was eliminated. The inclusion of XPHOZAH in the ESRD PPS creates additional uncertainty as to the commercial opportunity for XPHOZAH. In addition, CMS' March 27, 2026 operational guidance reiterating that ESRD facilities are expected by CMS to furnish XPHOZAH under the ESRD PPS bundled payment regardless of manufacturer distribution preferences could adversely affect XPHOZAH revenue. See "*—XPHOZAH became part of the ESRD PPS on January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is not available under Medicare Part D; this resulted in a negative and material impact on our XPHOZAH revenue in 2025; and the continued lack of Medicare Part D coverage for XPHOZAH will result in a materially lower pace of revenue growth as compared to expectations before XPHOZAH became part of the ESRD PPS*" below.

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 investments we may elect to make in building our pipeline, we will not be able to achieve or, if achieved, to sustain cash flow positivity, and our liquidity, financial condition, and business prospects may be materially affected.

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

We have substantial NOL and tax credit carryforwards for Federal and California income tax purposes. Such NOLs and tax credits carryforwards may be reduced as a result of certain intercompany restructuring transactions. In addition, the future utilization of such NOL 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 may 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 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; our ongoing efforts to evaluate and seek approval of tenapanor for the treatment of CIC, including our ongoing Phase 3 clinical trial in this indication; manufacturing for IBSRELA and XPHOZAH; investments to build a pipeline; and research and development related to potential new product candidates, including development costs related to RDX10531, an NHE3 inhibitor. The inability to access necessary capital when needed on acceptable terms, or at all, could force us to delay or limit our development of potential new products, or 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 continue to generate and increase 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 and any other regulatory action 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 extent to which the actions of the current administration may result in downward pressure on the price that we receive for IBSRELA and XPHOZAH;
- 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 milestones or royalties from our collaboration partners, if any;
- the cash requirements necessary to expand our business;
- the cash requirements for our ongoing efforts to evaluate and seek approval of tenapanor for the treatment of CIC, including our ongoing Phase 3 clinical trial in this indication;
- the cash requirements for the discovery and/or development of other potential product candidates, including RDX10531;
- 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 delay or limit additional clinical trials for tenapanor, or delay or limit our pursuit of other future business opportunities.

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 extent to which the actions of the current administration may result in downward pressure on the price that we receive for IBSRELA;

- the size of the treatable patient population;
- our ability to successfully expand the IBSRELA eligible patient population, including with respect to our ongoing efforts to evaluate and seek approval of tenapanor for the treatment of CIC;
- 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, if we are not able to continue to secure and maintain physician and patient acceptance of IBSRELA or adequate coverage and reimbursement for IBSRELA, or if we are not successful in our efforts to develop and obtain regulatory approval for IBSRELA for CIC patients in the time frame we expect, or at all, we may not generate sufficient revenue from sales of IBSRELA to achieve our business goals. 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 and any other regulatory action 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 extent to which the actions of the current administration may result in downward pressure on the price that we receive for XPHOZAH;
- 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 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. In addition, CMS' March 27, 2026 operational guidance reiterating that ESRD facilities are expected by CMS to furnish XPHOZAH under the ESRD PPS bundled payment regardless of manufacturer distribution preferences could adversely affect XPHOZAH revenue. See "—*XPHOZAH became part of the ESRD PPS on January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is not available under Medicare Part D; this resulted in a negative and material impact on our XPHOZAH revenue in 2025; and the continued lack of Medicare Part D coverage for XPHOZAH will result in a materially lower pace of revenue growth as compared to expectations before XPHOZAH became part of the ESRD PPS*" below.

XPHOZAH became part of the ESRD PPS on January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is not available under Medicare Part D; this resulted in a negative and material impact on our XPHOZAH revenue in 2025; and the continued lack of Medicare Part D coverage for XPHOZAH will result in a materially lower pace of revenue growth as compared to expectations before XPHOZAH became part of the ESRD PPS.

In January 2011, 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, eliminating coverage for XPHOZAH for Medicare beneficiaries under Medicare Part D. The change in Medicare reimbursement coverage had a negative and material impact on our XPHOZAH revenue in 2025 and may have a material adverse impact on our XPHOZAH revenue in future periods. We anticipate the continued lack of Medicare Part D coverage for XPHOZAH will result in a materially lower pace of revenue growth as compared to expectations before XPHOZAH became part of the ESRD PPS. On June 26, 2026, the U.S. Court of Appeals for the District of Columbia Circuit affirmed dismissal of our lawsuit against CMS regarding the inclusion of XPHOZAH in the ESRD PPS. See *Note 14. Commitments and Contingencies* for more information. In addition, on March 27, 2026, CMS issued operational guidance reiterating that ESRD facilities are expected by CMS to furnish XPHOZAH under the bundled payment, which may limit our ability to effectively pursue alternative distribution approaches for XPHOZAH and negatively impact our XPHOZAH revenue and pace of revenue growth.

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

- the extent to which this change, the March 2026 CMS operational guidance, the status of our lawsuit against CMS and any other regulatory action 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.

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. On January 1, 2025, XPHOZAH, along with other oral drugs for ESRD patients on dialysis without injectable or intravenous equivalents, became part of the ESRD PPS and coverage for XPHOZAH and these other oral drugs under Medicare Part D was eliminated. See "*—XPHOZAH became part of the ESRD PPS on January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is not available under Medicare Part D; this resulted in a negative and material impact on our XPHOZAH revenue in 2025; and the continued lack of Medicare Part D coverage for XPHOZAH will result in a materially lower pace of revenue growth as compared to expectations before XPHOZAH became part of the ESRD PPS*" 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 other countries has and will continue to put pressure on the pricing and usage of IBSRELA and XPHOZAH. 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 products. 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 our products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to continue 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 and the continued commercial success of established 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 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.

