Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

OR

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

For the transition period from to

Commission file number: 001-36485

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

Delaware	**26-1303944**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No)

400 Fifth Avenue, Suite 210, Waltham, Massachusetts 02451
(Address of Principal Executive Offices) (Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001	ARDX	The Nasdaq Global Market

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

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

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

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

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

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

The number of issued and outstanding shares of the registrant's Common Stock, $0.0001 par value per share, as of July 31, 2022, was 154,635,575.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our expectations regarding our participation in a Cardiovascular and Renal Drugs Advisory Committee (“Advisory Committee”) meeting in connection with the formal dispute resolution (“FDR”) process commenced in response to the Complete Response Letter (“CRL”) received from the U.S. Food and Drug Administration (“FDA”) relating to our new drug application (“NDA”) for XPHOZAH® (tenapanor) for the control of serum phosphorus in adult patients with chronic kidney disease on dialysis (“CKD”) (the “Hyperphosphatemia Indication”);
- our plans to address our operating cash flow requirements with our current cash and investments, cash generated from the sales of IBSRELA®, our potential receipt of anticipated milestones from our collaboration partners, our potential receipt of anticipated payments from our Japanese collaboration partner under the second amendment to our License Agreement; our ability to access the capital markets, as well as through the implementation of cash preservation activities to reduce or defer discretionary spending;
- our plans with respect to RDX013 and RDX020; and
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital.

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

SUMMARY OF PRINCIPAL RISKS ASSOCIATED WITH OUR BUSINESS

- We have incurred significant losses since our inception and will incur losses in the future, which makes it difficult for us to assess our future viability; although our financial statements have been prepared on a going concern basis, our current level of cash and investments alone is not sufficient to meet our operating plans for the next twelve months, raising substantial doubt regarding our ability to continue as a going concern.
- We will require substantial additional financing for the foreseeable future as we invest in the commercialization of IBSRELA and prepare for and participate in a Cardiovascular and Renal Drugs Advisory Committee (“Advisory Committee”) meeting. The Advisory Committee meeting has been convened in connection with the formal dispute resolution (“FDR”) process we commenced in response to the Complete Response Letter (“CRL”) received from the U.S. Food and Drug Administration (“FDA”) relating to our new drug application (“NDA”) for XPHOZAH (tenapanor) for the control of serum phosphorus in adult patients with chronic kidney disease (“CKD”) on dialysis (“Hyperphosphatemia Indication”) and the inability to access necessary capital when needed on acceptable terms, or at all, could force us to limit, reduce or terminate our efforts to commercialize IBSRELA or to seek and obtain approval for XPHOZAH for the Hyperphosphatemia Indication.
- Our failure to meet the continued listing requirements of The Nasdaq Global Market ("Nasdaq") could result in a de-listing of our common stock.
- We have generated limited revenue from product sales and may never be profitable.
- We are substantially dependent on the successful launch and commercialization of IBSRELA for IBS-C, and there is no guarantee that we will achieve sufficient market acceptance for IBSRELA; secure adequate coverage and reimbursement for IBSRELA; or generate sufficient revenue from product sales of IBSRELA.

- We are pursuing regulatory approval for tenapanor for the Hyperphosphatemia Indication. There can be no assurances that we will be successful in obtaining such regulatory approval.
- Even if we are successful in obtaining regulatory approval for tenapanor for the Hyperphosphatemia Indication, the expense and time required to do so could adversely impact our ability to successfully commercialize XPHOZAH for the Hyperphosphatemia Indication.
- IBSRELA, and/or, if approved and commercialized, XPHOZAH, may cause undesirable side effects or have other properties that could limit the commercial success of the product.
- As a company, we have limited experience in the marketing, sale and distribution of pharmaceutical products; and there are significant risks in building and managing a commercial organization.
- Third-party payor coverage and reimbursement status of newly-commercialized products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for IBSRELA and, if approved, for XPHOZAH could limit our ability to market those products and decrease our ability to generate revenue.
- We rely completely on third parties 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, if approved and commercialized of XPHOZAH, and our future development efforts for tenapanor 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 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.

NOTE REGARDING TRADEMARKS

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

ARDELYX, INC.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 53,408	$ 72,428
Short-term investments	27,604	44,261
Accounts receivable	5,623	502
Inventory	4,529	—
Prepaid commercial manufacturing	17,793	9,406
Prepaid expenses and other current assets	5,150	7,052
Total current assets	114,107	133,649
Right-of-use assets	11,054	12,752
Property and equipment, net	1,541	2,362
Other assets	4,908	1,150
Total assets	$ 131,610	$ 149,913
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,294	$ 4,277
Accrued compensation and benefits	6,405	5,422
Current portion of long-term debt	26,373	32,264
Current portion of operating lease liability	3,691	3,492
Accrued expenses and other current liabilities	7,936	7,366
Total current liabilities	48,699	52,821
Operating lease liability, net of current portion	7,857	9,748
Deferred revenue, non-current	12,421	4,727
Deferred royalty obligation	9,591	—
Total liabilities	78,568	67,296
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively.	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized; 153,797,834 and 130,182,535 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively.	15	13
Additional paid-in capital	821,075	795,540
Accumulated deficit	(767,939)	(712,930)
Accumulated other comprehensive loss	(109)	(6)
Total stockholders' equity	53,042	82,617
Total liabilities and stockholders' equity	$ 131,610	$ 149,913

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,	
	2022	2021	2022	2021
Revenues:				
Product sales, net	$ 1,564	$ —	$ 2,014	$ —
Product supply revenue	952	—	966	126
Licensing revenue	10	3	14	5,005
Collaborative development revenue	—	1,310	—	2,764
Total revenues	2,526	1,313	2,994	7,895
Operating expenses:				
Cost of revenue	138	—	223	1,000
Research and development	9,741	26,021	18,592	46,477
Selling, general and administrative	18,862	20,124	38,201	37,255
Total operating expenses	28,741	46,145	57,016	84,732
Loss from operations	(26,215)	(44,832)	(54,022)	(76,837)
Interest expense	(787)	(1,202)	(1,533)	(2,302)
Other income, net	70	847	554	798
Loss before provision for income taxes	(26,932)	(45,187)	(55,001)	(78,341)
Provision for income taxes	6	2	8	3
Net loss	$ (26,938)	$ (45,189)	$ (55,009)	$ (78,344)
Net loss per common share, basic and diluted	$ (0.19)	$ (0.45)	$ (0.40)	$ (0.79)
Shares used in computing net loss per share - basic and diluted	145,544,372	100,040,083	138,279,945	98,617,564
Comprehensive loss:				
Net loss	$ (26,938)	$ (45,189)	$ (55,009)	$ (78,344)
Unrealized losses on available-for-sale securities	(21)	11	(103)	8
Comprehensive loss	$ (26,959)	$ (45,178)	$ (55,112)	$ (78,336)

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

ARDELYX, INC.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
For the Three and Six Months ended June 30, 2022 and 2021
(Unaudited)
(in thousands, except shares)

	Three Months Ended June 30, 2022					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of March 31, 2022	136,330,360	$ 14	$ 805,265	$ (741,001)	$ (88)	$ 64,190
Issuance of common stock upon vesting of restricted stock units	2,882,673	—	—	—	—	—
Issuance of common stock in at the market offering	14,584,801	1	12,556	—	—	12,557
Stock-based compensation	—	—	3,254	—	—	3,254
Unrealized losses on available-for-sale securities	—	—	—	—	(21)	(21)
Net loss	—	—	—	(26,938)	—	(26,938)
Balance as of June 30, 2022	153,797,834	$ 15	$ 821,075	$ (767,939)	$ (109)	$ 53,042

	Six Months Ended June 30, 2022					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2021	130,182,535	$ 13	$ 795,540	$ (712,930)	$ (6)	$ 82,617
Issuance of common stock under employee stock purchase plan	127,100	—	83	—	—	83
Issuance of common stock upon vesting of restricted stock units	2,996,142	—	—	—	—	—
Issuance of common stock in at the market offering	20,492,057	2	18,476	—	—	18,478
Stock-based compensation	—	—	6,976	—	—	6,976
Unrealized losses on available-for-sale securities	—	—	—	—	(103)	(103)
Net loss	—	—	—	(55,009)	—	(55,009)
Balance as of June 30, 2022	153,797,834	$ 15	$ 821,075	$ (767,939)	$ (109)	$ 53,042

	Three Months Ended June 30, 2021					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of March 31, 2021	98,688,577	$ 10	$ 718,728	$ (587,920)	$ (7)	$ 130,811
Issuance of common stock upon exercise of options	194,799	—	543	—	—	543
Issuance of common stock upon vesting of restricted stock units	44,684	—	—	—	—	—
Issuance of common stock in at the market offering	4,038,957	—	28,174	—	—	28,174
Stock-based compensation	—	—	3,219	—	—	3,219
Unrealized gains on available-for-sale securities	—	—	—	—	11	11
Net loss	—	—	—	(45,189)	—	(45,189)
Balance as of June 30, 2021	102,967,017	$ 10	$ 750,664	$ (633,109)	$ 4	$ 117,569

	Six Months Ended June 30, 2021					
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2020	93,599,975	9	680,872	(554,765)	(4)	$ 126,112
Issuance of common stock under employee stock purchase plan	102,208	—	478	—	—	478
Issuance of common stock upon exercise of options	205,306	—	563	—	—	563
Issuance of common stock upon vesting of restricted stock units	79,784	—	—	—	—	—
Issuance of common stock in at the market offering	8,979,744	1	62,445	—	—	62,446
Stock-based compensation	—	—	6,306	—	—	6,306
Unrealized gains on available-for-sale securities	—	—	—	—	8	8
Net loss	—	—	—	(78,344)	—	(78,344)
Balance as of June 30, 2021	102,967,017	$ 10	$ 750,664	$ (633,109)	$ 4	$ 117,569

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,	
	2022	2021
Operating activities		
Net loss	$ (55,009)	$ (78,344)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	407	787
Amortization of deferred financing costs	226	316
Amortization of deferred compensation for services	105	145
Amortization of premium on investment securities	16	274
Non-cash lease expense	1,698	1,318
Stock-based compensation	6,976	6,306
Change in derivative liabilities	18	(713)
Debt refinancing costs	102	—
Gain on sale of equipment	(853)	—
Non-cash interest associated with debt discount accretion	151	141
Changes in operating assets and liabilities:		
Accounts receivable	(5,121)	—
Inventory	(4,529)	—
Prepaid commercial manufacturing	(12,197)	(8,481)
Prepaid expenses and other assets	1,848	1,102
Accounts payable	17	(3,039)
Accrued compensation and benefits	983	267
Operating lease liabilities	(1,692)	(1,361)
Accrued and other liabilities	259	2,607
Deferred revenue	7,694	182
Net cash used in operating activities	(58,901)	(78,493)
Investing activities		
Proceeds from maturities and redemptions of investments	42,300	60,550
Purchases of investments	(25,762)	(48,314)
Proceeds from sale of property and equipment	1,268	—
Purchases of property and equipment	—	(1,517)
Net cash provided by investing activities	17,806	10,719
Financing activities		
Proceeds from 2022 Loan, net of issuance costs	26,971	—
Repayment of 2018 Loan, net of settlement costs	(33,038)	—
Proceeds from the sale of future royalties, net of issuance costs	9,581	—
Proceeds from issuance of common stock in at the market offering, net of issuance costs	18,478	62,446
Proceeds from issuance of common stock under equity incentive and stock purchase plans	83	1,041
Net cash provided by financing activities	22,075	63,487
Net decrease in cash and cash equivalents	(19,020)	(4,287)
Cash and cash equivalents at beginning of period	72,428	91,032
Cash and cash equivalents at end of period	$ 53,408	$ 86,745
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ 1,360	$ 1,936
Cash paid for income taxes	$ 6	$ 3
Supplementary disclosure of non-cash activities:		
Right-of-use assets obtained in exchange for lease obligations	$ —	$ 14,379
Issuance of derivative in connection with issuance of loan payable	$ 375	$ —

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

ARDELYX, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)
(amounts in thousands, except per share amounts and where otherwise noted)

NOTE 1. ORGANIZATION AND BASIS OF PRESENTATION

Ardelyx, Inc. (the "Company," "we," "us" or "our") is a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative first-in-class medicines that meet significant unmet medical needs.

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

Basis of Presentation

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

The accompanying condensed financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2021. The results for the three and six months ended June 30, 2022 are not necessarily indicative of results to be expected for the entire year ending December 31, 2022, or for any other interim period or future year.

Use of Estimates

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

Liquidity

As of June 30, 2022, we had cash and investments of approximately $81.0 million. We have incurred operating losses since inception and our accumulated deficit as of June 30, 2022 is $767.9 million. Our current level of cash and investments alone is not sufficient to meet our plans for the next twelve months following the issuance of these financial statements. These factors raise substantial doubt regarding our ability to continue as a going concern for a period of one year from the issuance of these financial statements. We plan to address our operating cash flow requirements with our current cash and investments, cash generated from sales of IBSRELA, our potential receipt of anticipated milestones from our collaboration partners, our potential receipt of anticipated payments from our Japanese collaboration partner under the second amendment to our License Agreement, our ability to access the capital markets, as well as through the implementation of cash preservation activities to reduce or defer discretionary spending.

There are no assurances that our efforts to meet our operating cash flow requirements will be successful. If our current cash and investments as well as our plans to meet our operating cash flow requirements are not sufficient to fund necessary expenditures and meet our obligations for at least the next twelve months following the issuance of these financial statements, our liquidity, financial condition and business prospects will be materially affected. These financial statements have been prepared on a going concern basis and do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary in the event that we can no longer continue as a going concern.

Summary of Significant Accounting Policies

Our significant accounting policies are described in Note 1 to our audited financial statements for the fiscal year ended December 31, 2021, included in our Annual Report on Form 10-K. Our significant accounting policies for the three and six months ended June 30, 2022 also included the policies discussed below related to accounts receivable, inventory, revenue and cost of revenue for commercial product sales. With the exception of those noted below, there have been no material changes in our significant accounting policies as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Accounts Receivable

Accounts receivable is reported net of allowances for returns, chargebacks and contractual discounts offered to our customers. Our estimate of the allowance for doubtful accounts is based on an evaluation of the aging of our receivables. Trade receivable balances are written off against the allowance when it is probable that the receivable will not be collected. To date, we have determined that an allowance for doubtful accounts is not required. As of June 30, 2022 our accounts receivable balance is comprised of $4.1 million from our collaborators and $1.5 million from commercial customers. As of December 31, 2021 our accounts receivable balance was comprised of $0.5 million from our collaborators.

Inventory

Prior to the regulatory approval of drug product candidates, we incurred expenses for the manufacture of drug product that could potentially be available to support the commercial launch of our products. We began to capitalize inventory costs associated with IBSRELA during the fourth quarter of 2021, when our intent to commercialize IBSRELA was established and we commenced preparation for the commercial launch of IBSRELA, which was when it was determined that the inventory had a probable future economic benefit.

Inventory is stated at the lower of cost or estimated net realizable value with cost determined under the first-in first-out method. Inventory costs include third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, and indirect overhead costs. We primarily use actual costs to determine the cost basis for inventory. The determination of whether inventory costs will be realizable requires management review of the expiration dates of IBSRELA compared to our forecasted sales. If actual market conditions are less favorable than projected by management, write-downs of inventory may be required, which would be recorded as cost of goods sold in the condensed statement of operations and comprehensive loss.