We may rely on foreign CROs and CMOs, which 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. For example, the U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from “biotechnology companies of concern”, or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from “biotechnology companies of concern”. Congress has interpreted a “biotechnology company of concern” as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (e.g., collection of genomic information). While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veterans Affairs’ discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. If the foreign CROs and CMOs we rely on become subject to trade restrictions, sanctions, increased tariffs or other regulatory requirements by the U.S. government (including designation as a “biotechnology

company of concern" under the U.S. BIOSECURE Act), or if the U.S. or Chinese government take retaliatory actions due to recent or increased tensions between the U.S. and China, it may have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain "biotechnology companies of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government.

Our future business prospects may depend on our ability, alone or through our current or future collaborations, to successfully develop, gain regulatory approval of and commercialize our current and future product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, including new uses for currently approved products, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. The drug development process, including obtaining regulatory approval for a product, is a long, expensive and uncertain process, involving a high degree of risk. We cannot be certain that we will be able to complete ongoing clinical trials or to announce results of such trials with respect to any of our product candidates, on the timelines we expect or at all, or that the results of our clinical trials or other activities under our development programs will be positive. We cannot be certain that we will be able to advance such product candidates into additional trials or to successfully develop, obtain regulatory approval for, or successfully commercialize any of our product candidates, if approved.

For example, in October 2025, we announced the initiation of a development program for RDX10531, an NHE3 inhibitor with potential application across multiple therapeutic areas. In January 2026, we initiated ACCEL (TEN-03-301), a Phase 3 clinical trial designed to assess the safety and efficacy of tenapanor for the treatment of CIC. Enrollment in ACCEL is expected throughout 2026, with topline data read out in the second half of 2027. We may not be able to demonstrate the efficacy and safety of these or any future product candidates, or we may encounter other issues with any clinical trials or non-clinical studies required for regulatory submissions of our product candidates. The results of clinical trials or non-clinical studies of our product candidates at any stage may not support further development or may not be sufficient to file for and obtain regulatory approval on the timelines we expect or at all. The FDA or other regulatory authorities may not agree with our interpretation of the results of clinical trials or non-clinical studies. Other decisions or actions of the FDA or other regulatory authorities may affect our plans, progress, results, timing or next steps, including whether to proceed with further development. Some or all of our current or future non-clinical studies or clinical trials may fail to meet their primary or key secondary endpoints, raise safety issues or generate mixed results, resulting in delays to or discontinuation of certain development efforts and/or additional expense.

In the conduct of 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 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 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.

Our ongoing and planned development activities may be negatively impacted by a number of factors. Widespread healthcare and vendor staffing shortages and increased competition for patients and clinical sites may make it difficult to enroll patients in our non-clinical studies and/or clinical trials and/or identify and activate participating clinical sites for our trials, may cause other delays at clinical trial sites and/or vendors, and may increase the rates of patients withdrawing from our clinical trials following enrollment. Some clinical sites may decline or delay participation in our trials due to capacity and resource constraints. These or other factors may substantially slow clinical site identification and activation and enrollment in our clinical trials, or cause us to pause trials, which may, in each case, significantly impact our ability to meet our expected timelines, budgets, or other plans.

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.

In addition, limitations or modifications to study procedures, study visits or data collection, restrictions on key clinical trial activities such as monitoring or auditing, or other restrictions that may affect data analysis activities may require additional assessment and evaluation from IRBs, negatively impact the integrity or completeness of our trial data, the powering of a trial, the integrity or relevance of clinical study endpoints, or impact the timing of availability of results. Any of these factors could delay or increase the expense of our ongoing or future development programs.

The drug development process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources. Of the large number of drugs in development in the U.S., only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized. Accordingly, even if we have the requisite financial resources, when needed, to continue to fund our development efforts, our current or future product candidates may never be successfully developed or commercialized. Even if we conduct the trials required by the FDA, the FDA may ultimately decide that the design, number and type of trials, number of patients studied or results, even if positive, are not sufficient to file for or gain regulatory approval of any of our product candidates in the indications we study, or do not support the safety or efficacy or our intended profile for the product. Any of these negative outcomes could materially impact our ongoing or future development programs and adversely affect our business, results of operations, financial condition and prospects and could lead us to make significant further changes to the scope and nature of our development efforts.

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, tariffs 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 would be time consuming and costly. Furthermore, any new CMO would need to complete validation batches and be approved by regulatory authorities as our manufacturer, including passing any required inspections, before we would be able to utilize the drug product or drug substance they manufacture for commercial purposes, which could result in significant costs and delays in product availability. 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 Loan Agreement) with SLR as collateral agent and the lenders listed in the Loan Agreement (collectively, the Lenders). The Loan Agreement was subsequently amended in August 2022 (the First Amendment), February 2023 (the Second Amendment), October 2023 (the Third Amendment), October 2024 (Fourth Amendment), June 2025 (Fifth Amendment) and April 2026 (Sixth Amendment). The loan was funded in the

amount of $27.5 million on February 23, 2022. An additional amount of $22.5 million was drawn on October 19, 2023, and an additional $50.0 million was drawn on each of March 1, 2024, October 29, 2024, June 30, 2025 and June 29, 2026, respectively. These are referred to as the Terms A, B, C, D, E and F Loans, respectively. In connection with the Sixth Amendment, a portion of the $200.0 million in outstanding principal previously allocated among the Term A through C Loans was refinanced with a new Term H Loan, and the interest rate was collectively reduced under all term loans, including the undrawn term loans. As of June 30, 2026, we have the option to draw up to an additional $50.0 million pursuant to the Term G Loan, which is available at the Company's election through December 20, 2026. Until we have repaid all funded indebtedness, the 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 Loan Agreement. An event of default will occur if, among other things, we fail to make payments under the Loan Agreement; we breach any of our covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches; a 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 a 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. In addition, if successfully developed and approved for the treatment of CIC, we believe IBSRELA will also face competition from branded products Linzess (linaclotide) and Trulance (plecanatide) as well as generic lubiprostone and prucalopride.