Product Sales, Net

We account for our commercial product sales, net in accordance with Topic 606 - *Revenue from Contracts with Customers*. We received approval from the U.S. Food and Drug Administration (“FDA”) in September 2019 to market IBSRELA, the first and only sodium hydrogen exchanger 3 (“NHE3”) inhibitor for the treatment of irritable bowel syndrome with constipation ("IBS-C") in adults, in the United States ("U.S."). We began selling IBSRELA in the U.S. in March 2022. We distribute IBSRELA principally through a limited number of wholesalers and specialty pharmacy providers (collectively, our "Customers"). Our Customers subsequently sell IBSRELA to pharmacies and patients. Separately, we enter into arrangements with third parties that provide for government-mandated and privately-negotiated rebates, chargebacks and discounts. Revenue from product sales is recognized when our performance obligations are satisfied, which is when Customers obtain control of our product and occurs upon delivery.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration, including rebates, discounts, patient copay assistance programs, and estimated product returns. These estimates are based on the amounts earned or to be claimed for related sales and are classified as reductions of gross accounts receivable if the amount is payable to our Customers or a current liability if the amount is payable to a party other than a Customer. Where appropriate, these estimates are based on factors such as industry data and forecasted customer buying and payment patterns, our historical experience, current contractual and statutory requirements, specific known market events and trends. Overall, these reductions to gross sales reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we adjust these estimates, which would affect product revenue and earnings in the period such variances become known. As we gain more historical experience, estimates will be more heavily based on the expected utilization from historical data we have accumulated since the IBSRELA product launch.

Rebates: Rebates include mandated discounts under the Medicaid Drug Rebate Program ("Medicaid") and the Medicare Coverage Gap Program ("Medicare"). Rebates are amounts owed after the final dispensing of products to a benefit plan participant and are based upon contractual agreements or legal requirements with the public-sector benefit providers. These estimates for rebates are recorded in the same period the related gross revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the condensed balance sheets. We estimate our Medicaid and Medicare rebates based upon the estimated payor mix, and statutory discount rates. Our estimates for payor mix are guided by payor information received from specialty pharmacies, expected utilization for wholesaler sales to pharmacies, and available industry payor information.

Chargebacks: Chargebacks are discounts that occur when certain contracted purchasers purchase directly from our wholesalers at a discounted price. The wholesaler, in turn, charges back the difference between the price initially paid to us by the wholesaler and the discounted price paid to the wholesaler by the contracted purchaser. Amounts for estimated chargebacks are established in the same period that the related gross revenue is recognized, resulting in a reduction of product revenue and accounts receivable. The accrual for wholesaler chargebacks is estimated based on known chargeback rates, known sales to wholesalers, and estimated utilization by types of contracted purchasers.

Discounts and Fees: Our payment terms are generally 30 to 60 days. Wholesalers and specialty pharmacies are offered various forms of consideration, including service fees. Wholesalers may also receive prompt pay discounts for payment within a specified period. We expect prompt pay discounts to be earned when offered and therefore, we deduct the full amount of these discounts and service fees from product sales when revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

Other Reserves: Patients who have commercial insurance may receive co-pay assistance when product is dispensed by pharmacies to patients. We estimate the amount of co-pay assistance provided to eligible patients based on the terms of the program and redemption information provided by third-party claims processing organizations and are recorded in accounts payable and accrued expenses and other current liabilities on the condensed balance sheets.

Cost of Revenue

Cost of revenue consists of the cost of commercial goods sold to our Customers, international partners under product supply agreements, and royalty expense based on sales of tenapanor. We capitalize inventory costs associated with the production of our products after regulatory approval or when, based on management’s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Otherwise, such costs are expensed as research and development. A portion of the costs of IBSRELA units recognized as revenue during the three and six months ended June 30, 2022 were expensed prior to the fourth quarter of 2021, at which time our intent to commercialize IBSRELA was established and we commenced preparation for the commercial launch of IBSRELA.

Cost of revenue includes payments due to AstraZeneca, which under the terms of a termination agreement entered into in 2015 (the "AZ Termination Agreement") is entitled to (i) future royalties at a rate of 10% of net sales of tenapanor or other NHE3 products by us or our licensees, and (ii) 20% of non-royalty revenue received from our collaboration partners as a result of the development and commercialization of tenapanor or certain other NHE3 inhibitors. We have agreed to pay AstraZeneca up to a maximum of $75.0 million in the aggregate for (i) and (ii). We recognize these expenses as cost of revenue when we recognize the corresponding revenue that gives rise to payments due to AstraZeneca. To date, we have recognized an aggregate of $11.9 million as cost of revenue under the AZ Termination Agreement.

Non-cash Interest Expense on Deferred Royalty Obligation

The net proceeds we receive from the sale of certain future royalties are amortized to non-cash interest expense over the estimated life of the associated agreement using the effective interest method. As we earn royalties and remit those royalties pursuant to the agreement, the balance of the deferred royalty obligation will be effectively repaid over the life of agreement. To determine the amortization of our deferred royalty obligation, we are required to estimate the total amount of future royalty payments we expect to earn. There are a number of factors that could materially affect the amount and timing of royalty payments, most of which are not within our control. We periodically assess the amount of royalty payments we expect to receive which are subject to the agreement 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.

Recent Accounting Pronouncements

New Accounting Pronouncements - Recently Adopted

We have adopted no new accounting pronouncements other than those disclosed in our most recent Annual Report on Form 10-K.

Recent Accounting Pronouncements Not Yet Adopted

There were various accounting standards and interpretations issued recently, none of which are expected to a have a material impact on our financial position, operations or cash flows.

NOTE 2. CASH, CASH EQUIVALENTS AND INVESTMENTS

Securities classified as cash, cash equivalents and investments as of June 30, 2022 and December 31, 2021 are summarized below (in thousands):

	June 30, 2022			
		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 2,975	$ —	$ —	$ 2,975
Money market funds	50,433	—	—	50,433
Total cash and cash equivalents	53,408	—	—	53,408
Short-term investments:				
Commercial paper	$ 16,931	$ —	$ (49)	$ 16,882
U.S. government-sponsored agency bonds	8,768	—	(45)	8,723
Corporate bonds	1,011	—	(12)	999
Asset-backed securities	1,003	—	(3)	1,000
Total short-term investments	27,713	—	(109)	27,604
Total cash equivalents and investments	$ 81,121	$ —	$ (109)	$ 81,012

	December 31, 2021			
		Gross Unrealized		
	Amortized Cost	Gains	Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 1,253	$ —	$ —	$ 1,253
Money market funds	71,175	—	—	71,175
Total cash and cash equivalents	72,428	—	—	72,428
Short-term investments				
Commercial paper	$ 31,936	$ 1	$ (2)	$ 31,935
Corporate bonds	7,025	—	(3)	7,022
Asset backed securities	5,306	—	(2)	5,304
Total short-term investments	44,267	1	(7)	44,261
Total cash equivalents and investments	$ 116,695	$ 1	$ (7)	$ 116,689

Cash equivalents consist of money market funds and other debt securities with original maturities of three months or less at the time of purchase, and the carrying amount is a reasonable approximation of fair value. We invest our cash in high quality securities of financial and commercial institutions. These securities are carried at fair value, which is based on readily available market information, with unrealized gains and losses included in accumulated other comprehensive income (loss) within stockholders' equity on our balance sheets. We use the specific identification method to determine the amount of realized gains or losses on sales of marketable securities. Realized gains or losses have been insignificant and are included in other income (expense), net, in the statement of operations and comprehensive loss.

All short-term available-for-sale securities held as of June 30, 2022 had contractual maturities of less than one year. Our available-for-sale securities are subject to a periodic impairment review. We consider a debt security to be impaired when its fair value is less than its carrying cost, in which case we would further review the investment to determine whether it is other-than-temporarily impaired. When we evaluate an investment for other-than-temporary impairment, we review factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and any changes thereto, intent to sell, and whether it is more likely than not we will be required to sell the investment before the recovery of its cost basis. If an investment is other-than-temporarily impaired, we write it down through the statement of operations and comprehensive loss to its fair value and establishes that value as a new cost basis for the investment. We did not identify any of our available-for-sale securities as other-than-temporarily impaired in any of the periods presented. As of June 30, 2022, no investment was in a continuous unrealized loss position for more than one year and we believe that it is more likely than not that the investments will be held until maturity or a forecasted recovery of fair value.

NOTE 3. FAIR VALUE MEASUREMENTS

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

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

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

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

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

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

	June 30, 2022			
	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 50,433	$ 50,433	$ —	$ —
Commercial paper	16,882	—	16,882	—
U.S. government-sponsored agency bonds	8,723	—	8,723	—
Corporate bonds	999	—	999	—
Asset-backed securities	1,000	—	1,000	—
Total	$ 78,037	$ 50,433	$ 27,604	$ —
Liabilities:				
Derivative liabilities for exit fees	$ 1,091	$ —	$ —	$ 1,091
Total	$ 1,091	$ —	$ —	$ 1,091

	December 31, 2021			
	Total Fair Value	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 71,175	$ 71,175	$ —	$ —
Commercial paper	31,935	—	31,935	—
Corporate bonds	7,022	—	7,022	—
Asset-backed securities	5,304	—	5,304	—
Total	$ 115,436	$ 71,175	$ 44,261	$ —
Liabilities:				
Derivative liability for exit fee	$ 698	$ —	$ —	$ 698
Total	$ 698	$ —	$ —	$ 698

Where quoted prices are available in an active market, securities are classified as Level 1. We classify money market funds as Level 1. When quoted market prices are not available for the specific security, we estimate fair value by using benchmark yields, reported trades, broker/dealer quotes and issuer spreads. We classify U.S. government-sponsored agency bonds, U.S. treasury notes, corporate bonds, commercial paper, and asset-backed securities as Level 2. In certain cases, where there is limited activity or less transparency around inputs to valuation, securities or derivative liabilities, such as the 2018 Exit Fee and 2022 Exit Fee, as defined and discussed in *Note 9. Derivative Liability*, are classified as Level 3.

The carrying amounts reflected in the balance sheets for cash equivalents, short-term investments, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values at both June 30, 2022 and December 31, 2021, due to their short-term nature.

Fair Value of Debt

The interest rates of our deferred royalty obligation and term loan facility approximate the rate at which we could obtain alternative financing. Therefore, the carrying amount of the deferred royalty obligation and the term loan facility approximated their fair values at June 30, 2022 and December 31, 2021. See *Note 7. Deferred Royalty Obligation and Note 8. Borrowing* for a description of the Level 3 inputs used to estimate the fair value of each respective liability.

NOTE 4. INVENTORY

We began capitalizing inventory during the fourth quarter of 2021, at which time our intent to commercialize IBSRELA was established and we commenced preparation for the commercial launch of IBSRELA. Inventory consisted of the following (in thousands):

	June 30, 2022
Raw materials	$ 460
Work in process	3,606
Finished goods	463
Total	$ 4,529

Prepaid commercial manufacturing of $17.8 million and $9.4 million as of June 30, 2022 and December 31, 2021, respectively, consist of prepayments to third party contract manufacturing organizations for the manufacture of IBSRELA for production orders which we expect work to commence within the next 12 months. Prepayments for commercial manufacturing of $3.8 million as of June 30, 2022 that are expected to be converted into inventory after 12 months are included in other assets on our Condensed Balance Sheets.

NOTE 5. PRODUCT REVENUE, NET

We received approval from the FDA in September 2019 to market IBSRELA, the first and only NHE3 inhibitor for the treatment of IBS-C in adults, in the U.S. We began selling IBSRELA in the U.S. in March 2022. We recorded net revenue for IBSRELA of $1.6 million and $2.0 million during the three and six months ended June 30, 2022, respectively.

Sales to AmerisourceBergen Drug Corporation, Cardinal Health, and McKesson Corporation made up 40.2%, 22.7%, and 24.6% of our gross product revenue during the three months ended June 30, 2022 and 35.1%, 21.7%, and 22.5% during the six months ended June 30, 2022.

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

	Discounts and Chargebacks	Rebates	Other Fees, Copay and Returns	Total
Balance as of December 31, 2021	$ —	$ —	$ —	$ —
Activity related to 2022 sales	84	329	322	735
Credits/deductions issued	(41)	(15)	(133)	(189)
Balance as of June 30, 2022	$ 43	$ 314	$ 189	$ 546

There were no product sales or gross-to-net accruals during the three and six months ended June 30, 2021.

NOTE 6. COLLABORATION AND LICENSING AGREEMENTS

Kyowa Kirin Co., Ltd. ("KKC")

2019 KKC Agreement

In November 2019, we entered into a research collaboration and option agreement with KKC (the "2019 KKC Agreement") for research associated with identifying two preclinical compounds that are ready for designation as development compounds ("DCs"), with one compound inhibiting the first undisclosed target ("Program 1"), and a second inhibiting the second undisclosed target ("Program 2"). Pursuant to the 2019 KKC Agreement, upon completion of the research and designation by the research steering committee of one or more DCs, KKC has the right to execute one or more separate collaborative agreements relating to the development and commercialization of one or both DCs in certain specified territories.

Under the terms of the 2019 KKC Agreement, KKC paid us a non-refundable, non-creditable upfront fee of $10.0 million in two installments as follows: the first installment of $5.0 million within 30 days of November 11, 2019 (the “Effective Date”), and the second installment of $5.0 million on the first anniversary of the Effective Date. The original term of the 2019 KKC Agreement commenced on the Effective Date and was to end on the earliest of: (i) 2 years following the Effective Date, (ii) the nomination of a program DC for both programs, (iii) the nomination of one program DC and the decision by the parties to cease research for the other program, or (iv) the decision by the parties to cease research for both programs. We entered into three amendments to the 2019 KKC Agreement, which have resulted in the extension of the original term. Under the third amendment to the 2019 KKC Agreement entered into on June 28, 2022, the current term will end on February 28, 2023.

We have no material future obligations under the 2019 KKC Agreement and recorded no revenue under the 2019 KKC Agreement during the three and six months ended June 30, 2022. During the three and six months ended June 30, 2021, we recognized $1.3 million and $2.8 million, respectively, as collaborative development revenue under the 2019 KKC Agreement in the accompanying condensed statement of operations and comprehensive loss.

2017 KKC Agreement

In November 2017, we entered into an exclusive license agreement with KKC (the “2017 KKC Agreement”), for the development, commercialization, and distribution of tenapanor in Japan for cardiorenal indications. We granted KKC an exclusive license to develop and commercialize certain NHE3 inhibitors including tenapanor in Japan for the treatment of cardiorenal diseases and conditions, excluding cancer. We retained the rights to tenapanor outside of Japan, and also retained the rights to tenapanor in Japan for indications other than those stated above. Pursuant to the 2017 KKC Agreement, KKC is responsible for all costs and expenses incurred in the development and commercialization of tenapanor for all licensed indications in Japan. We are responsible for supplying the tenapanor drug substance for KKC’s use in development and commercialization throughout the term of the 2017 KKC Agreement, provided that KKC may exercise an option to manufacture the tenapanor drug substance under certain conditions.

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

Under the terms of the 2017 KKC Agreement, KKC paid us an up-front license fee of $30.0 million. We may be entitled to receive up to $55.0 million in total development and regulatory milestones, of which $10.0 million has been received and recognized as revenue as of June 30, 2022. We may also be eligible to receive approximately ¥8.5 billion for commercialization milestones, or approximately $62.3 million at the currency exchange rate on June 30, 2022, as well as reimbursement of costs plus a reasonable overhead for the supply of product and royalties on net sales throughout the term of the agreement. As discussed in *Note 7. Deferred Royalty Obligation*, the future royalties and commercial milestone payments we may receive under the 2017 KKC Agreement will be remitted to HealthCare Royalty Partners IV, L.P. pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement. The variable consideration related to the remaining milestone payments has not been included in the transaction price as these were fully constrained at June 30, 2022.

On April 11, 2022, we entered into a second amendment (the "Amendment") to the 2017 KKC Agreement. Under the terms of the Amendment, we and KKC have agreed to a reduction in the royalty rate payable to us by KKC upon net sales of tenapanor in Japan. The royalty rate will be reduced from the high teens to low double digits for a two-year period of time following the first commercial sale in Japan, and then to mid-single digits for the remainder of the royalty term. As discussed in *Note 7. Deferred Royalty Obligation*, the future commercial milestones and royalties we may receive under the 2017 KKC Agreement will be remitted to HealthCare Royalty Partners IV, L.P. pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement. As consideration for the reduction in the royalty rate, KKC has agreed to pay us up to an additional $40.0 million payable in two tranches, with the first payment due following KKC's filing with the Japanese Ministry of Health, Labour and Welfare of its application for marketing approval for tenapanor and the second payment due following KKC’s receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan. The variable consideration related to the reduction in the royalty rate has not been included in the transaction price as these were fully constrained at June 30, 2022.