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 Phase 2; and TS-172, developed by Taisho Pharmaceutical and currently in Phase 3. On June 30, 2026, Unicycive Therapeutics, which is developing OLC, announced the receipt of a Complete Response Letter from the FDA citing manufacturing deficiencies. 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 XPHOZAH. For example, we may be sued if any product we develop and/or commercialize allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

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

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

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

Recruiting and retaining qualified scientific, 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 continues to rapidly evolve, 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 continue to 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.

A number of 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, 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, we may be subject to the European Union General Data Protection Regulation (EU GDPR) and to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the UK GDPR) (the EU GDPR and UK GDPR together referred to as the GDPR). The GDPR imposes strict requirements for processing the personal data of individuals within the EEA and UK. 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/£17.5 million or four percent 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. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue, and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we operate our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

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.

Our business may be affected by the evolving regulatory framework for AI Technologies

We use artificial intelligence (AI), machine learning, and automated decision-making technologies, (collectively, AI Technologies) throughout our business, and are making investments in this area. We expect that increased investment will be required in the future to continuously improve our use of AI Technologies. As with many technological innovations, there are significant risks involved in developing, maintaining and deploying these technologies, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. There can be no assurance that the usage of our investments in such technologies will always enhance our products or services or be beneficial to our business, including our efficiency or profitability.

In particular, if the models underlying our AI Technologies are: incorrectly designed or implemented; trained or reliant on incomplete, inadequate, inaccurate, biased or otherwise poor quality data, or on data to which we do not have sufficient rights or in relation to which we and/or the providers of such data have not implemented sufficient legal compliance measures; used without sufficient oversight and governance to ensure their responsible use; and/or adversely impacted by unforeseen defects, technical challenges, cybersecurity threats or material performance issues, the performance of our products, services and business, as well as our reputation, could suffer or we could incur liability resulting from the violation of laws or contracts to which we are a party or civil claims.

We are in varying stages of development in relation to our products and internal business processes involving AI Technologies. The continuous development, maintenance and operation of our AI Technologies is expensive and complex, and may involve unforeseen difficulties including material performance problems, undetected defects or errors. For instance, the models underlying AI Technologies can experience decay (also known as “model drift”) in which its performance and accuracy decrease over time without further human intervention to correct such decay.

We may not be successful in our ongoing development and maintenance of these technologies in the face of novel and evolving technical, reputational and market factors. Our efforts to develop proprietary AI models may increase our operating costs. Our ability to develop proprietary AI models may be limited by our access to processing infrastructure or training data, and we may be dependent on third-party providers for such resources.

Additionally, our use of AI Technologies in research and development could introduce unique intellectual property risks. Shifting legal standards creates substantial uncertainty regarding whether AI-generated inventions, chemical structures, or therapies are eligible for patent protection. If we are unable to obtain or maintain strong patent exclusivity for product candidates developed with the assistance of AI, our competitive position and long-term profitability could be materially harmed. We also face the risk that the AI tools we utilize could inadvertently ingest third-party proprietary data, exposing us to infringement claims, or that deploying our own proprietary data into these models could compromise our trade secrets.

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. Failure to appropriately respond to this evolving

landscape may result in reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

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.

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 diverse threat vectors, such as 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.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. 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, including artificial intelligence, 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. Additionally, any integration of artificial intelligence in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. 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. We cannot guarantee that any costs and liabilities incurred in relation to an attack or incident will be covered by our existing insurance policies or that applicable insurance will be available to us in the future on economically reasonable terms or at all.

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; and with METiS for the development and commercialization of a portfolio of TGR5 agonist compounds for all therapeutic areas. Our previous collaboration partnership in Canada with Knight for commercialization of tenapanor for IBS-C and hyperphosphatemia was terminated in March 2026.

While we may pursue future collaborations, 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. Delays in identifying suitable additional collaboration partners and entering into agreements to commercialize our products in ex-U.S. territories and/or develop our product candidates will delay commercialization thereof, which may reduce their competitiveness even if they reach the market. In addition, current or future collaborations or partnerships with ex-U.S. parties and the expected benefits therefrom could be materially and adversely impacted by current or future healthcare reform legislation and initiatives (including evolving "most favored nation" pricing proposals) that may require U.S. pricing for our products to be tied to, or otherwise impacted by, ex-U.S. prices obtained by collaborators or partners. There is no guarantee that our current collaboration partnerships or any such arrangements we enter into in the future will be successful, or that any collaboration partner will commit sufficient resources to the development, regulatory approval, and commercialization effort for such products, or that such alliances will result in us achieving revenues that justify such transactions.