During the three and six months ended June 30, 2022 we recognized no licensing revenue upon the achievement of development milestones. During the three and six months ended June 30, 2021, we recognized zero and $5.0 million respectively, as licensing revenue upon the initiation of phase 3 clinical studies by KKC in Japan to evaluate tenapanor for hyperphosphatemia. During the three and six months ended June 30, 2022, we recognized $952 thousand and $966 thousand, respectively, as product supply revenue related to the manufacturing supply of tenapanor and other materials to KKC pursuant to the 2017 KKC Agreement. During the three and six months ended June 30, 2021, we recognized zero and $126 thousand, respectively, as product supply revenue pursuant to the 2017 KKC Agreement.

As detailed below under the heading *Deferred revenue - non-current*, we have received prepayments from KKC for the manufacturing of tenapanor drug substance that will be used to satisfy KKC needs.

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

In December 2017, we entered into an exclusive license agreement with Fosun Pharma (the "Fosun Agreement"), for the development, commercialization and distribution of tenapanor in China for both hyperphosphatemia and IBS-C. Under the terms of the Fosun Agreement, Fosun paid us a $12.0 million upfront license fee. We may be entitled to receive development and commercialization milestones of up to $113.0 million, of which $3.0 million has been received and recognized as revenue as of June 30, 2022, as well as reimbursement of cost plus a reasonable overhead for the supply of product and tiered royalties on net sales ranging from the mid-teens to 20%. The variable consideration related to the remaining development milestone payments has not been included in the transaction price as these were fully constrained at June 30, 2022.

We have recorded no revenue during the three and six months ended June 30, 2022 or 2021 related to the Fosun Agreement.

Knight Therapeutics, Inc. ("Knight")

In March 2018, we entered into an exclusive license agreement with Knight (the "Knight Agreement") for the development, commercialization and distribution of tenapanor in Canada for hyperphosphatemia and IBS-C. Under the terms of the Knight Agreement, Knight paid us a $2.3 million upfront payment. We may also be eligible to receive approximately CAD22.2 million for development and commercialization milestones, or approximately $17.2 million at the currency exchange rate on June 30, 2022, of which $0.7 million has been received and recognized as revenue as of June 30, 2022. We are also eligible to receive royalties throughout the term of the agreement, and a transfer price for manufacturing services. The variable consideration related to the remaining development milestone payments has not been included in the transaction price as they were fully constrained at June 30, 2022.

AstraZeneca AB ("AstraZeneca")

In June 2015, we entered into a termination agreement with AstraZeneca (the "AstraZeneca Termination Agreement") pursuant to which we have agreed to pay AstraZeneca (i) future royalties at a royalty rate of 10% of net sales of tenapanor or other NHE3 products by us or our licensees, and (ii) 20% of non-royalty revenue received from a licensee of tenapanor or another NHE3 inhibitor, up to a maximum of $75.0 million in aggregate for (i) and (ii). As of June 30, 2022, to date in aggregate, we have recognized $11.9 million of the $75.0 million, which has been recorded as cost of revenue, and have paid AstraZeneca $11.6 million. During the three and six months ended June 30, 2022 we recognized and recorded as cost of revenue $0.2 million and $0.3 million, respectively, related to the AstraZeneca Termination Agreement. During the three and six months ended June 30, 2021 we recognized zero and $1.0 million, respectively, as cost of revenue related to the AstraZeneca Termination Agreement.

Deferred Revenue

The following tables present changes in our current and non-current deferred revenue balances during the reporting period. The June 30, 2022 and 2021 current deferred revenue balance is attributable entirely to the 2019 KKC Agreement and the non-current deferred revenue balances are attributable entirely to the 2017 KKC Agreement (in thousands):

Deferred revenue - current	**2022**	**2021**
Balance at January 1,	$ —	$ 4,177
Decreases due to revenue recognized in the period for which cash has been received	—	(2,765)
Balance at June 30,	$ —	$ 1,412

Deferred revenue - non-current	**2022**	**2021**
Balance at January 1,	$ 4,727	$ —
Increases due to cash received during the period	3,829	2,947
Increases to amounts invoiced, for which cash has not yet been received	3,865	—
Balance at June 30,	$ 12,421	$ 2,947

NOTE 7. DEFERRED ROYALTY OBLIGATION

On June 28, 2022, we and HealthCare Royalty Partners IV, L.P. (“HCR”) entered into a Royalty and Sales Milestone Interest Acquisition Agreement (the “HCR Agreement”). Under the terms of the HCR Agreement, HCR has agreed to pay us up to $20.0 million in exchange for the royalty payments and commercial milestone payments (collectively the “Royalty Interest Payments”) that we may receive under our 2017 License Agreement with KKC based upon KKC's net sales of tenapanor in Japan. As consideration for the sale of the Royalty Interest Payments, HCR paid to us a $10.0 million upfront payment, and we are eligible to receive a $5.0 million payment following KKC's receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan, and another $5.0 million payment in the event net sales by KKC in Japan exceed a certain annual target level by the end of 2025.

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

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

We received the $10.0 million upfront payment from HCR during June 2022 and recorded it as a deferred royalty obligation on our condensed balance sheet. As part of the sale, we incurred approximately $0.4 million in transaction costs, which, along with the deferred royalty obligation, will be amortized to non-cash interest expense over the estimated life of the HCR Agreement using the effective interest method. As future royalties are remitted to us by KKC, and subsequently from us to HCR, the balance of the deferred royalty obligation will be effectively repaid over the life of the HCR Agreement. To determine the amortization of the deferred royalty obligation, we are required to estimate the total amount of future royalty payments to be received from KKC for sales of tenapanor in Japan. There are a number of factors that could materially affect the amount and timing of royalty payments from KKC, most of which are not within our control. We will periodically assess the estimated royalty payments from KKC and, to the extent that the amount or timing of such payments is materially different than our original estimates, we will prospectively adjust the imputed interest rate and the related amortization of the deferred royalty obligation. As of June 30, 2022, our effective interest rate used to amortize the liability is 34.4%. During the three and six months ended June 30, 2022, we did not recognize a material amount of non-cash interest expense for the amortization of the deferred royalty obligation.

NOTE 8. BORROWING

Solar Capital and Western Alliance Bank Loan Agreement

On May 16, 2018, we entered into a loan and security agreement (as amended on October 9, 2020, March 1, 2021, May 5, 2021, and July 29, 2021) (the "2018 Loan Agreement") with Solar Capital Ltd. and Western Alliance Bank (collectively the “2018 Lenders”). The 2018 Loan Agreement provided for a $50.0 million loan facility with a maturity date of November 1, 2022 (the “2018 Loan”). As of the Closing Date for the 2022 Loan, as discussed below, we owed $25.0 million in principal payments from the 2018 Loan, which we repaid in full at that time.

As discussed in *Note 9. Derivative Liability*, in connection with entering into the 2018 Loan Agreement, we entered into an agreement pursuant to which we agreed to pay $1.5 million in cash upon the occurrence of certain conditions (the "2018 Exit Fee"). Our obligations for the 2018 Exit Fee remain outstanding following the full repayment of the 2018 Loan in February 2022.

SLR Investment Corp. Loan Agreement

On February 23, 2022 (the “Closing Date”), we entered into a loan and security agreement (the “2022 Loan Agreement”) with SLR Investment Corp. as collateral agent (the “Agent”), and the lenders listed in the 2022 Loan Agreement (collectively the “2022 Lenders”). The 2022 Loan Agreement provides for a senior secured loan facility, with $27.5 million (the “Term A Loan”) funded on the Closing Date and an additional $22.5 million that we may borrow on or prior to July 25, 2023; provided that (i) we have received approval by the FDA for our NDA for the control of serum phosphorus in chronic kidney disease patients on dialysis by December 31, 2022, and (ii) we have achieved certain product revenue milestone targets described in the 2022 Loan Agreement (the “Term B Loan”, and collectively, the Term A Loan and the Term B Loan, the “2022 Loan”). On August 1, 2022, we entered into an amendment to the 2022 Loan Agreement with SLR Investment Corp. that extends the date by which we must receive approval by the FDA for our NDA for the control of serum phosphorus in chronic kidney disease patients on dialysis in order to borrow the additional $22.5 million from December 31, 2022 to March 31, 2023. The 2022 Term A Loan funds were used to repay the 2018 Loan with the 2018 Lenders. The 2022 Loan has a maturity date of March 1, 2027.

Borrowings under the 2022 Loan bear interest at a floating per annum rate equal to 7.95% plus the greater of (i) one tenth percent (0.10%) and (ii) the one-month rate published by the Intercontinental Exchange Benchmark Administration Ltd or its successor. We are permitted to make interest-only payments on the 2022 Loan through March 31, 2024. Accordingly, beginning on April 1, 2024, we will be required to make monthly payments of interest plus repay the 2022 Loan in consecutive equal monthly installments of principal over 36 months. We were obligated to pay $0.2 million, upon the closing of the Term A Loan, and we are obligated to pay $0.1 million on the earliest of (i) the funding date of the Term B Loan, (ii) July 25, 2023, and (iii) the prepayment, refinancing, substitution, or replacement of the Term A Loan on or prior to July 25, 2023. We are obligated to pay a final fee equal to 4.95% of the aggregate original principal amount of the 2022 Loan funded upon the earliest to occur of the maturity date, the acceleration of the 2022 Loan, and the prepayment, refinancing, substitution, or replacement of the 2022 Loan. We may voluntarily prepay the outstanding 2022 Loan balance, subject to a prepayment premium of (i) 3% of the outstanding principal amount of the 2022 Loan if prepaid prior to or on the first anniversary of the Closing Date, (ii) 2% of the outstanding principal amount of the 2022 Loan if prepaid after the first anniversary of the Closing Date through and including the second anniversary of the Closing Date, or (iii) 1% of the outstanding principal amount of the 2022 Loan if prepaid after the second anniversary of the Closing Date and prior to the maturity date. The 2022 Loan is secured by substantially all of our assets, except for our intellectual property and certain other customary exclusions. Additionally, in connection with the 2022 Loan, we entered into an agreement, whereby we agreed to pay an exit fee in the amount of 2% of the 2022 Loan funded (the "2022 Exit Fee") upon (i) any change of control transaction or (ii) our achievement of net revenue from the sale of any products equal to or greater than $100.0 million, measured on a six (6) months basis, tested monthly at the end of each month. Notwithstanding the prepayment or termination of the 2022 Loan, the 2022 Exit Fee will expire 10 years from the Closing Date.

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

In addition, the 2022 Loan Agreement contains customary events of default that entitle the Agent to cause our indebtedness under the 2022 Loan Agreement to become immediately due and payable, and to exercise remedies against us and the collateral securing the 2022 Term Loan, including our cash. Under the 2022 Loan Agreement, an event of default will occur if, among other things, we fail to make payments under the 2022 Loan Agreement, we breach any of our covenants under the 2022 Loan Agreement, subject to specified cure periods with respect to certain breaches, certain Lenders determine that a material adverse change has occurred, we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings, we are unable to pay our debts as they become due or we default on contracts with third parties which would permit the holder of indebtedness to accelerate the maturity of such indebtedness or that could have a material adverse change on us. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal to 4% per annum will apply to all obligations owed under the 2022 Loan Agreement. We have classified the 2022 Loan balance as a current liability as of June 30, 2022 due to the determination of the existence of substantial doubt about our ability to continue operating as a going concern discussed in *Note 1. Organization and Basis of Presentation: Liquidity* and our assessment that the material adverse change clause under the 2022 Loan Agreement is not within our control. The lenders have not invoked the material adverse change clause as of the date of issuance of these financial statements.

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

Total repayment obligations	$	28,862
Less: Unamortized discount		(1,259)
Less: Unaccreted value of final fee		(1,230)
Long-term debt		26,373
Less: Current portion of long-term debt		(26,373)
Long-term debt, net of current portion	$	—

NOTE 9. DERIVATIVE LIABILITY

2018 Exit Fee

In May 2018, in connection with entering into the 2018 Loan Agreement, we entered into an agreement pursuant to which we agreed to pay $1.5 million in cash (the “2018 Exit Fee”) upon any change of control transaction in respect of the Company or if we obtain both (i) FDA approval of tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis and (ii) FDA approval of tenapanor for the treatment of patients with IBS-C, which was obtained on September 12, 2019 when the FDA approved IBSRELA® (tenapanor), a 50 milligram, twice daily oral pill for the treatment of IBS-C in adults (the “2018 Exit Fee Agreement”). Notwithstanding the February 2022 prepayment of the 2018 Loan our obligation to pay the 2018 Exit Fee will expire on May 16, 2028. We concluded that the 2018 Exit Fee is a freestanding derivative which should be accounted for at fair value on a recurring basis. The estimated fair value of the 2018 Exit Fee is recorded as a derivative liability and included in accrued expenses and other current liabilities on the accompanying condensed balance sheets. As of both June 30, 2022 and December 31, 2021, the estimated fair value of the 2018 Exit Fee was $0.7 million.

The fair value of the derivative liability was determined using a discounted cash flow analysis and is classified as a Level 3 measurement within the fair value hierarchy since our valuation utilized significant unobservable inputs. Specifically, the key assumptions included in the calculation of the estimated fair value of the 2018 derivative liability include: (i) our estimates of both the probability and timing of a potential $1.5 million payment to the 2018 Lenders as a result of the FDA approvals and (ii) a discount rate which was derived from our estimated cost of debt, adjusted with current LIBOR (or a comparable successor rate if LIBOR no longer exists). Generally, increases or decreases in the probability of occurrence would result in a directionally similar impact in the fair value measurement of the derivative liability and it is estimated that a 10.0% increase (decrease), not to exceed 100%, in the probability of occurrence would result in a fair value fluctuation of no more than $0.1 million.

2022 Exit Fee

On February 23, 2022, in connection with entering into the 2022 Loan Agreement, we entered into an agreement, whereby we agreed to pay an exit fee in the amount of 2% of the 2022 Loan funded (the “2022 Exit Fee”) upon (i) any change of control transaction or (ii) our achievement of net revenue from the sale of any products equal to or greater than $100.0 million, measured on a six (6) months basis (the "Revenue Milestone"), tested monthly at the end of each month. Notwithstanding the prepayment or termination of the 2022 Loan, the 2022 Exit Fee will expire on February 23, 2032. We concluded that the 2022 Exit Fee is a freestanding derivative which should be accounted for at fair value on a recurring basis. The estimated fair value of the 2022 Exit Fee is recorded as a derivative liability and included in accrued expenses and other current liabilities on the accompanying condensed balance sheets. As of June 30, 2022, the estimated fair value of the 2022 Exit Fee is $0.4 million.

The fair value of the derivative liability was determined using a discounted cash flow analysis and is classified as a Level 3 measurement within the fair value hierarchy since our valuation utilized significant unobservable inputs. Specifically, the key assumptions included in the calculation of the estimated fair value of the 2022 derivative liability include: (i) our estimates of both the probability and timing of achieving the Revenue Milestone and (ii) the probability and timing of funding the Term B Loan, which is dependent upon (a) approval by the FDA for our NDA for the control of serum phosphorus in chronic kidney disease patients on dialysis by December 31, 2022, and (b) achievement of certain product revenue milestone targets. Generally, increases or decreases in the probability of occurrence would result in a directionally similar impact in the fair value measurement of the derivative liability and it is estimated that a 10.0% increase (decrease) in the probability of occurrence would not result in a material fair value fluctuation.

Changes in the fair value of our exit fee derivative liabilities recurring measurements included in Level 3 of the fair value hierarchy are presented as other income, net in our statements of operations and were as follows for the three and six months ended June 30, 2022 and 2021 (in thousands):

	2022	2021
Balance at January 1,	$ 698	$ 1,376
2022 Exit Fee addition at fair value	375	—
Changes in estimated fair value:		
2018 Exit Fee	$ (29)	$ (713)
2022 Exit Fee	$ 47	$ —
Balance at June 30,	$ 1,091	$ 663

NOTE 10. LEASES

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

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

Facilities	**June 30, 2022**	**December 31, 2021**
Right-of-use assets	$ 11,054	$ 12,752
Current portion of lease liabilities	3,691	3,492
Operating lease liability, net of current portion	7,857	9,748
Total	$ 11,548	$ 13,240
Weighted-average remaining life (years)	2.9	3.4
Weighted-average discount rate	6.8 %	6.9 %

Lease costs, which are included in operating expenses in our statements of operations, were as follows (in thousands):

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2022	**2021**	**2022**	**2021**
Operating lease expense	$ 1,064	$ 837	$ 2,128	$ 1,510
Cash paid for operating lease	$ 1,064	$ 766	$ 2,122	$ 1,554

The following table summarizes our undiscounted cash payment obligations for our operating lease liabilities as of June 30, 2022 (in thousands):

Remainder of 2022	$ 2,170
2023	4,440
2024	4,589
2025	1,321
2026	252
Total undiscounted operating lease payments	12,772
Imputed interest expenses	(1,224)
Total operating lease liabilities	11,548
Less: Current portion of operating lease liability	(3,691)
Operating lease liability, net of current portion	$ 7,857

NOTE 11. STOCKHOLDERS' EQUITY

At the Market Offerings Agreement

In July 2020, we filed a Form S-3 registration statement, which became effective in August 2020 ("Registration Statement"), containing (i) a base prospectus for the offering, issuance and sale by us of up to a maximum aggregate offering price of $250.0 million of our common stock, preferred stock, debt securities, warrants and/or units, from time to time in one or more offerings; and (ii) a prospectus supplement for the offering, issuance and sale by us of up to a maximum aggregate offering price of $100.0 million of our common stock that may be issued and sold, from time to time, under a sales agreement with Jefferies LLC ("Jefferies"), deemed to be "at the market offerings" (the "2020 Open Market Sales Agreement"). The 2020 Open Market Sales Agreement was fully utilized as of December 31, 2021. During the six months ended June 30, 2021 we sold 9.0 million shares and received gross proceeds of $63.8 million at a weighted average sales price of approximately $7.10 per share under the 2020 Open Market Sales Agreement.

In August 2021, we filed an additional prospectus supplement under the Registration Statement for the offering, issuance and sale by us of up to a maximum aggregate offering price of $150.0 million of our common stock that may be issued and sold, from time to time, under an additional sales agreement we entered into with Jefferies (the "2021 Open Market Sales Agreement"), pursuant to which we may, from time to time, sell up to $150.0 million in shares of our common stock through Jefferies. We are not required to sell shares under the 2021 Open Market Sales Agreement. Pursuant to the 2021 Open Market Sales Agreement, Jefferies, as our sales agent, receives a commission of up to 3% of the gross sales price for shares of common stock sold under the 2021 Open Market Sales Agreement. During the six months ended June 30, 2022 we sold 20.5 million shares and received gross proceeds of $18.9 million at a weighted average sales price of approximately $0.92 per share under the 2021 Open Market Sales Agreement.

NOTE 12. EQUITY INCENTIVE PLANS

Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Selling, general and administrative	$ 2,220	$ 2,132	$ 4,728	$ 4,127
Research and development	973	1,087	2,096	2,179
Total	$ 3,193	$ 3,219	$ 6,824	$ 6,306

As of June 30, 2022, the balance of inventory included in our condensed balance sheet includes $0.2 million stock-based compensation. During the three and six months ending June 30, 2022, the amount of stock-based compensation released from inventory into cost of revenue was not material.

As of June 30, 2022, our total unrecognized stock-based compensation expense, net of estimated forfeitures, and average remaining vesting period, included the following (dollars in thousands):

	Unrecognized Compensation Expense	Average Remaining Vesting Period (Years)
Stock option grants	$ 13,096	2.7
RSU grants	$ 3,524	2.9
ESPP	$ 21	0.2

Stock Options

A summary of our stock option activity and related information for the six months ended June 30, 2022 is as follows (in thousands, except dollar amounts):

	Number of Shares		Weighted-Average Exercise Price per Share
Balance at December 31, 2021	10,417	$	7.00
Options granted	4,773	$	0.88
Options exercised	—	$	—
Options forfeited or canceled	(1,190)	$	7.04
Balance at June 30, 2022	14,000	$	4.91
Exercisable at June 30, 2022	7,085	$	6.91

Restricted Stock Units

A summary of our RSUs activity and related information for the six months ended June 30, 2022 is as follows (in thousands, except dollar amounts):

	Number of RSUs		Weighted-Average Grant Date Fair Value Per Share
Non-vested restricted stock units at December 31, 2021	3,529	$	2.04
Granted	1,980	$	0.81
Vested	(3,714)	$	1.26
Forfeited	(121)	$	2.85
Non-vested restricted stock units at June 30, 2022	1,674	$	2.26

Employee Stock Purchase Plan

In February 2022, we sold approximately 0.1 million shares of our common stock under the ESPP. The shares were purchased by employees at a purchase price of $0.65 per share resulting in proceeds to us of approximately $0.1 million.

Issuance of Common Stock for Services

Under Our Amended and Restated Non-Employee Director Compensation Program, members of our board of directors may elect to receive shares of our stock in lieu of their cash fees. During the six months ended June 30, 2022, we issued no shares of our common stock to members of the board of directors in accordance with the program.

NOTE 13. NET LOSS PER SHARE

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, less shares subject to repurchase, and excludes any dilutive effects of stock-based awards and warrants. Diluted net loss per common share is computed giving effect to all potential dilutive common shares, including common stock issuable upon exercise of stock options, and unvested restricted common stock and stock units. As we had net losses for the six months ended June 30, 2022 and 2021, all potential common shares were determined to be anti-dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
Numerator:	**2022**	**2021**	**2022**	**2021**
Net loss	$ (26,938)	$ (45,189)	$ (55,009)	$ (78,344)
Denominator:				
Weighted average common shares outstanding - basic and diluted	145,544	100,040	138,280	98,618
Net loss per share - basic and diluted	$ (0.19)	$ (0.45)	$ (0.40)	$ (0.79)

For the periods presented, all common stock equivalents are excluded from the computation of diluted loss per share, as the result would be anti-dilutive, including the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Options to purchase common stock	$ 13,099	$ 12,447	$ 13,182	$ 12,211
Restricted stock units	3,520	1,125	3,963	1,006
ESPP shares issuable	200	230	176	188
Total	$ 16,819	$ 13,802	$ 17,321	$ 13,406

NOTE 14. CONTINGENCIES

From time to time we may be involved in claims arising in connection with our business. Based on information currently available, management believes that the amount, or range, of reasonably possible losses in connection with any pending actions against us will not be material to our financial condition or cash flows, and no contingent liabilities were accrued as of June 30, 2022 or 2021.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the condensed financial statements and notes thereto included elsewhere in this report and with the audited financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2021. This discussion and analysis and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk Factors." These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason. Unless the context requires otherwise, the terms "Ardelyx", "Company", "we", "us", and "our" refer to Ardelyx, Inc.

Overview

We are a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative first-in-class medicines that meet significant unmet medical needs.

Since commencing operations in October 2007, substantially all our efforts have been dedicated to our research and development ("R&D") activities, including developing tenapanor and developing our proprietary drug discovery and design platform. We realized our first product sales of IBSRELA® (tenapanor) in March 2022. As of June 30, 2022, we had an accumulated deficit of $767.9 million.

We expect to continue to incur substantial operating losses for the foreseeable future as we commercialize IBSRELA, seek to gain approval for XPHOZAH® (tenapanor) for the control of serum phosphorus in adult patients with CKD on dialysis; prepare for the potential commercialization of XPHOZAH, if approved; and incur manufacturing and development cost for, tenapanor. To date, we have funded our operations from the sale and issuance of common stock and convertible preferred stock, funds from our collaboration partnerships, which includes license fees, milestones and product supply revenue, as well as funds from our loan agreements with our lenders.

Our Commercial Product

IBSRELA for IBS-C

Our unique discovery platform and deep understanding of the primary mechanism of sodium transport in the intestine resulted in our discovery and development of IBSRELA, a first-in-class, U.S. Food and Drug Administration (“FDA”) approved, sodium hydrogen exchanger 3 ("NHE3") inhibitor for the treatment of irritable bowel syndrome with constipation (“IBS-C”) in adults. IBSRELA acts locally in the gut and is minimally absorbed. IBS-C is a gastrointestinal disorder characterized by both abdominal pain and altered bowel movements, estimated to affect 11 million people in the U.S. IBS-C is associated with significantly impaired quality of life, reduced productivity, and substantial economic burden.

For our commercial launch of IBSRELA, we built a commercial organization highly experienced in launching novel therapies into specialty areas. We recognized our first sales of IBSRELA in the U.S. in March 2022. The established nature of the market, limited number of players, concentration of prescribers, recognized unmet need, and favorable response to the novel mechanism IBSRELA product profile enable a targeted promotional effort centered on the 9,000 health care providers that account for 50% of IBS-C prescriptions. Central to the go to market strategy for IBSRELA is a highly experienced specialty sales force, many with existing relationships across their GI target base, full company engagement, and innovative peer-to-peer and digital initiatives leveraging the rapidly evolving market dynamics in how HCPs receive information and interact with industry.

Our Product Pipeline

Development Candidate XPHOZAH for The Control of Serum Phosphorus in Adult Patients with CKD on Dialysis

XPHOZAH is a first-in-class medicine being developed for the control of serum phosphorus in adult patients with CKD on dialysis. XPHOZAH has a unique mechanism of action and acts locally in the gut to inhibit NHE3. This results in the tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption. If approved, XPHOZAH would be the first therapy for phosphate management that blocks phosphorus absorption at the primary site of uptake. It is not a phosphate binder.

In June 2020, we submitted a new drug application ("NDA") to the FDA for XPHOZAH for the control of serum phosphorus in adult patients with CKD on dialysis. The NDA was supported by three Phase 3 trials involving over 1,000 adult patients that evaluated the use of tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis, with two trials evaluating tenapanor as monotherapy and one trial evaluating tenapanor as part of a dual mechanism approach with phosphate binders. All three Phase 3 trials met their primary and key secondary endpoints.

On July 28, 2021, we received a Complete Response Letter ("CRL") from the FDA regarding our NDA for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis. According to the CRL, while the FDA agrees “that the submitted data provide substantial evidence that tenapanor is effective in reducing serum phosphorus in adult patients with CKD on dialysis,” the FDA characterizes the magnitude of the treatment effect as “small and of unclear clinical significance.” In December 2021, we submitted a Formal Dispute Resolution Request (“FDRR”). The FDRR was focused on demonstrating that the data submitted in the NDA supported the clinical significance of the treatment effect of tenapanor.

On February 4, 2022, we received an Appeal Denied Letter (“ADL”) from the FDA’s Office of Cardiology, Hematology, Endocrinology and Nephrology (“OCHEN”). On February 18, 2022, we submitted an appeal of the ADL to the FDA’s Center for Drug Evaluation and Research, Office of New Drugs (“OND”).

On April 25, 2022, we announced that OND had provided an interim response to our second level of appeal of the CRL. The OND noted that additional input from the Cardiovascular and Renal Drug Advisory Committee ("Advisory Committee") in general, and specifically, from experts, including expert clinicians, would be valuable in further considering the clinical meaningfulness of the phosphate lowering effect observed in our phase 3 clinical program for XPHOZAH. Accordingly, the OND directed the Division of Cardiology and Nephrology to convene the Advisory Committee, and indicated that a response to our appeal could be expected within thirty calendar days after the conclusion of the Advisory Committee meeting. On June 21, 2022 we announced that the FDA has informed us that a meeting of the Advisory Committee is tentatively scheduled for November 16, 2022. There can be no assurances that the response from the Advisory Committee will be positive, or if the outcome of the Advisory Committee is positive, that approval of our NDA will ultimately be granted by the FDA.

RDX013 Program: Small Molecule for Treating Hyperkalemia

Our small molecule potassium secretagogue program, RDX013, is focused on the development of a potential treatment for hyperkalemia. Hyperkalemia is a common problem in patients with heart and kidney disease, particularly in patients taking customary blood pressure medications known as renin-angiotensin-aldosterone system ("RAAS") inhibitors. RDX013 is a novel mechanism agent designed to target the underlying biological mechanisms of potassium secretion to lower elevated potassium.

On April 25, 2022, we reported that we have completed our data analyses of the Phase 2 dose ranging clinical trial for RDX013 evaluating the safety and efficacy of our potassium secretagogue for the treatment of hyperkalemia, or elevated potassium, in chronic kidney disease patients who are not on dialysis. While the results of the study demonstrated an acceptable safety and tolerability profile for RDX013 and supported proof of concept in its ability to lower serum potassium levels, with statistically significant reductions compared to placebo after eight days of treatment, the study did not meet its primary endpoint of significantly reducing serum potassium levels compared to placebo after four weeks of treatment. We currently expect that the next steps for the program will be to evaluate a new formulation that potentially enhances subject compliance and the efficacy of RDX013 in an additional Phase 2 clinical study at such time as we have determined our available resources support conducting such an additional clinical study after prioritization of the commercialization of IBSRELA and preparations for the Advisory Committee meeting for XPHOZAH.

RDX020 Program: Small molecule for Treating Metabolic Acidosis

We have an ongoing discovery program targeting the inhibition of bicarbonate exchange for the treatment of metabolic acidosis, a highly prevalent comorbidity in CKD patients that is strongly correlated with disease progression and adverse outcomes. We have identified lead compounds that are potent, selective and proprietary inhibitors of bicarbonate secretion. Our research organization was eliminated as part of our October 2021 restructuring, and therefore, we currently expect to continue to advance this discovery program utilizing third-party resources managed by internal non-clinical expertise.

Collaboration Partners

We have exclusive rights to tenapanor in the U.S. and we have established agreements with Kyowa Kirin Co., Ltd. ("KKC") in Japan, Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ("Fosun Pharma") in China and Knight Therapeutics, Inc. ("Knight") in Canada for the development and commercialization of tenapanor for certain indications in their respective territories.

Knight has exclusive rights for the development, commercialization and distribution of tenapanor in Canada for hyperphosphatemia and IBS-C. In March 2021, Knight announced the commercial availability of IBSRELA in Canada, following its approval by Health Canada in April 2020. Under the terms of the Knight Agreement, Knight paid us a $2.3 million upfront payment. We may also be eligible to receive approximately CAD22.2 million for development and commercialization milestones, or approximately $17.2 million at the currency exchange rate on June 30, 2022, of which $0.7 million has been received and recognized as revenue as of June 30, 2022. We are also eligible to receive royalties throughout the term of the agreement, and a transfer price for manufacturing services. The variable consideration related to the remaining development milestone payments has not been included in the transaction price as they were fully constrained at June 30, 2022.

KKC has exclusive rights for the development, commercialization and distribution of tenapanor in Japan for cardiorenal indications. Under the terms of the agreement with KKC, we received a $30.0 million upfront payment from KKC, and we may be entitled to receive up to $55.0 million in total development and regulatory milestones, of which $10.0 million has been received and recognized as revenue as of June 30, 2022. We may also be eligible to receive approximately ¥8.5 billion for commercialization milestones, or approximately $62.3 million at the currency exchange rate on June 30, 2022, as well as reimbursement of costs plus a reasonable overhead for the supply of product and royalties on net sales throughout the term of the agreement. As discussed in *Note 7. Deferred Royalty Obligation*, the future royalties and commercial milestone payments we may receive under the 2017 KKC Agreement will be remitted to HealthCare Royalty Partners IV, L.P. pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement.