We 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 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 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 of 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 into 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 both U.S. and 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 or the third parties upon whom we depend may be adversely affected by natural disasters, severe weather, public health emergencies and other catastrophic events, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Events outside of our control, including natural disasters, severe or inclement weather (such as extreme snow and ice, extreme heat, tornados and flooding), public health emergencies, power outages, cyber or telecommunications disruptions, transportation incidents or other catastrophic events, could severely disrupt our operations and have a material adverse effect on our business, operating results, prospects or financial condition. Such events could disrupt our sales efforts, ongoing clinical trials and/or other operations by damaging or limiting access to critical infrastructure and facilities, including those operated by third parties on whom we rely, such as contract research organizations, contract manufacturing organizations, suppliers, specialty pharmacies and logistics and distribution providers, or by restricting travel, staffing availability or site access. If any such event prevents or materially impairs our ability, or the ability of these third parties, to manufacture or ship product or product candidates, conduct clinical trial activities, perform quality testing and release, or otherwise operate in the ordinary course, it may be difficult or, in certain cases, impossible for us to continue our business as currently planned.

In addition, the shipment of product and product candidates, active pharmaceutical ingredients and other materials may be delayed, diverted or disrupted by severe weather or other events in any location where our third-party service providers operate or through which shipments must travel, including as a result of extreme snow or ice, extreme heat, tornados, flooding, transportation accidents or carrier interruptions. These disruptions could result in missed or delayed patient deliveries, delayed site resupply, inventory constraints, product loss or spoilage (including due to temperature excursions), increased shipping and handling costs, and delays in manufacturing, release or crucial business timelines, any of which could materially impact our sales, financial results, patient fulfillment efforts and reputation.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event, including because we may not have sufficient redundancies, alternative suppliers, alternative distribution channels, backup manufacturing capacity or additional inventory to mitigate the impact of such disruptions. We may incur substantial expenses in connection with responding to and recovering from these events, and any of the foregoing could have a material adverse effect on our business, operating results, prospects or financial condition.

Risks Related to Government Regulation

Current and future healthcare reform legislation, regulation or action by the current administration may increase the difficulty and cost for us to commercialize our approved products and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations.

In the U.S. and some foreign jurisdictions, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, restrict or regulate post approval activities with respect to our approved products and affect our ability to profitably sell our products.

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. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the MDRP, extended manufacturer rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations and established annual fees and taxes on manufacturers of certain branded prescription drugs. Since its enactment, certain provisions of the ACA have been subject to judicial, executive, and legislative challenges. For example, on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. There have also been ongoing changes to the implementation of the ACA since its adoption. For example, the availability of enhanced premium tax credits and other subsidies under the ACA expired as of December 31, 2025, and absent legislative action to reinstate or replace them, many individuals may experience higher out-of-pocket premium costs. These changes could result in an increase in uninsured or underinsured patients, which could negatively affect patients' ability or willingness to start or continue treatment with our products or future product candidates, if successfully developed and approved, or may otherwise increase prescription abandonment rates or place greater downward pressure on drug pricing generally.

Moreover, on January 1, 2025, XPHOZAH, along with other oral drugs for ESRD patients on dialysis without injectable or intravenous equivalents, became part of the ESRD PPS and coverage under Medicare Part D was eliminated. See "*—XPHOZAH became part of the ESRD PPS on January 1, 2025, which means coverage for XPHOZAH for Medicare beneficiaries is not available under Medicare Part D; this resulted in a negative and material impact on our XPHOZAH revenue in 2025; and the continued lack of Medicare Part D coverage for XPHOZAH will result in a materially lower pace of revenue growth as compared to expectations before XPHOZAH became part of the ESRD PPS*" above.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These laws, among other things, included aggregate reductions of Medicare payments to providers that will remain in effect through 2032, 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. The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap beginning January 1, 2024. The rebate was previously capped at 100% of a drug's AMP.

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. In 2022, the IRA was signed into law in August 2022. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; redesigns the Medicare Part D benefit; and replaces the Part D coverage gap discount program with a new manufacturer discount program. CMS has published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and the subsequent 15 drugs, which will first be effective in 2027. CMS has also published the next set of 15 drugs that will be subject to negotiation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of our partner's products or of any product candidate that we commercialize.

The current administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how these proposals will be implemented, the current administration's policies are likely to have a negative impact on the

pharmaceutical industry and on our ability to receive adequate revenues for IBSRELA and XPHOZAH. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have entered into confidential pricing agreements with the federal government. On the other hand, the current administration is pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, referred to as GLOBE and GUARD. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the GLOBE and GUARD proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

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. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution.

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.

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 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 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 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, agency or other 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 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 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 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 FDA's ability to perform routine functions. For example, over the last several years, the U.S. government has shut down several times, including October 2025 and November 2025 and a subsequent partial government shutdown in January and February 2026, and certain regulatory agencies, such as the FDA, have had to furlough FDA employees and suspend certain activities.

Disruptions at the 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 continues, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the 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 FDA and other regulatory agencies through their facilities inspection programs. In addition, before approving an NDA, the facilities and quality systems of some, or all, of the relevant CMOs must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. The FDA will not approve a product candidate unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. 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. We enter into quality agreements with our CMOs, pursuant to which we expect our CMOs to comply with cGMPs and applicable regulatory requirements. 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 direct control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict requirements of relevant regulatory authorities, and pass regulatory inspections, on the timelines we expect or at all, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities with respect to our products, which could materially impact our ability to supply product and harm our business.

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 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 may result in delays to 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 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 FDA and other government agencies. With respect to the commercialization of IBSRELA and/or XPHOZAH, we are 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 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 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 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 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 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: FDA regulations, including those laws that require the reporting of true, complete and accurate financial and other information to the 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 FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the 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 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 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, FDA regulations and guidance are often revised or reinterpreted by the 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.

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 are 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 HHS 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 and Medicare Part B. 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.

The IRA imposes rebates under Medicare Part B and Medicare Part D that are triggered by price increases that outpace inflation, as described under "—*Current and future healthcare reform legislation, regulation or action by the current administration may increase the difficulty and cost for us to commercialize our approved products and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations*." The Medicare Part D rebate, if applicable, will be calculated on the basis of the AMP figures we report pursuant to the MDRP.

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 covered outpatient drugs under Medicaid and Medicare Part B. We participate in the 340B program, which is administered by HRSA, and requires us to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient 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 outpatient 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 Medicare Part B 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 (FCP), 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 also participate in the Tricare Retail Pharmacy program, under which we are required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our innovator products on a Tricare Agreement in order for them to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges could result in allegations against us under the False Claims Act and other laws and regulations. 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 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 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.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (Bayh-Dole Act). The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. If we choose to collaborate with academic institutions to accelerate our preclinical research or development, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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 partes 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 Appeal 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 and XPHOZAH are currently claimed by patents that are listed in the 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, XPHOZAH 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 FDA approval of a drug containing an NCE. The FDA is prohibited during those five years from approving an ANDA or 505(b)(2) NDA that references the NDA that has been granted NCE exclusivity. However, if any patents are listed in the FDA Orange Book for such NCE-containing drug, a follow-on product manufacturer may file an ANDA or 505(b)(2) NDA that references an 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 FDA from approving, another full 505(b)(1) NDA 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 and XPHOZAH, if an ANDA or 505(b)(2) sponsor has provided a Paragraph IV certification to the FDA when filing its application, the 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 FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months after the NCE NDA owner's receipt of the Paragraph IV certification notice, a final decision in the infringement case in favor of the ANDA or 505(b)(2) sponsor, or another date established by the court. There can be no assurances that an ANDA or 505(b)(2) NDA that references our IBSRELA or XPHOZAH NDAs 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 or 505(b)(2) sponsor. Furthermore, any Paragraph IV litigation, whether settled or litigated to resolution, could involve substantial expense, result in patent invalidation, trigger earlier-than-expected generic entry, or expose us to legal and regulatory challenges under federal and state antitrust laws.

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 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 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. There could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government. 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.

The European Union’s (EU) new Unified Patent Court (UPC), which took effect on June 1, 2023, may, in particular, present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe, including those based on European patent applications filed after introduction of the new system. Under the new system, the proprietor of a European patent can opt for that patent to become a unitary patent which will cover all of the EU states that have ratified the Agreement on the Unified Patent Court at that point in time (hereinafter referred to as UPC Countries), and the European patent will then be subject to the jurisdiction of the UPC. During a transition period of the first seven years of the UPC's existence (which under the current legislation could potentially be extended by the Administrative Committee of the UPC for up to seven additional years), European patent applications can be opted out of the jurisdiction of the UPC, and validated as exclusively national patents in any one or more of the UPC Countries, even if those patents grant after the end of the transition period.

We may decide to opt out future European patents from the UPC, but doing so may preclude us from realizing some benefits of the UPC. If we do opt a European patent out of the jurisdiction of the UPC, we may decide to opt that European patent back into the jurisdiction of the UPC in the future if we do wish to take advantage of certain benefits of the UPC, but we will only be able to do this if no actions have been brought before a national court in relation to the European patent concerned. In addition, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC.

We may decide not to opt out of future European Patents from the UPC, but not opting out will put our European patent under the jurisdiction of the UPC for all UPC Countries and we will still be required to validate the European patent in countries that are not signatories to the unitary patent system, such as Spain, Switzerland and the United Kingdom, and failure to validate would prevent us from securing patent rights in those countries. European patents that are under the jurisdiction of the UPC may be challenged in a single UPC-based revocation proceeding that could invalidate the patent in all UPC countries.

The UPC will also 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 injunction against us in infringement proceedings, in at least all countries which are signatories to the UPC. Further, because the UPC is a new court system having little established precedent for the court's decisions, there is increased uncertainty regarding the outcome of any patent litigation. We are unable to predict what impact the new patent regime may have on our ability to exclude competitors in the European market.

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. We may need to share our proprietary information, including trade secrets, with our current and future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. 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 regarding the results of clinical trials we may run evaluating tenapanor for CIC, RDX10531 or any other product candidates;
- 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;
- failure to meet any of our projected timelines or goals with regard to the commercialization of IBSRELA and XPHOZAH, or the clinical development and commercialization of any of our product candidates;
- the success of our efforts to acquire or license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- the success of our efforts to obtain adequate intellectual property protection for our products and 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;
- 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.

General Risk Factors

We incur significant costs as a result of operating as a public company, and our management devotes 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 need to devote a substantial amount of time to ensure that we comply with all of these requirements. 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, geopolitical tensions, 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. 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 three months ended June 30, 2026, no Section 16 officer or director adopted or terminated any contracts, instructions or written plans for the purchase or sale of our securities.

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	06/24/2014	3.1	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation.	8-K	06/20/2023	3.1	
3.3	Second Amended and Restated Bylaws.	8-K	08/04/2025	3.1	
10.1†	First Amendment to the Commercial Supply Agreement, dated May 11, 2026, by and between the Company and Catalent Pharma Solutions, LLC.				X
10.2†	Second Amendment to the Manufacturing Services Agreement, dated May 15, 2026, by and between the Company and Patheon Pharmaceuticals Inc.				X
10.3#	Second Amendment to the Ardelyx, Inc. Amended and Restated 2014 Equity Incentive Award Plan.	8-K	06/17/2026	10.1	
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following financial statements, formatted in Inline Extensible Business Reporting Language (XBRL): (i) Condensed Balance Sheets as of June 30, 2026 and December 31, 2025, (ii) Condensed Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2026 and 2025, (iii) Condensed Statements of Changes in Stockholders' Equity for the three and six months ended June 30, 2026 and 2025, (iv) Condensed Statements of Cash Flows for the six months ended June 30, 2026 and 2025, 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

† Certain portions of this exhibit have been redacted pursuant to Item 601(b)(10) of Regulation S-K. A copy of the omitted portions will be furnished supplementally to the SEC upon request.