On April 11, 2022, we entered into a second amendment (the "Amendment") to the 2017 KKC Agreement. Under the terms of the Amendment, we and KKC have agreed to a reduction in the royalty rate payable to us by KKC upon net sales of tenapanor in Japan. The royalty rate will be reduced from the high teens to low double digits for a two-year period of time following the first commercial sale in Japan, and then to mid-single digits for the remainder of the royalty term. As discussed in *Note 7. Deferred Royalty Obligation*, the future royalties we may receive under the 2017 KKC Agreement will be remitted to HealthCare Royalty Partners IV, L.P. pursuant to a Royalty and Sales Milestone Interest Acquisition Agreement. As consideration for the reduction in the royalty rate, KKC has agreed to pay us up to an additional $40.0 million payable in two tranches, with the first payment due following KKC's filing with the Japanese Ministry of Health, Labour and Welfare of its application for marketing approval for tenapanor and the second payment due following KKC’s receipt of regulatory approval to market tenapanor for hyperphosphatemia in Japan.

Fosun Pharma has exclusive rights for the development and commercialization of tenapanor in China for both hyperphosphatemia and IBS-C. Under the terms of the Fosun Agreement, Fosun paid us a $12.0 million upfront license fee. We may be entitled to receive development and commercialization milestones of up to $113.0 million, of which $3.0 million has been received and recognized as revenue as of June 30, 2022, as well as reimbursement of cost plus a reasonable overhead for the supply of product and tiered royalties on net sales ranging from the mid-teens to 20%.

Impact of COVID-19

The global COVID-19 pandemic has impacted the operational decisions of companies worldwide. It also has created and may continue to create significant uncertainty in the global economy. We have undertaken measures to protect our employees, partners, collaborators, and vendors, some of which impact our normal operations. To date, we have been able to continue our operations with our workforce, most of whom are working remotely, and our pre-existing infrastructure that supports secure access to our internal systems. If, however, the COVID-19 pandemic has a substantial impact on the productivity of our employees, the results of our operations and overall financial performance may be adversely impacted. The extent of the impact from the COVID-19 pandemic on our business will depend largely on future developments that are highly uncertain and cannot be predicted. For a discussion of risks of COVID-19 relating to our business, see “Part II: Other Information-Item 1A.- Risk Factors- Risks Related to Our Business- *The ongoing effects of the COVID-19 pandemic, or any other outbreak of epidemic diseases, or the perception of their effects, could have a material adverse effect on our business, financial condition, results of operations or cash flows.*” As of the date of issuance of this financial report, we are not aware of any specific event or circumstance that would require updates to our estimates and judgments or revisions to the carrying value of our assets or liabilities. These estimates may change as new events occur and additional information is obtained.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

The critical accounting policies that we believe impact significant judgments and estimates used in the preparation of our condensed financial statements presented in this report are described in Part II, Item 7, *Management’s Discussion and Analysis of Financial Condition and Results of Operations*, in our Annual Report on Form 10-K filed with the SEC on February 28, 2022.

During the six months ended June 30, 2022, we adopted the following critical accounting policies and significant judgements and estimates:

Product Sales, Net

We account for our commercial product sales, net in accordance with Topic 606 - *Revenue from Contracts with Customers*. We received approval from the FDA in September 2019 to market IBSRELA, the first and only NHE3 inhibitor for the treatment of IBS-C in adults, in the United States (the "U.S."). We began selling IBSRELA in the U.S. in March 2022. We distribute our products principally through a limited number of distributors and specialty pharmacy providers (collectively, our "Customers"). Our Customers subsequently sell our products to pharmacies and patients. Separately, we enter into arrangements with third parties that provide for government-mandated and privately-negotiated rebates, chargebacks and discounts. Revenue from product sales is recognized when our performance obligations are satisfied, which is when Customers obtain control of our product and occurs upon delivery.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration, including rebates, discounts, patient copay assistance programs, and estimated product returns. These estimates are based on the amounts earned or to be claimed for related sales and are classified as reductions of gross accounts receivable if the amount is payable to our Customers or a current liability if the amount is payable to a party other than a Customer. Where appropriate, these estimates are based on factors such as industry data and forecasted customer buying and payment patterns, our historical experience, current contractual and statutory requirements, specific known market events and trends. Overall, these reductions to gross sales reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we adjust these estimates, which would affect product revenue and earnings in the period such variances become known. As we gain more historical experience, estimates will be more heavily based on the expected utilization from historical data we have accumulated since the IBSRELA product launch. Rebates are generally invoiced and paid quarterly in arrears.

Rebates: Rebates include mandated discounts under the Medicaid Drug Rebate Program ("Medicaid") and the Medicare Coverage Gap Program ("Medicare"). Rebates are amounts owed after the final dispensing of products to a benefit plan participant and are based upon contractual agreements or legal requirements with the public-sector benefit providers. These estimates for rebates are recorded in the same period the related gross revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the condensed balance sheets. We estimate our Medicaid and Medicare rebates based upon the estimated payor mix, and statutory discount rates. Our estimates for payor mix are guided by payor information received from specialty pharmacies, expected utilization for wholesaler sales to pharmacies, and available industry payor information.

Chargebacks: Chargebacks are discounts that occur when certain contracted purchasers purchase directly from our wholesalers at a discounted price. The wholesaler, in turn, charges back the difference between the price initially paid to us by the wholesaler and the discounted price paid to the wholesaler by the contracted purchaser. Amounts for estimated chargebacks are established in the same period that the related gross revenue is recognized, resulting in a reduction of product revenue and accounts receivable. The accrual for wholesaler chargebacks is estimated based on known chargeback rates, known sales to wholesalers, and estimated utilization by types of contracted purchasers.

Discounts and Fees: Our payment terms are generally 30 to 60 days. Wholesalers and specialty pharmacies are offered various forms of consideration, including service fees. Wholesalers may also receive prompt pay discounts for payment within a specified period. We expect prompt pay discounts to be earned when offered and therefore, we deduct the full amount of these discounts and service fees from product sales when revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

Other Reserves: Patients who have commercial insurance may receive co-pay assistance when product is dispensed by pharmacies to patients. We estimate the amount of co-pay assistance provided to eligible patients based on the terms of the program and redemption information provided by third-party claims processing organizations and are recorded in accounts payable and accrued expenses and other current liabilities on the condensed balance sheets.

Non-cash Interest Expense on Deferred Royalty Obligation

The net proceeds we receive from the sale of certain future royalties are amortized to non-cash interest expense over the estimated life of the associated agreement using the effective interest method. As we earn royalties and remit those royalties pursuant to the agreement, the balance of the deferred royalty obligation will be effectively repaid over the life of agreement. To determine the amortization of our deferred royalty obligation, we are required to estimate the total amount of future royalty payments we expect to earn. There are a number of factors that could materially affect the amount and timing of royalty payments, most of which are not within our control. We periodically assess the amount of royalty payments we expect to receive which are subject to the agreement 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.

Recent Accounting Pronouncements

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

Financial Operations Overview

Revenue

Our revenue to date has been generated primarily through license, research and development collaborative agreements with various collaboration partners. We realized our first commercial product sales of IBSRELA in March 2022. In the future, we may generate revenue from a combination of our own product sales and payments in connection with our current or future collaborative partnerships, including license fees, other upfront payments, milestone payments, royalties and payments for drug product and/or drug substance. We expect that any revenue we generate will fluctuate in future periods as a result of, among other factors: whether and the extent to which we are successful in our commercialization of IBSRELA, whether we are able to gain approval from the FDA for our NDA for XPHOZAH; the timing and progress of goods and services provided pursuant to our current or future collaborative partnerships; our or our collaborators' achievement of clinical, regulatory or commercialization milestones, to the extent achieved; the timing and amount of any payments to us relating to the aforementioned milestones; and the extent to which tenapanor is approved and successfully commercialized by a collaboration partner. If our current collaboration partners or any future collaboration partners fail to obtain regulatory approval for tenapanor, our ability to generate future revenue from our collaborative arrangements, and our results of operations and financial position, would be materially and adversely affected. Our past revenue performance is not necessarily indicative of results to be expected in future periods.

Cost of Revenue

Cost of revenue consists of the cost of commercial goods sold to Customers, collaboration partners under product supply agreements, and royalty expense based on sales of tenapanor. We capitalize inventory costs associated with the production of our products after regulatory approval or when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Otherwise, such costs are expensed as research and development. A portion of the costs of IBSRELA units recognized as revenue during the three and six months ended June 30, 2022 were expensed prior to the fourth quarter of 2021, when our intent to commercialize IBSRELA was established and we commenced preparation for the commercial launch of IBSRELA. We believe our cost of goods sold for the three and six months ended June 30, 2022 would have been $140 thousand and $149 thousand higher, respectively, if we had not previously expensed certain material and production costs with respect to the units sold. As of June 30, 2022, we had approximately $31.2 million of inventory on hand that was previously expensed as research and development expense and will not be reported as cost of goods sold in future periods when sales of IBSRELA are recognized as revenue.

Cost of revenue includes payments due to AstraZeneca, which under the terms of a termination agreement entered into in 2015 (the "AZ Termination Agreement") is entitled to (i) future royalties at a rate of 10% of net sales of tenapanor or other NHE3 products by us or our licensees, and (ii) 20% of non-royalty revenue received from our collaboration partners in connection with the development and commercialization of tenapanor or certain other NHE3 inhibitors. We have agreed to pay AstraZeneca up to a maximum of $75.0 million in the aggregate for (i) and (ii). We recognize these expenses as cost of revenue when we recognize the corresponding revenue that gives rise to payments due to AstraZeneca. To date, we have recognized an aggregate of $11.9 million as cost of revenue under the AZ Termination Agreement.

Research and Development

Pursuant to the October 2021 restructuring plan, we eliminated our internal research organization and expect to continue our discovery efforts with respect to RDX020 through the use of third-parties managed internally by non-clinical expertise. We recognize all research and development expenses as they are incurred to support the discovery, research, development and manufacturing of our product candidates. Research and development expenses include, but are not limited to, the following:

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

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, for certain of our executives, our board members, and our finance, legal, business development, market development, commercial and support staff. Other selling, general and administrative expenses include facility related costs and professional fees for legal, accounting and audit, investor relations, other consulting services and allocated facility related costs not otherwise included in research and development expenses.

Interest Expense

Interest expense represents the interest paid on our loan payable.

Other Income, net

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

RESULTS OF OPERATIONS

The results of operations are not necessarily indicative of the results to be expected for the year ending December 31, 2022, for any other interim period, or for any other future year.

Comparison of the three and six months ended June 30, 2022 and 2021

Revenue

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

	Three Months Ended June 30,		Change 2022 vs. 2021		Six Months Ended June 30,		Change 2022 vs. 2021	
	2022	2021	$	%	2022	2021	$	%
Product sales, net	$ 1,564	$ —	$ 1,564	(a)	$ 2,014	$ —	$ 2,014	(a)
Product supply revenue	952	—	952	(a)	966	126	840	666.7 %
Licensing revenue	10	3	7	233.3 %	14	5,005	(4,991)	(99.7)%
Collaborative development revenue	—	1,310	(1,310)	(100.0)%	—	2,764	(2,764)	(100.0)%
Total revenues	$ 2,526	$ 1,313	$ 1,213	92.4 %	$ 2,994	$ 7,895	$ (4,901)	(62.1)%

(a) Percent change is not meaningful.

The increase to total revenues during the three months ended June 30, 2022 is primarily attributable to $1.6 million of net product sales for IBSRELA to our Customers in connection with the commercial launch of IBSRELA, as well as $1.0 million product supply revenue for which there was no comparable revenue during the three months ended June 30, 2021. Partially offsetting these increases was the full recognition of upfront payments associated with the 2019 KKC Agreement through the end of 2021.

The decrease to total revenues during the six months ended June 30, 2022 is primarily attributable to a $5.0 million development milestone that was earned during the prior year that did not recur during the current year, as well as the full recognition of upfront payments associated with the 2019 KKC Agreement through the end of 2021, for which there was no comparable revenue during the six months ended June 30, 2022. Partially offsetting these decreases is recognition of $2.0 million of net product sales for sales of IBSRELA to our Customers in connection with the commercial launch of IBSRELA.

Operating Expenses

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

	Three Months Ended June 30,		Change 2022 vs. 2021		Six Months Ended June 30,		Change 2022 vs. 2021	
	2022	2021	$	%	2022	2021	$	%
Cost of revenue	$ 138	$ —	$ 138	(a)	$ 223	$ 1,000	$ (777)	(77.7)%
Research and development	9,741	26,021	(16,280)	(62.6)%	18,592	46,477	(27,885)	(60.0)%
Selling, general and administrative	18,862	20,124	(1,262)	(6.3)%	38,201	37,255	946	2.5 %
Total operating expenses	$ 28,741	$ 46,145	$ (17,404)	(37.7)%	$ 57,016	$ 84,732	$ (27,716)	(32.7)%

(a) Percent change is not meaningful.

Cost of Revenue

The fluctuations in cost of revenue for the three and six months ended June 30, 2022 are primarily attributable to payments due to AstraZeneca under the AZ Termination Agreement related to the commercial sales of IBSRELA during the three and six months ended June 30, 2022 and a development milestone we earned during the six months ended June 30, 2021. In addition, during the three and six months ended June 30, 2022, we incurred cost of revenue from sales of IBSRELA to our Customers in connection with the commercial launch of IBSRELA.

Research and Development

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

	Three Months Ended June 30,		Change 2022 vs. 2021		Six Months Ended June 30,		Change 2022 vs. 2021	
	2022	2021	$	%	2022	2021	$	%
External R&D expenses	$ 4,607	$ 17,499	$ (12,892)	(73.7)%	$ 7,547	$ 29,007	$ (21,460)	(74.0)%
Employee-related expenses	3,575	6,512	(2,937)	(45.1)%	7,752	13,732	(5,980)	(43.5)%
Facilities, equipment and depreciation expenses	716	1,439	(723)	(50.2)%	1,830	2,723	(893)	(32.8)%
Other	843	571	272	47.6 %	1,463	1,015	448	44.1 %
Total research and development expenses	$ 9,741	$ 26,021	$ (16,280)	(62.6)%	$ 18,592	$ 46,477	$ (27,885)	(60.0)%

The decrease in our external R&D expenses for the three months ended June 30, 2022 is primarily the result of lower clinical study costs from the OPTIMIZE study, lower tenapanor manufacturing expense as we have begun to capitalize costs associated with the production of IBSRELA to inventory, and lower expenses for research following the elimination of our research function in the fourth quarter of 2021. The decrease in our employee-related expenses for the three and six months ended June 30, 2022 is due to lower compensation and benefits expenses for our research and development workforce following restructuring actions in 2021.

Selling, General and Administrative

The fluctuations in general and administrative expenses for the three and six months ended June 30, 2022 is primarily due to the timing of costs associated with building and staffing our commercial infrastructure and teams as we prepared for the U.S. launch of IBSRELA. The changes consisted of headcount and related personnel costs and external spending for disease awareness initiatives, commercial infrastructure and strategy.

Interest Expense

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

	Three Months Ended June 30,		Change 2022 vs. 2021		Six Months Ended June 30,		Change 2022 vs. 2021	
	2022	2021	$	%	2022	2021	$	%
Interest expense	$ (787)	$ (1,202)	$ 415	(34.5)%	$ (1,533)	$ (2,302)	$ 769	(33.4)%

The decrease in interest expense for the three and six months ended June 30, 2022 was primarily due to lower principal outstanding on our loan payable.

Other Income, net

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

	Three Months Ended June 30,		Change 2022 vs. 2021		Six Months Ended June 30,		Change 2022 vs. 2021	
	2022	2021	$	%	2022	2021	$	%
Other income, net	$ 70	$ 847	$ (777)	(91.7)%	$ 554	$ 798	$ (244)	(30.6)%

The decrease in other income, net for the three and months ended June 30, 2022 is primarily due to revaluation of our 2018 Exit Fee during the three months ended June 30, 2021 following the receipt of the CRL from the FDA. Partially offsetting this decrease are sales of certain lab equipment and supplies for a net gain of $1.1 million.