# Indicates management contract or compensatory plan.

* The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the SEC and are 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: August 6, 2026

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:

2025 Form 10-K	Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on February 19, 2026	HCR	HealthCare Royalty Partners IV, L.P.
340B Program	Public Health Service's 340B Drug Pricing Program	HCR Agreement	Royalty and Sales Milestone Interest Acquisition Agreement
AAKP	American Association of Kidney Patients	HHS	Department of Health and Human Services
ACA	Affordable Care Act	HIPAA	Health Insurance Portability and Accountability Act of 1996, as amended, and regulations promulgated thereunder
AI Technologies	Artificial intelligence (AI), machine learning, and automated decision-making technologies, (collectively, AI Technologies)	HRSA	Health Resources and Services Administration
AMP	average manufacturer price	IBS-C	irritable bowel syndrome with constipation
ANDA	abbreviated New Drug Application	IND	Investigational New Drug
API	active pharmaceutical ingredient	IRA	Inflation Reduction Act of 2022
AstraZeneca	AstraZeneca AB	IRB	Institutional Review Board
ASU	Accounting Standards Update	IT	information technology
CCPA	California Consumer Privacy Act, as amended by the California Privacy Rights Act	Jefferies	Jefferies LLC
cGMP	current Good Manufacturing Practice	Knight	Knight Therapeutics, Inc.
CIC	chronic idiopathic constipation	Kyowa Kirin	Kyowa Kirin Co., Ltd.
CKD	chronic kidney disease	MDRP	Medicaid Drug Rebate Program
CME	Chicago Mercantile Exchange	MIPPA	Medicare Improvements for Patients and Providers Act
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	NCE	new chemical entity
Customers	collectively, major wholesalers, specialty pharmacies and GPOs (IBSRELA) and specialty wholesaler (XPHOZAH)	NDA	New Drug Application
DPF	EU-US Data Privacy Framework	NHE3	sodium hydrogen exchange 3
EEA	European Economic Area	NMPA	National Medical Products Administration
ESPP	Employee Stock Purchase Plan	NMQF	National Minority Quality Forum
ESRD	End-Stage Renal Disease	NOL	net operating loss
ESRD PPS	End-Stage Renal Disease Prospective Payment System	Non-FAMP	Non-Federal Average Manufacturer Price
EU Patent Package	European Patent Package	OLC	Oxylanthanum Carbonate
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	SEC	Securities and Exchange Commission
Fosun Pharma	Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd.	SLR	SLR Investment Corp.
FSS	Federal Supply Schedule	SOFR	Secured Overnight Financing Rate
FTC	Federal Trade Commission	TDAPA	Transitional Drug Add-on Payment Adjustment
GCP	Good Clinical Practice	UPC	Unified Patent Court
GDPR	European Union General Data Protection Regulation	U.S.	United States
GLP	Good Laboratory Practice	USPTO	U.S. Patent and Trademark Office
GPO	group purchasing organization	VA	Department of Veterans Affairs
GTN	gross-to-net		

Exhibit 10.1

AMENDMENT No. 1 TO COMMERCIAL SUPPLY AGREEMENT

This Amendment No. 1 to the Commercial Supply Agreement ("**Amendment**") is effective as of May 11th, 2026 ("**Amendment No. 1 Effective Date**") by and between Ardelyx, Inc., a Delaware corporation, having a place of business at 400 Fifth Avenue, Suite 210, Waltham, Massachusetts 02451, U.S.A. ("**Client**"), and Catalent Pharma Solutions, LLC, a Delaware limited liability company, having a place of business at 200 Crossing Blvd., Floor 7, Bridgewater, New Jersey 08807, U.S.A. ("**Catalent**"). This Amendment refers to Catalent and Client individually as "**Party**" and collectively as the "**Parties**".

WITNESSETH:

WHEREAS, Client and Catalent are Parties to the Commercial Supply Agreement dated July 23rd, 2024 (the "**Agreement**"); and

WHEREAS, Catalent and Client wish to amend certain terms of the Agreement, and include new Product strengths to the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, terms, and conditions set forth below, the Parties agree as follows:

1. Capitalized Terms. Capitalized terms used in this Amendment and not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement. For clarity, the term "Agreement" as used in the Agreement and herein shall mean the Agreement as amended hereby.

2. Amendment to Agreement.

   2.1. Section 1.20 of the Agreement is hereby deleted in its entirety and replaced with the following:

   *1.20 "**Commencement Date**" means, with respect to each Product Brand separately, the first date upon which Client receives all Regulatory Approvals required for sale in the first market in the Territory of each Product Processed by Catalent at the Facility. For the avoidance of doubt, the Commencement Date shall be recorded by way of written document (substantially in the form of Attachment A1 and Attachment A2) within 3 months after the occurrence of the first relevant Regulatory Authority approval for each Product Brand, signed by both Parties, and attached as Attachment A1 for the Ibsrela® Product Brand and as Attachment A2 for the Xphozah® Product Brand.*

   2.2. Attachment A of the Agreement is hereby deleted in its entirety and replaced with the Attachment A1 and Attachment A2 attached hereto.