Liquidity and Capital Resources

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

	June 30, 2022	December 31, 2021	Change $	Change %
Cash and cash equivalents	$ 53,408	$ 72,428	$ (19,020)	(26.3)%
Short-term investments	27,604	44,261	(16,657)	(37.6)%
Total liquid funds	$ 81,012	$ 116,689	$ (35,677)	(30.6)%

As of June 30, 2022, we had cash, cash equivalents and investments totaling $81.0 million compared to $116.7 million as of December 31, 2021. We have incurred operating losses since inception and our accumulated deficit as of June 30, 2022 is $767.9 million. Our current level of cash and investments alone is not sufficient to meet our plans for the next twelve months following the filing of these financial statements on August 4, 2022. These factors raise substantial doubt regarding our ability to continue as a going concern for a period of one year from the issuance of these financial statements. We plan to address our operating cash flow requirements with our current cash and investments, cash generated from the product launch of IBSRELA, our potential receipt of anticipated milestone payments from our collaboration partners, our potential receipt of anticipated payments from KKC under the Amendment, our ability to access the capital markets, and execute asset monetization strategies, as well as through the implementation of cash preservation activities to reduce or defer discretionary spending.

There are no assurances that our efforts to meet our operating cash flow requirements will be successful. If our current cash and investments as well as our plans to meet our operating cash flow requirements are not sufficient to fund necessary expenditures and meet our obligations for at least the next twelve months following the issuance of these financial statements, our liquidity, financial condition and business prospects will be materially affected. These financial statements have been prepared on a going concern basis and do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary in the event that we can no longer continue as a going concern.

In July 2020, we filed a Form S-3 registration statement, which became effective in August 2020 ("Registration Statement"), containing (i) a base prospectus for the offering, issuance and sale by us of up to a maximum aggregate offering price of $250.0 million of our common stock, preferred stock, debt securities, warrants and/or units, from time to time in one or more offerings; and (ii) a prospectus supplement for the offering, issuance and sale by us of up to a maximum aggregate offering price of $100.0 million of our common stock that may be issued and sold, from time to time, under a sales agreement with Jefferies LLC ("Jefferies"), deemed to be “at the market offerings” (the "2020 Open Market Sales Agreement"). The 2020 Open Market Sales Agreement was fully utilized as of December 31, 2021. During the six months ended June 30, 2021 we sold 9.0 million shares and received gross proceeds of $63.8 million at a weighted average sales price of approximately $7.10 per share under the 2021 Open Market Sales Agreement.

In August 2021, we filed an additional prospectus supplement under the Registration Statement for the offering, issuance and sale by us of up to a maximum aggregate offering price of $150.0 million of our common stock that may be issued and sold, from time to time, under an additional sales agreement we entered into with Jefferies (the "2021 Open Market Sales Agreement"), pursuant to which we may, from time to time, sell up to $150.0 million in shares of our common stock through Jefferies. We are not required to sell shares under the 2021 Open Market Sales Agreement. Pursuant to the 2021 Open Market Sales Agreement, Jefferies, as our sales agent, receives a commission of up to 3% of the gross sales price for shares of common stock sold under the 2021 Open Market Sales Agreement. During the six months ended June 30, 2022 we sold 20.5 million shares and received gross proceeds of $18.9 million at a weighted average sales price of approximately $0.92 per share under the 2021 Open Market Sales Agreement.

In February 2022, we entered into a loan and security agreement (the “2022 Loan Agreement”) with SLR Investment Corp. The 2022 Loan Agreement provides for a senior secured term loan facility, with $27.5 million funded at closing and an additional $22.5 million that we may borrow on or prior to July 25, 2023; provided that (i) we have received approval by the FDA for our NDA for tenapanor for the control of serum phosphorus in chronic kidney disease patients on dialysis by December 31, 2022, and (ii) we have achieved certain product revenue milestone targets described in the 2022 Loan Agreement. The initial funding of $27.5 million is being used to repay the 2018 Loan and to fund our ongoing operations. On August 1, 2022, we entered into an amendment to the 2022 Loan Agreement with SLR Investment Corp. that extends the date by which we must receive approval by the FDA for our NDA for the control of serum phosphorus in chronic kidney disease patients on dialysis in order to borrow the additional $22.5 million from December 31, 2022 to March 31, 2023. We had $25.0 million principal from the 2018 Loan outstanding as of the closing date. In connection with entering into the 2022 Loan Agreement, we entered into an agreement, whereby we agreed to pay an exit fee in the amount of 2% of the 2022 Loan funded (the “2022 Exit Fee”) upon (i) any change of control transaction or (ii) our achievement of net revenue from the sale of any products equal to or greater than $100.0 million, measured on a six (6) months basis (the "Revenue Milestone"), tested monthly at the end of each month. Notwithstanding the prepayment or termination of the 2022 Loan, the 2022 Exit Fee will expire on February 23, 2032. We concluded that the 2022 Exit Fee is a freestanding derivative which should be accounted for at fair value on a recurring basis. The estimated fair value of the 2022 Exit Fee is recorded as a derivative liability and included in accrued expenses and other current liabilities on the accompanying condensed balance sheets.

Our primary sources of cash have been from the sale and issuance of common stock (in both public offerings and private placements) and private placements of convertible preferred stock, funds from our collaboration partnerships and funds from our 2018 Loan Agreement and 2022 Loan Agreement.

Our primary uses of cash have been to fund operating expenses, primarily research and development expenditures, pre-commercial and commercial expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Our future funding requirements are difficult to forecast and will depend on many factors, including:

- the extent to which we are able to generate product revenue from sales of IBSRELA;
- whether we are successful in our efforts under the FDR process, including the Advisory Committee meeting to be convened as part of the FDR process, to secure approval for our NDA for XPHOZAH, or to reach resolution with the FDA regarding a path to address the deficiencies in the NDA noted in the CRL and ADL, and the time and cost associated with such path;
- the availability of adequate third-party reimbursement for IBSRELA and, if approved, the sales price and the availability of adequate third-party reimbursement for XPHOZAH;
- the manufacturing costs of IBSRELA and XPHOZAH;
- the selling and marketing costs associated with IBSRELA and, if approved, XPHOZAH;
- our ability to maintain our existing collaboration partnerships and to establish additional collaboration partnerships, in-license/out-license, joint ventures or other similar arrangements and the financial terms of such agreements;
- the timing, receipt and amount of any milestones that may be received from our collaboration partners in connection with tenapanor, if any;
- the timing, receipt and amount of revenue, if any, that may be received from KKC in connection with the 2022 KKC Amendment;
- the timing, receipt, and amount of sales of, or royalties on, tenapanor, if any;
- the cash requirements of any future acquisitions or discovery of product candidates;
- any clinical trials we are required to or decide to pursue for tenapanor or RDX013;
- 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, including 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 the 2022 Loan Agreement.

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

CASH FLOW ACTIVITIES

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

	Six Months Ended June 30,			
	2022	2021	Change $	Change %
Net cash used in operating activities	$ (58,901)	$ (78,493)	$ 19,592	(25.0)%
Net cash provided by investing activities	17,806	10,719	7,087	66.1 %
Net cash provided by financing activities	22,075	63,487	(41,412)	(65.2)%
Net decrease in cash and cash equivalents	$ (19,020)	$ (4,287)	$ (14,733)	343.7 %

Cash Flows from Operating Activities

Net cash used in operating activities during the six months ended June 30, 2022 decreased by $19.6 million primarily as a result of our net loss which was $23.3 million less than during the six months ended June 30, 2021. Partially offsetting the net loss improvement were changes to our operating assets and liabilities related to expenditures for commercial manufacturing and inventory for the production of IBSRELA.

Cash Flows from Investing Activities

Net cash provided by investing activities increased by $7.1 million due to the timing of our investment maturities and purchases, as well as $1.3 million proceeds from sale of laboratory equipment and supplies during the six months ended June 30, 2022.

Cash Flows from Financing Activities

Net cash provided by financing activities decreased by $41.4 million primarily due to net proceeds from issuance of our common stock pursuant to the at the market offerings of $62.4 million during the six months ended June 30, 2021 compared to $18.5 million during the six months ended June 30, 2022. In addition, during the six months ended June 30, 2022, we received net proceeds of $27.0 million pursuant to the 2022 Loan Agreement, $9.6 million in proceeds for the sale of certain future royalties, and repaid $33.0 million, net of settlement costs, to repay the 2018 Loan.

Off-Balance Sheet Arrangements

As of June 30, 2022 and 2021, respectively, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K as promulgated by the SEC.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk. We are subject to market risks, including interest rate fluctuation exposure through our investments, in the ordinary course of our business. However, the goals of our investment policy are the preservation of capital, fulfillment of liquidity needs and fiduciary control of cash. To achieve our goal of maximizing income without assuming significant market risk, we maintain our excess cash and cash equivalents in money market funds and short-term debt securities. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in interest rates would have any material negative impact on the fair value of our cash equivalents.

As of June 30, 2022, we had cash, cash equivalents and investments of $81.0 million, which consist of bank deposits and money market funds, as well as high quality fixed income instruments including corporate bonds, commercial paper, and asset-backed securities collateralized by non-mortgage consumer receivables. The credit rating of our investments must be rated A-1/P-1, or better by Standard and Poor's and Moody's Investors Service. Asset-backed securities must be rated AAA/Aaa. Money Market funds must be rated AAA/Aaa. Such interest-earning instruments carry a degree of interest rate risk. However, because our investments are high quality and short-term in duration, we believe that our exposure to interest rate risk is not significant and that a 10% movement in market interest rates would not have a significant impact on the total value of our portfolio, as noted above. We do not enter into investments for trading or speculative purposes.

We are subject to interest rate fluctuation exposure through our borrowings under the Loan Agreement and our investment in money market accounts which bear a variable interest rate. Borrowings under the 2022 Loan bear interest at a floating per annum rate equal to 7.95% plus the greater of (i) one tenth percent (0.10%) and (ii) the one-month rate published by the Intercontinental Exchange Benchmark Administration Ltd ("ICE") or its successor. A hypothetical increase in one-month ICE of 100 basis points above the current one-month ICE rates would have increased our interest expense by approximately $0.1 million for the three and six months ended June 30, 2022. As of June 30, 2022, we had an aggregate principal amount of $27.5 million outstanding pursuant to our 2022 Loan Agreement.

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

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

As of June 30, 2022, we had no open forward foreign currency exchange contracts.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (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, 2022. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2022, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the six months ended June 30, 2022, we implemented certain internal controls in connection with our product launch. There were no other changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On July 30 and August 12, 2021, two putative securities class action lawsuits were commenced in the U.S. District Court for the Northern District of California naming as defendants Ardelyx and two current officers captioned *Strezsak v. Ardelyx, Inc., et al.*, Case No. 4:21-cv-05868-HSG, and *Siegel v. Ardelyx, Inc., et al.*, Case No. 5:21-cv-06228-HSG (together, the "Securities Class Actions"). The complaints allege that the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder, by making false and misleading statements and omissions of material fact related to tenapanor. The plaintiffs seek to represent all persons who purchased or otherwise acquired Ardelyx securities between August 6, 2020, and July 19, 2021. The plaintiffs seek damages and interest, and an award of costs, including attorneys' fees. On September 28, 2021, several shareholders filed motions to consolidate the two putative class actions and to be appointed lead plaintiff and have their selection of counsel be appointed lead counsel, and on July 19, 2022, the court issued an order to consolidate the two putative class actions and appointed the lead plaintiff and lead counsel. The parties have agreed upon a proposed schedule for the lead plaintiff to file a consolidated amended complaint and for defendants to file a motion to dismiss. We believe the plaintiff's claims are without merit and we have not recorded any accrual for a contingent liability associated with these legal proceedings.

On December 7, 2021 and March 29, 2022, two verified shareholders derivative lawsuits were filed purportedly on behalf of Ardelyx against certain of Ardelyx's executive officers and members of our board of directors, captioned *Go v. Raab, et al.*, Case No. 4:21-cv-09455-HSG, and *Morris v. Raab, et al.*, Case No. 4:22-cv-01988-JSC. The complaints allege violations of Section 14(a) of the Exchange Act, breaches of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste, and seek contribution under Sections 10(b) and 21D of the Securities Exchange Act of 1934 from two executive officers. On January 19, and April 27, 2022, the court granted the parties' stipulation to stay the *Go* and *Morris* actions, respectively, until resolution of the anticipated motion(s) to dismiss in the Securities Class Actions, and the cases remain stayed.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. As of June 30, 2022, there is no litigation pending that would reasonably be expected to have a material adverse effect on our results of operations and financial condition, and no contingent liabilities were accrued as of June 30, 2022.

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 significant losses since our inception and we will incur losses in the future, which makes it difficult to assess our future viability; although our financial statements have been prepared on a going concern basis, our current level of cash and investments alone is not sufficient to meet our operating plans for the next twelve months, raising substantial doubt regarding our ability to continue as a going concern.

We recently commenced the commercialization of our first product, IBSRELA® (tenapanor) for the treatment of irritable bowel syndrome with constipation ("IBS-C"), and have generated limited revenue from product sales to date.

We are not profitable and have incurred losses in each year since our inception in October 2007, and we do not know whether or when we will become profitable. We continue to incur significant commercialization, development and other expenses related to our ongoing operations. As of June 30, 2022, we had an accumulated deficit of $767.9 million.

We expect to continue to incur substantial operating losses for the foreseeable future as we commercialize IBSRELA, seek to gain approval for XPHOZAH® (tenapanor) for the control of serum phosphorus in adult patients with chronic kidney disease ("CKD") on dialysis (the "Hyperphosphatemia Indication"); prepare for the potential commercialization of XPHOZAH, if approved; and incur manufacturing and development cost for, tenapanor.

Ernst & Young LLP, our independent registered public accounting firm for the fiscal year ended December 31, 2021, has included an explanatory paragraph in their opinion that accompanies our audited financial statements as of the year ended December 31, 2021, indicating our current liquidity position raises substantial doubt about our ability to continue as a going concern. We plan to address our operating cash flow requirements with our current cash and investments, cash generated from the product launch of IBSRELA, our potential receipt of anticipated milestone payments from our collaboration partners, our potential receipt of anticipated payments from our collaboration partner, Kyowa Kirin, Co., Ltd. ("KKC") in connection with the transaction entered into with KKC in March 2022 which amended our License Agreement entered into with KKC in 2017 (the "2022 KKC Amendment"); our ability to access the capital markets, as well as through the implementation of cash preservation activities to reduce or defer discretionary spending.

There are no assurances that our efforts to meet our operating cash flow requirements will be successful. If our current cash and investments as well as our plans to meet our operating cash flow requirements are not sufficient to fund necessary expenditures and meet our obligations for at least the next twelve months, our liquidity, financial condition and business prospects will be materially affected.

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

We have substantial net operating loss and tax credit carryforwards for Federal and California income tax purposes. Such net operating losses and tax credits carryforwards may be reduced as a result of certain intercompany restructuring transactions. In addition, the future utilization of such net operating loss and tax credit carryforwards and credits will be subject to limitations, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that have occurred previously and additional limitations may be applicable as a result of ownership changes that could occur in the future.

We will require substantial additional financing for the foreseeable future as we invest in the commercialization of IBSRELA and prepare for and participate in a Cardiovascular and Renal Drugs Advisory Committee ("Advisory Committee") meeting in connection with the formal dispute resolution ("FDR") process commenced in response to the Complete Response Letter ("CRL") received from the U.S. Food and Drug Administration ("FDA") relating to our New Drug Application ("NDA") for tenapanor for the Hyperphosphatemia Indication and the inability to access necessary capital when needed on acceptable terms, or at all, could force us to limit, reduce or terminate our efforts to commercialize IBSRELA or to seek and obtain approval for tenapanor for the Hyperphosphatemia Indication.