2.3. Section 1.22 of the Agreement is hereby deleted in its entirety and replaced with the following:

*1.22 "**Contract Year**" means for each Product Brand separately, (i) for the first Contract Year, the partial 12-month period beginning on the Commencement Date for such Product and ending on December 31 thereafter ("**Contract Year 1**") and (ii) following Contract Year 1, each consecutive 12-month period beginning on January 1 and ending on December 31 ("**Contract Year 2**", "**Contract Year 3**", etc.).*

2.4. Section 1.45 of the Agreement is hereby deleted in its entirety and replaced with the following:

*"**Product**" means the bulk pharmaceutical products containing the API (including different strengths), Processed in accordance with the Specifications. The 50 mg Product will be under the Ibsrela® brand, and the 20 mg and 30 mg Products will be under the Xphozah® brand, which will be referred to as "**Product Brand(s)**".*

2.5. Attachment C of the Agreement is hereby deleted in its entirety and replaced with the revised Attachment C attached hereto.

2.6. Section 7.1(C) of the Agreement is hereby deleted in its entirety and replaced with the following:

7.1(C) Client shall pay Catalent (i) the Annual Product Maintenance Fees for Product Maintenance Services, and (ii) [***].

2.7. Section 16.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

*16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of the 5th Contract Year of the Product Brand with the last Commencement Date, unless earlier terminated in accordance with Section 16.2 (such term, including any extension in accordance with this Section 16.1, the "**Term**"). Unless this Agreement is terminated in accordance with Section 16.2, the Term shall automatically extend for successive 2-year periods unless and until one Party gives the other Party at least 24 months' prior written notice of its desire to terminate as of the end of the then-current Term.*

2.8. Section 3(d) shall be incorporated to Attachment D of the Agreement as follows:

[***]

3. Entire Agreement. This Amendment and the Agreement constitute the entire agreement between the Parties relating to the subject matter hereof and thereof and may not be varied except in writing signed by a duly authorized representative of each Party.

4. Reference to Agreement. From and after the Amendment No. 1 Effective Date, each reference in the Agreement to "this Agreement", "hereof", or "hereunder" or words of like import, and all references to the Agreement in any and all agreements, instruments, documents, notes, certificates and other writings of every kind and nature shall be deemed to mean the Agreement, as amended by this Amendment.

5. Ratification. The Agreement shall remain in full force and effect and is hereby ratified, approved, and confirmed in all respects. There shall be no changes to the Agreement except as expressly set forth herein.

6. Governing Law. This Amendment shall be governed by, and construed in accordance with, the laws of the internal laws of the State of Delaware, U.S.A., without giving effect to any laws, rules, or provisions of State of Delaware that would cause the application of the laws, rules or provisions of any other jurisdiction other than State of Delaware. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Amendment.

7. Counterparts. This Amendment may be executed in counterparts, each of which when executed and delivered shall be deemed to be an original, and all of which when taken together shall constitute one and the same instrument. Any photocopy, facsimile, or electronic reproduction of this Amendment shall constitute an original.

IN WITNESS WHEREOF, the Parties have caused their respective duly authorized representatives to execute this Amendment effective as of the Amendment No. 1 Effective Date.

CATALENT PHARMA SOLUTIONS, LLC	**ARDELYX, INC.**
By: /s/ Aris Gennadios	By: /s/ John E. Bishop
Name: Aris Gennadios	Name: John E. Bishop
Title: Group President, Pharma & Consumer Health	Title: Chief Technical Operations Officer

ATTACHMENT A1

[To be completed and signed by both Parties and to be attached as Attachment A1 within three (3) months of the Commencement Date]

The Parties hereby acknowledge and agree that the Commencement Date, as defined in Section 1.20 of the Agreement, is [insert date], which is the date upon which the [insert Regulatory Authority] approved the Ibsrela® Product Brand for sale in the market in [insert country/region].

Catalent Pharma Solutions, LLC	**Ardelyx, Inc.**
Signature	Signature
Printed Name	Printed Name
Title	Title

ATTACHMENT A2

[To be completed and signed by both Parties and to be attached as Attachment A2 within three (3) months of the Commencement Date]

The Parties hereby acknowledge and agree that the Commencement Date, as defined in Section 1.20 of the Agreement, is [insert date], which is the date upon which the [insert Regulatory Authority] approved the Xphozah® Product Brand for sale in the market in [insert country/region].

Catalent Pharma Solutions, LLC	**Ardelyx, Inc.**
Signature	Signature
Printed Name	Printed Name
Title	Title

ATTACHMENT C

UNIT PRICING AND FEES

[***]

Exhibit 10.2

SECOND AMENDMENT TO MANUFACTURING SERVICES AGREEMENT

This **AMENDMENT #2 TO THE MANUFACTURING SERVICES AGREEMENT** (the "**Second Amendment**") effective as of May 15, 2026 ("**Amendment Effective Date**"), is by and between **Ardelyx Inc.**, a Delaware corporation with its principal place of business at 400 Fifth Avenue, Suite 210, Waltham, MA 02451 ("**Client**"), and **Patheon Pharmaceuticals Inc.**, a Delaware corporation with its principal place of business at 2110 East Galbraith Road, Cincinnati, OH 45237 ("**Patheon**"). Client and Patheon may be referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, Patheon and Client entered into that certain Manufacturing Services Agreement dated May 18, 2020, as amended February 27, 2023 (the "**Agreement**"); and

WHEREAS, the Parties desire to further amend the Agreement to supplement and clarify the terms applicable to packaging, labeling, and related services, when Client orders Finished Packaged Product, and to incorporate additional pricing for agreed upon configurations through the addition of Exhibit A to this Amendment;

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the Parties hereby agree as follows:

1. **Capitalized Term**. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement, as applicable.

2. **Amendments**. The Agreement shall be revised or expanded in accordance with the terms set forth below.

   a. Section 1.1 (Definitions) of the Agreement is hereby revised to include the following definitions:

      "**Bulk Product**" means Product in bulk, unpackaged form (i.e., prior to packaging and labeling).

      "**Finished Packaged Product**" means Product that (i) has undergone packaging and labeling in accordance with the applicable Processing Instructions and Packaging Instructions, and (ii) has been released by Patheon in accordance with the Quality Agreement.

      "**Long Lead Packaging Components**" means components (including packaging components) that require procurement lead times longer than standard components as determined by Patheon based on supplier timeline and designated as such in the applicable Firm Order .

   b. Section 3.3 (Change Control Requests) of the Agreement is hereby amended by adding the following sentence at the end thereof:

      "For clarity, changes to Processing Instructions, packaging configuration, Components (including labels, inserts, and other packaging components), or serialization/aggregation mechanics are subject to the change control process under the Quality Agreement and, where applicable, a mutually agreed change order addressing cost and schedule impacts."

   c. Section 3.5 of the Agreement is hereby deleted in its entirety and replaced with the following:

      "3.5 Packaging, Artwork, and Serialization (when Finished Packaged Product is ordered).

(a) **Scope.** When a Firm Order specifies Finished Packaged Product, Patheon will perform [***] in accordance with (i) the Agreement, (ii) the applicable Processing Instructions, (iii) cGMPs and Applicable Laws, and (iv) the Quality Agreement.

(b) **Artwork.** Client is responsible for artwork development and content accuracy and for obtaining required approvals. Patheon will not implement new or revised artwork without Client's prior written approval. Client will provide final, approved artwork in electronic format by [***] and, in any event, no later than [***] days prior to the applicable Delivery Date (unless the Parties agree otherwise in writing).

(c) **Printing/marking; lot/expiry.** Patheon will implement [***] consistent with cGMPs, Applicable Laws, the Specifications, and the Packaging Instructions.

(d) **Serialization/data carriers (if required).** If [***] apply to the Finished Packaged Product, the [***] will be specified in the Packaging Instructions and subject to change control under the Quality Agreement and Section 3.3.

(e) **No changes without approval.** Patheon will not make material changes to [***] without Client's prior written approval, and any change with a material cost or schedule impact will be documented via a mutually agreed change order.

(f) **Long-lead components.** Patheon will notify Client in writing of any [***] identified for an applicable Firm Order, including procurement lead time and any Client dependencies (e.g., artwork approval deadlines).

(g) **Reconciliation; packaging batch documentation**: Patheon shall provide [***] and [***] sufficient to evidence conformance, including [***], in accordance with the Quality Agreement and Processing Instructions."

d. Section 5.1 (Orders and Forecasts) of the Agreement is hereby revised to include the following:

"(g) **Deliverable Type**. Each purchase order/Firm Order shall specify whether the deliverable is (i) Bulk Product or (ii) Finished Packaged Product. For clarity, Patheon will [***] as part of Manufacturing Services only when Finished Packaged Product is ordered."

e. Section 6.1(d) (Supply Failure) of the Agreement is hereby amended by adding the following sentence at the end thereof:

"For purposes of Section 6.1(d), when a Firm Order specifies Finished Packaged Product, [***]."

f. The Parties acknowledge that Appendix 1 [***]. Effective as of the Amendment Effective Date, and solely for the configurations expressly listed in Exhibit A, [***] shall apply and shall supersede any [***] in Appendix 1 or elsewhere in the Agreement. [***].

3. **Amendment Effective Date**. This Amendment shall be effective as of the Amendment Effective Date and shall apply to all Firm Orders issued on or after the Amendment Effective Date.

4. **No Other Amendments**. Except as herein set forth, the Agreement has not been modified, and as amended by this Amendment, remains in full force and effect. To the extent there are any inconsistencies or ambiguities between the specific subject matter of this Amendment and the Agreement, the terms of this Amendment shall supersede the Agreement.

5. **Counterparts**. This Amendment may be executed in one or more counterparts (including by .pdf or electronic signature), each of which shall be an original and all of which together shall constitute one instrument.

IN WITNESS WHEREOF, the Parties have hereunto signed this Amendment effective as of the day and year first written above.

PATHEON PHARMACEUTICALS INC.

Signature: /s/ [***]

By: [***]

(Print Name)

Title: General Manager, Cincinnati

Date: 6/1/2026

ARDELYX, INC.

Signature: /s/ Paul Sainsbury

By: Paul Sainsbury

(Print Name)

Title: Vice President, Supply Chain

Date: 5/26/2026

EXHIBIT A

Patheon Pricing Schedule
Bulk Product and Finished Packaged Product

[***]

Exhibit 31.1

CERTIFICATION

I, Michael Raab, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2026

By: /s/ Michael Raab

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

Exhibit 31.2

CERTIFICATION

I, Susan Hohenleitner, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 6, 2026

By: /s/ Susan Hohenleitner

Susan Hohenleitner
Chief Financial 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 ended June 30, 2026, 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 Susan Hohenleitner, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 6, 2026

By: /s/ Michael Raab

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

Date: August 6, 2026

By: /s/ Susan Hohenleitner

Susan Hohenleitner
Chief Financial Officer
(Principal Financial Officer)