Since our inception, most of our resources have been dedicated to our research and development activities, including developing tenapanor. Following the receipt of the CRL, we implemented two restructuring plans in order to reduce operating costs and to better align our workforce with the needs of our business. Notwithstanding the restructurings, we believe that we will continue to expend substantial resources for the foreseeable future, including, costs associated with our efforts to commercialize IBSRELA, which we began selling in the U.S. in March 2022, cost associated with our efforts to pursue approval for our NDA for tenapanor for the Hyperphosphatemia Indication through the FDR process, and Advisory Committee meeting; conducting pediatric clinical trials for IBSRELA and XPHOZAH, if approved, and manufacturing for IBSRELA and, if approved, XPHOZAH. Our future funding requirements will depend on many factors, including, but not limited to:

- the extent to which we are able to generate product revenue from sales of IBSRELA;
- whether we are successful in our efforts under the FDR process, including the Advisory Committee meeting to be convened as part of the FDR process, to secure approval for our NDA for tenapanor for the Hyperphosphatemia Indication, or to reach resolution with the FDA regarding a path to address the deficiencies in the NDA noted in the CRL and ADL, and the time and cost associated with such path;

- the availability of adequate third-party reimbursement for IBSRELA and, if approved, the sales price and the availability of adequate third-party reimbursement for XPHOZAH;
- the manufacturing costs of IBSRELA and XPHOZAH;
- the selling and marketing costs associated with IBSRELA and, if approved, XPHOZAH;
- our ability to maintain our existing collaboration partnerships and to establish additional collaboration partnerships, in-license/out-license, joint ventures or other similar arrangements and the financial terms of such agreements;
- the timing, receipt and amount of any milestones that may be received from our collaboration partners in connection with tenapanor, if any;
- the timing, receipt and amount of revenue, if any, that may be received from KKC in connection with the 2022 KKC Amendment;
- the timing, receipt, and amount of sales of, or royalties on, tenapanor, if any;
- the cash requirements of any future acquisitions or discovery of product candidates;
- any clinical trials we are required to or decide to pursue for tenapanor or RDX013;
- 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, including costs of defending any claims of infringement brought by others in connection with the development, manufacture or commercialization of tenapanor or any of our product candidates; and
- the payment of interest and principal related to our loan and security agreement entered into with SLR Investment Corp. in February 2022.

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

Our failure to meet the continued listing requirements of The Nasdaq Global Market could result in a de-listing of our common stock.

If we fail to satisfy the continued listing requirements of The Nasdaq Global Market ("Nasdaq") such as the minimum stockholders' equity requirement or the minimum closing bid price requirement, Nasdaq may take steps to de-list our common stock. For example, on each of February 28, 2022 and May 23, 2022, we received a letter from Nasdaq indicating that Nasdaq had determined that we had failed to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550(a)(2). Nasdaq Listing Rule 5550(a)(2) requires that companies listed on the Nasdaq Global Market maintain a minimum closing bid price of at least $1.00 per share (the "Listing Requirement"). We received a letter from Nasdaq dated March 31, 2022, indicating that we had regained compliance with the Listing Requirement after the closing bid price for its common stock listed on Nasdaq equaled or exceeded $1.00 per share for ten (10) consecutive business days. However, we have not yet regained compliance with the Listing Requirement following the second letter we received on May 23, 2022 letter, and there can be no assurances that we will regain compliance with the Listing Requirement during the 180 day grace period afforded us by Nasdaq. On April 29, 2022, we filed our definitive Proxy Statement with the U.S. Securities and Exchange Commission (the "SEC") indicating our intention to seek approval from our stockholders during our Annual Meeting of Stockholders to be held on June 15, 2022, for a proposal to grant our Board of Directors authority to effect a reverse stock split of our authorized common stock and issued and outstanding common stock by amending our Amended and Restated Certificate of Incorporation

by September 15, 2022 and within a range of not less than 1-for-2 and not more than 1-for-10, if our Board of Directors deems it within our best interests. This proposal failed to receive a sufficient number of votes for approval from our stockholders during our Annual Meeting of Stockholders and the adjournment thereof. We are monitoring the bid price of our common stock and will consider options available to us to regain compliance with the Listing Requirement. There can be no assurances that we will have other options available to regain compliance with the Listing Requirement. If we fail to regain compliance with this requirement, or any other of the continued listing requirements of The Nasdaq Global Market, Nasdaq may take steps to de-list our common stock.

If Nasdaq de-lists our securities for trading on the Nasdaq or takes other actions with respect to our Nasdaq listing, we could face significant adverse consequences, including:

• a limited availability of market quotations for our common stock;

• reduced liquidity with respect to our common stock;

• reduced trading volume in and market price of our common stock;

• a limited amount of news and analyst coverage for our company; and

• a decreased ability to issue additional securities or obtain additional financing in the future.

Such a de-listing would likely have an adverse effect on the price of our common stock and would impair the ability of our stockholders to sell or purchase our common stock. We may take actions to avoid such a de-listing or in the event of a de-listing, we may take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to remain listed or to become listed again, stabilize the market price or improve the liquidity or trading volume of our common stock, prevent our common capitalization and stockholder's equity from dropping below the Nasdaq minimum requirements, or prevent other future non-compliance with Nasdaq's continued listing requirements.

We have generated limited revenue from product sales and may never be profitable.

We began selling IBSRELA in the U.S. in March 2022, and have generated limited revenue from product sales to date. We have no other products approved for sale and have received a CRL from the FDA for our NDA for the Hyperphosphatemia Indication and an Appeal Denied Letter ("ADL") in response to our first level of appeal of the CRL to the FDA Office of Cardiology, Hematology, Endocrinology and Nephrology ("OCHEN"). Additionally, we have received an Interim Response (the "Interim Response") to our second level of appeal to the Office of New Drugs ("OND"), Center for Drug Evaluation and Research (CDER), in which OND indicated that additional input from the Advisory Committee, in general, and specifically from experts, including clinicians would be valuable in further considering the clinical meaningfulness of the phosphate lowering effect observed in our phase 3 clinical program for XPHOZAH. OND has directed the Division of Cardiology and Nephrology of OCHEN (the "Division") to convene the Advisory Committee, and a tentative date for the Advisory Committee meeting has been set for November 16, 2022. There can be no assurances that the response from the Advisory Committee will be positive, or thatthat approval of our NDA will ultimately be granted by the FDA. To date, we have generated limited product revenue from product sales of IBSRELA. There can be no assurances that we will be successful in increasing the amount of product revenue from sales of IBSRELA. There can be no assurances that we will generate sufficient product revenue from sales of IBSRELA and, if approved, XPHOZAH, to cover our expenses. Our ability to generate product revenue from sales or pursuant to milestone payments depends heavily on many factors, including but not limited to:

- our ability to successfully commercialize IBSRELA;
- obtaining market acceptance of IBSRELA as a viable treatment option for IBS-C;
- our ability to obtain and sustain an adequate level of coverage and reimbursement for IBSRELA by third-party payors;

- whether we are successful in our efforts during the Advisory Committee meeting and under the FDR process to secure approval for our NDA for tenapanor for the Hyperphosphatemia Indication, or whether we are otherwise able during the FDR to reach resolution with the FDA regarding a path to addressing the deficiencies in our NDA noted in the CRL, ADL and Interim Response that is achievable in terms of clinical study design, time and cost;
- 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, if approved, XPHOZAH;
- addressing any competing technological and market developments;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how, and our ability to develop, manufacture and commercialize our product candidates and products without infringing intellectual property rights of others; and
- attracting, hiring, and retaining qualified personnel.

With respect to our commercialization of IBSRELA, and if we are successful in obtaining regulatory approval to market XPHOZAH, our revenue will be dependent, in part, upon the size of the markets in the U.S. and the label for which approval is or was granted, acceptance of the price for the product, and the ability to get reimbursement at any price. While there is significant uncertainty related to the insurance coverage and reimbursement of newly approved products in general in the United States, there is additional uncertainty related to insurance coverage and reimbursement for drugs, like XPHOZAH, which, if approved, will be marketed for the control of serum phosphorus in adult patients with CKD on dialysis or for another other related indication. If we are successful in obtaining regulatory approval to market XPHOZAH for such indication, our ability to generate and sustain future revenues from sales of tenapanor for such indication, may be dependent upon whether and when XPHOZAH, along with other oral ESRD related drugs without an injectable or intravenous equivalent, are bundled into the ESRD prospective payment system, and the manner in which such introduction into the ESRD prospective payment system may occur. See “Third-party payor coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for IBSRELA or, if approved, XPHOZAH, could limit our ability to market those products and decrease our ability to generate revenue” below. Additionally, if the number of adult patients for IBSRELA or, if approved, XPHOZAH is not as significant as we estimate, the indication approved by regulatory authorities for XPHOZAH is narrower than we expect, coverage and reimbursement for either IBSRELA or, if approved, XPHOZAH are not available in the manner and to the extent we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from the sale of IBSRELA or, if approved, XPHOZAH. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to generate adequate revenue from product sales would likely depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations. A decline in the value of our common stock could cause our stockholders to lose all or part of their investment.

Principal Risks Related to Our Business

We are substantially dependent on the successful launch and commercialization of IBSRELA for IBS-C, and there is no guarantee that we will achieve sufficient market acceptance for IBSRELA; secure adequate coverage and reimbursement for IBSRELA; or generate sufficient revenue from product sales of IBSRELA.

We began selling IBSRELA, our approved treatment for IBS-C in adults 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 launch and market demand for IBSRELA;
- our ability to obtain and sustain an adequate level of coverage and reimbursement for IBSRELA by third-party payors;
- the effectiveness of IBSRELA as a treatment for adult patients with IBS-C;
- the size of the treatable patient population;

- the effectiveness of our sales, market access and marketing efforts;
- whether physicians view IBSRELA as a safe and effective treatment for adult patients with IBS-C, which will impact the adoption of IBSRELA by physicians for the treatment of IBS-C;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of IBSRELA compared to alternative and competing treatments;
- the prevalence and severity of adverse side effects of IBSRELA;
- our potential involvement in lawsuits in connection with enforcing intellectual property rights in and to IBSRELA;
- our potential involvement in third-party interference, opposition, derivation or similar proceedings with respect to our patent rights directed to IBSRELA, and avoiding other challenges to our patent rights and patent infringement claims; and
- a continued acceptable safety and tolerability profile of IBSRELA following approval.

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

We are pursuing regulatory approval for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis, and there can be no assurances that we will be successful in obtaining such regulatory approval.

We are pursuing regulatory approval for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis. To date, we have invested a significant amount of our efforts and financial resources in the research and development of tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis. On July 28, 2021, we received a CRL from the Division regarding our NDA for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis. According to the CRL, the FDA has determined that the magnitude of the treatment effect observed in our Phase 3 clinical trials was small and of unclear of clinical significance. Following an End-of-Review Type A meeting ("End of Review Meeting") in October 2021, with the Division, we submitted a Formal Dispute Resolution Request ("FDRR") in December 2021. The FDRR was focused on demonstrating that the data submitted in the NDA supported the clinical significance of the treatment effect of tenapanor. On February 4, 2022, we received an ADL from OCHEN. On February 18, 2022, we submitted an appeal of the ADL to the FDA's Center for Drug Evaluation and Research, Office of New Drugs ("OND"), and on April 15, 2022, we received an Interim Response from OND. The Interim Response indicated that OND would direct the Division to convene the Advisory Committee to provide additional input for consideration by OND, and the Advisory Committee meeting has been tentatively scheduled for November 16, 2022. OND expects to provide a response to the FDR within thirty (30) days after the conclusion of the Advisory Committee meeting. There can be no assurances that the response from the Advisory Committee will be positive, or that approval of the NDA will ultimately be granted by the FDA.

Even if we are successful in obtaining regulatory approval for tenapanor for control of serum phosphorus in adult patients with CKD on dialysis, the expense and time required to do so could adversely impact our ability to successfully commercialize XPHOZAH for the Hyperphosphatemia Indication.

We may not be successful in obtaining approval for tenapanor for the Hyperphosphatemia Indication, and if we are able to obtain approval, the expense and time to do so could adversely impact our ability to successfully commercialize XPHOZAH for the Hyperphosphatemia Indication, our business and our results of operations. If we are successful in obtaining approval for XPHOZAH for the Hyperphosphatemia Indication, the commercial success of XPHOZAH 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 both IBSRELA and XPHOZAH;

- whether or not the content and breadth of the label approved by the FDA for XPHOZAH may materially and adversely impact our ability to commercialize the product for the approved indication;
- whether or when XPHOZAH, along with other oral end-stage renal disease ("ESRD") related drugs without an injectable or intravenous equivalent, are bundled into the ESRD prospective payment system, and the manner in which such introduction into the ESRD prospective payment system may occur;
- 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, and, the extent to which the issuance of a CRL by the FDA has impacted the potential acceptance of XPHOZAH as safe, effective and well-tolerated;
- our ability to manage the commercialization of IBSRELA and XPHOZAH and the complex pricing and reimbursement negotiations that may arise with marketing the same product 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.

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

Undesirable side effects caused by IBSRELA, and/or, if approved, XPHOZAH, could cause us or regulatory authorities to interrupt, delay or halt the commercialization of the product. Despite our receipt of marketing approval for IBSRELA and the completion of our Phase 3 clinical program for XPHOZAH, the prevalence and/or severity of side effects caused by IBSRELA, and/or if approved, XPHOZAH, could result in a number of potentially significant negative consequences could occur, including:

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

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

As a company, we have limited experience in the marketing, sale and distribution of pharmaceutical products; and there are significant risks in building and managing a commercial organization.

As a company, we have limited experience in building and managing a commercial organization, or in the marketing, sale and distribution of pharmaceutical products. There can be no assurances that we will be successful in our efforts to retain, and incentivize qualified individuals, generate sufficient sales leads, comply with regulatory requirements applicable to the marketing and sale of drug products and effectively manage a geographically dispersed sales and marketing team.

If we fail or are delayed in the development of our internal sales, marketing and distribution capabilities, the commercialization of IBSRELA could be adversely impacted.

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

On February 23, 2022, we entered into a loan and security agreement with SLR Investment Corp. (the "Lender") pursuant to which the Lender agreed to provide us a $50.0 million term loan facility with a maturity date of March 1, 2027. The loan was funded in the amount of $27.5 million on February 23, 2022 and the remaining $22.5 million may be funded upon the satisfaction of both (i) receipt from the FDA of approval of the NDA for tenapanor for the Hyperphosphatemia Indication on or prior to December 31, 2022 and (ii) our achievement of certain product revenue milestone targets described in the 2022 Loan Agreement. On August 1, 2022, we entered into an amendment to the 2022 Loan Agreement with SLR Investment Corp. that extends the date by which we must receive approval by the FDA for our NDA for the Hyperphosphatemia Indication in order to borrow the additional $22.5 million from December 31, 2022 to March 31, 2023. Until we have repaid all funded indebtedness, the loan and security agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock, to redeem capital stock, to enter into licensing agreements, to engage in transactions with affiliates, and to encumber our intellectual property. Our business may be adversely affected by these restrictions on our ability to operate our business.

We are permitted to make interest only payments on the loan facility through March 2024, with principal repayments commencing on April 1, 2024, however, we may be required to repay the outstanding indebtedness under the loan facility if an event of default occurs under the loan and security agreement. An event of default will occur if, among other things, we fail to make payments under the loan and security agreement; we breach any of our covenants under the loan and security agreement, subject to specified cure periods with respect to certain breaches; the Lender determines that a material adverse change has occurred; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; we are unable to pay our debts as they become due; or we default on contracts with third parties which would permit the Lender to accelerate the maturity of such indebtedness or that could have a material adverse change on us. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to delay, limit, reduce or terminate our activities necessary to commercialize IBSRELA, and/or if approved, XPHOZAH, or clinical trials for tenapanor. The Lender could also exercise its rights as collateral agent to take possession of and to dispose of the collateral securing the term loans, which collateral includes substantially all of our property (excluding intellectual property, which is subject to a negative pledge). Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

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

The pricing, coverage and reimbursement of IBSRELA and, if approved, 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, if approved and commercialized, 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, if approved, 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.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare & Medicaid Services (“CMS”), an agency within the United States Department of Health and Human Services responsible for administering the Medicare program, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products such as ours.

There is increased uncertainty related to insurance coverage and reimbursement for drugs, like XPHOZAH for the Hyperphosphatemia Indication, which, if approved, will be marketed for the control of serum phosphorus in adult patients with CKD on dialysis or for another other related indication. In January 2011, CMS implemented a new prospective payment system for dialysis treatment. Under the ESRD prospective payment system, 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 routine drugs. The inclusion of oral medications without injectable or intravenous equivalents in the bundled payment was initially delayed until January 1, 2014, and through several subsequent legislative actions was delayed until January 1, 2025. As a result, absent further legislation or regulation on this matter, beginning in 2025, oral ESRD-related drugs without injectable or intravenous equivalents may be included in the ESRD bundle and separate Medicare payment for these drugs will no longer be available, as is the case today under Medicare Part D. While it is too early to project the full impact that bundling may have on sales of XPHOZAH, if approved and commercialized, and on our business should XPHOZAH be brought into the bundle in 2025, or at any time, we may be unable to sell XPHOZAH for the Hyperphosphatemia Indication, if approved, to dialysis providers on a profitable basis if third-party payors reduce their current levels of payment, or if our costs of production are higher than levels necessary for an appropriate gross margin after payment of all discounts, rebates and chargebacks.

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

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, these caps may not cover or provide adequate payment for IBSRELA, and if approved and commercialized, XPHOZAH. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We rely completely on third parties 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, if approved and commercialized, XPHOZAH, and our future development efforts for tenapanor may be materially harmed.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture IBSRELA, or any of other our product candidates on a commercial scale, or to manufacture our drug supplies for use in the conduct of our nonclinical and clinical studies. The facilities used by our contract manufacturers 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 contract manufacturer. Although they are contractually required to so do, we are completely dependent on our contract manufacturing partners for compliance with the regulatory requirements, known as current Good Manufacturing Practice requirements (“cGMPs”), for manufacture of both active drug substances and finished drug products.

The manufacture of pharmaceutical products requires significant expertise and capital investment. Manufacturers of pharmaceutical products often encounter difficulties in commercial production. These problems may include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, and shortages of qualified personnel, as well as compliance with federal, state and foreign regulations and the challenges associated with complex supply chain management. Even if our contract manufacturers 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 contract manufacturers fail to adhere to applicable GMP or other regulatory requirements, experience delays or disruptions in the availability of raw materials or experience manufacturing or distribution problems, we may suffer significant consequences, including the inability to meet our product requirements for our clinical development programs, and if tenapanor is commercialized for any indication, 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, if approved, XPHOZAH, may be materially harmed.

Additional Risks Related to Our Business and Industry

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. For example, while the results of our Phase 2 clinical trial evaluating RDX013 for the treatment of hyperkalemia demonstrated an acceptable safety and tolerability profile for RDX013 and supported proof of concept in its ability to lower serum potassium levels, with statistically significant reductions compared to placebo after eight days of treatment, the study did not meet its primary endpoint of significantly reducing serum potassium levels compared to placebo after four weeks of treatment. We currently expect that the next step for the program will be to evaluate a new formulation that potentially enhances subject compliance and the efficacy of RDX013 in an additional Phase 2 clinical study at such time as we have determined that our available resources support conducting such an additional clinical study. There can be no assurances that any additional clinical study that we determine to conduct with RDX013 will be successful.

Additionally, if we conduct additional clinical trials with RDX013, we could encounter delays in our future 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.

In addition, identifying and qualifying patients to participate in any clinical trials is critical to the success of the clinical trials. The timing of any future clinical trials, including any additional RDX013 clinical trial 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 the program, or termination of the clinical studies altogether. Any of these occurrences may significantly harm our business, financial condition and prospects.

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

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

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

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

The biotechnology and pharmaceutical industries are highly competitive, and we face significant competition from companies in the biotechnology, pharmaceutical and other related markets that are researching and marketing products designed to address diseases that we are currently developing products to treat. If approved for marketing by the FDA or other regulatory agencies, tenapanor, as well as our other product candidates, would compete against existing treatments.

For example, numerous treatments exist for constipation and the constipation component of IBS-C, many of which are over-the-counter. These include psyllium husk (such as Metamucil), methylcellulose (such as Citrucel), calcium polycarbophil (such as FiberCon), lactulose (such as Cephulac), polyethylene glycol (such as MiraLax), sennosides (such as Exlax), bisacodyl (such as Ducolax), docusate sodium (such as Colace), magnesium hydroxide (such as Milk of Magnesia), saline enemas (such as Fleet), and sorbitol. These agents are generally inexpensive and work well to temporarily relieve constipation.

We are aware of four prescription products marketed for certain patients with IBS-C, including Linzess (linaclotide), Amitiza (lubiprostone), Trulance (plecanatide) and Zelnorm (tegaserod maleate).

Additionally, XPHOZAH, if approved for the Hyperphosphatemia Indication will compete with phosphate binders used for the same or similar indication`. If approved, our label for XPHOZAH may include data comparing the effectiveness of tenapanor to phosphate binders used for the same indication. The various types of phosphate binders commercialized in the United States include the following: Calcium carbonate (many over-the-counter brands including Tums and Caltrate); 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 phosphate binders listed above are available as generics in the U.S., with the exception of Velphoro and Auryxia. In addition to the currently available phosphate binders, we are aware of at least two other binders in development, including fermagate (Alpharen), an iron-based binder in Phase 3 being developed by Opko Health, Inc., and PT20, an iron-based binder in Phase 3 being developed by Shield Therapeutics.

It is possible that our competitors' drugs may be less expensive and more effective than our product candidates, or that will 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 anticipate that we will face increased competition in the future as new companies enter into our target markets.

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

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

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

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

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

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and our commercial launch of IBSRELA. For example, we may be sued if any product we develop 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, if approved, XPHOZAH.

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

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

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

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

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

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

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

Furthermore, the Federal Trade Commission (FTC) 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. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, in Europe, the European Union General Data Protection Regulation (GDPR) went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area (EEA). 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 United States; in July 2020, the Court of Justice of the EU (CJEU) limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Relatedly, following the United Kingdom's withdrawal from the European Economic Area and the European Union, and the expiry of the transition period, companies have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which may expose us to further compliance risk.

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

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

We and our collaborators, CROs, and other contractors and consultants collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we and our collaborators, CROs and other contractors and consultants collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal 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 digital 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 internal 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 damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks 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. As a result of the COVID-19 pandemic, 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. 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. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date. If such an event were to occur and cause interruptions in our operations, it could result in 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. We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

We have previously identified a material weakness in our internal control over financial reporting. 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.

In 2019, management and our independent registered public accounting firm identified a control deficiency that constituted a material weakness in our internal control over financial reporting. The material weakness was due to a failure in the design and implementation of controls over the evaluation of the terms of our clinical trial contracts for inclusion into our clinical financial model which estimates clinical trial expenses. Specifically, we had failed to properly interpret an expense in our clinical trial contracts which resulted in the over accrual of our clinical trial expenses during 2018 and the first quarter of 2019.

We developed and implemented a remediation plan for this material weakness which included modifications to the design and implementation of certain internal controls, and the material weakness was remediated as of December 31, 2019. Although we have remediated this material weakness, as attested by our independent registered public accounting firm, we can give no assurance that an additional material weakness or significant deficiency in our internal controls over financial reporting will not be identified in the future. 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 United States and abroad that we believe will complement or augment our existing business. In particular, we have formed collaboration partnerships with KKC 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 in Canada with Knight for commercialization of tenapanor for IBS-C and hyperphosphatemia. We face significant competition in seeking appropriate collaboration partners, and the process to identify an appropriate partner and negotiate appropriate terms is time-consuming and complex. Any delays in identifying suitable additional collaboration partners and entering into agreements to develop our product candidates could also delay the commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. There is no guarantee that our current collaboration partnerships or any such arrangements we enter into in the future will be successful, or that any collaboration partner will commit sufficient resources to the development, regulatory approval, and commercialization effort for such products, or that such alliances will result in us achieving revenues that justify such transactions. We have received a CRL from the FDA regarding our NDA for the Hyperphosphatemia Indication. While we are pursuing an appeal through the FDR process, and an Advisory Committee has been tentatively scheduled for November 16, 2022, there can be no assurances that the outcome of the Advisory Committee will be positive, or that approval of the NDA for the Hyperphosphatemia Indication will ultimately be granted by the FDA. Even if we are successful in obtaining approval for the NDA, the delay in obtaining such approval may result in delay in the regulatory process for our partners, which could have a material adverse effect on our business and results of operations.

The ongoing effects of the COVID-19 pandemic, or any other outbreak of epidemic diseases, or the perception of their effects, could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Outbreaks of epidemic, pandemic, or contagious diseases, such as the current novel coronavirus ("COVID-19") pandemic or, historically, the Ebola virus, Middle East Respiratory Syndrome, Severe Acute Respiratory Syndrome or the H1N1 virus, could disrupt our business. Economic and health conditions related to the COVID-19 pandemic in the United States and across most of the globe remain uncertain and continue to evolve. The continuing effects of the coronavirus outbreak may result in delays in the manufacture of tenapanor, or in the delivery of key intermediates or raw materials required to manufacture tenapanor or delays in clinical development activities by us, or our collaboration partners. Such effects could also materially and negatively impact our ability to successfully commercialize IBSRELA, and/or, if approved, XPHOZAH, or the ability of our collaboration partners to successfully commercialize such products, if approved for marketing and sale by the foreign regulatory authorities, including our ability, and that of our collaboration partners to educate physicians and patients about the benefits, administration and use of the product.

- Although we have reopened our offices and invited our personnel to return to the office, we continue to permit our personnel to work remotely, which could negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber-security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and important agencies and contractors.
- The FDA and comparable foreign regulatory agencies may continue to experience operational interruptions or delays, which may impact timelines for regulatory submission, trial initiation and regulatory approval.

The full effects of the COVID-19 remain unknown. The extent to which the outbreak may continue to impact our business, including, our commercialization and manufacturing will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as access to physician offices for our commercial and medical teams, business closures or business disruptions.

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, our continued efforts to seek approval for our NDA for tenapanor for the Hyperphosphatemia Indication and/or the development of RDX013 through the use of alternative structures. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, spin outs, collaboration partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- up-front, milestone and royalty payments, equity investments and financial support of new research and development candidates including increase of personnel, all of which may be substantial;
- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities;

- higher-than-expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

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

Our CMOs manufacture tenapanor API outside of the United States, and we may seek and obtain approval to commercialize IBSRELA or XPHOZAH outside of the United States, and as a result, a variety of risks associated with international operations could materially adversely affect our business.

We or our collaboration partners may decide to seek marketing approval for IBSRELA or XPHOZAH outside the United States. Additionally we have contractual arrangements with CMOs involving the manufacture of tenapanor API outside of the United States, and we may otherwise engage in business outside the United States, including entering into additional contractual agreements with third-parties. We are subject to additional risks related to entering these international business markets and relationships, including:

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

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

We and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials, including the components of our tenapanor and our product candidates. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our

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

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

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

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our California facility, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Risks Related to Government Regulation

Despite having received regulatory approval for IBSRELA, and even if we receive regulatory approval for XPHOZAH, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, IBSRELA, and, if approved, 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 if 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 contract manufacturers 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 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 contract manufacturers' 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, if approved, 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 United States 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, and policy changes. Average review times at the agency have fluctuated in recent years as a result.

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 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 contract manufacturers are subject to significant regulation with respect to manufacturing of 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 contract manufacturers 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 contract manufacturers 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. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the manufacture of our product or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. 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 is likely to result in a delay in our desired clinical and commercial timelines.

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

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

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

Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission 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 prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

IBSRELA and/or, if approved, 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.

Some participants in clinical studies of tenapanor have reported adverse effects after being treated with tenapanor, including diarrhea, abdominal distension, flatulence and dizziness. 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 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 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 (“MA”). Before the MA is granted, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain 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 may be 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 may be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate as a commercial organization include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;
- the federal Civil Monetary Penalties law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- the federal physician sunshine 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 United States 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.

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

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These new laws, among other things, included aggregate reductions of Medicare payments of 2% per fiscal year to providers that will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a 1% reduction from April 1, 2022 through June 30, 2022, unless additional action is taken by Congress, additional specific reductions in Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024. Recently, there has also been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. By way of example, the Build Back Better Act, if enacted, would introduce substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, and the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D. If the Build Back Better Act is not enacted, similar or other drug pricing proposals could appear in future legislation. Additionally, individual states have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and to encourage importation from other countries and bulk purchasing.

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

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

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

Federal law requires that a manufacturer that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program (the "340B program") in order for federal funds to be available for the manufacturer's drugs under Medicaid. We participate in the 340B program, which is administered by the Health Resources and Services Administration ("HRSA"), and requires us to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We will be 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 addition, legislation may be introduced that, if passed, would further expand the 340B program, such as adding further covered entities or requiring participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

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

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for IBSRELA, and 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. We cannot assure you 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 United States 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 United States 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 United States 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 United States 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 United States, the natural expiration of a utility patent is generally 20 years from the earliest effective non-provisional filing date. Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products or services. Patents, if issued, may be challenged, deemed unenforceable, invalidated, narrowed or circumvented. Proceedings challenging our patents or patent applications could result in either loss of the patent, or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Any successful challenge to our patents and patent applications could deprive us of exclusive rights necessary for our commercial success. In addition, defending such challenges in such proceedings may be costly. Thus, any patents that we may own may not provide the anticipated level of, or any, protection against competitors. Furthermore, an adverse decision may result in a third party receiving a patent right sought by us, which in turn could affect our ability to develop, manufacture or commercialize our products or technologies.

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

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

- Any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products or product candidates;
- Any of our pending patent applications will issue as patents;
- We were the first to make the inventions covered by each of our patents and pending patent applications;
- We were the first to file patent applications for these inventions;
- Others will not develop, manufacture and/or commercialize similar or alternative products or technologies that do not infringe our patents;
- Any of our challenged patents will be found to ultimately 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 United States or abroad. Such mechanisms include reexamination, post grant review, inter parties review, derivation or opposition proceedings before the United States Patent and Trademark Office (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 United States 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 our intellectual property related to IBSRELA, XPHOZAH, RDX013 or any future product candidates is not adequate or if we are not able to successfully enforce our intellectual property rights, the commercial value of IBSRELA, or our product candidates may be adversely affected and we may not be able to compete effectively in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States 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 successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. For example, U.S. patents can be challenged by any person before the new USPTO Patent Trial and Appeals Board at any time before one year after that person is served an infringement complaint based on the patents. Patents granted by the European Patent Office may be similarly opposed by any person within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in the United States, Europe and other jurisdictions third parties can raise questions of validity with a patent office even before a patent has granted. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our 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, XPHOZAH, RDX013 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. Further, we have reported that we have completed the data analysis from our Phase 2 clinical trial evaluating the safety and efficacy of RDX013 for the treatment of hyperkalemia, and that we currently expect that the next steps for the RDX013 program will be to evaluate a new formulation that potentially enhances subject compliance and the efficacy of RDX013 in an additional Phase 2 clinical study. We currently expect to delay further development of RDX013 until such time as we have determined that our available resources support conducting such additional formulation work and an additional clinical study. As a result of this delay in our development program for RDX013, the period of time during which we or our collaboration partners could market RDX013 under patent protection would be reduced.

Even where laws provide 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 and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-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 and unenforceability 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 and/or unenforceability against our intellectual property related to a product or a product candidate, we would lose at least part, and perhaps all, of the patent protection on such product or product candidate. Such a loss of patent protection would have a material adverse impact on our business. Moreover, our competitors could counterclaim that we infringe their intellectual property, and some of our competitors have substantially greater intellectual property portfolios than we do.

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, including APECCS, could require us to pursue legal action to protect our trade secrets and confidential information, which would 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 United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States 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.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for IBSRELA or our product candidates, our business may be materially harmed.

Following the approval by the FDA for our NDA to market tenapanor for IBS-C, we became eligible to seek and sought patent term restoration under the Hatch-Waxman Act for one of the U.S. patents covering our approved product or the use thereof. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. Despite seeking patent term extension for tenapanor or other product candidates, we may not be granted patent term extension either in the United States or 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 extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

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

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. 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.

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 United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

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

Many of our employees, consultants and contractors were previously employed at or engaged by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property and other proprietary information or know-how or trade secrets of others in their work for us, and do not perform work for us that is in conflict with their obligations to another employer or any other entity, we may be subject to claims that we or these employees, consultants and contractors have used or disclosed such intellectual property, including know-how, trade secrets or other proprietary information. In addition, an employee, advisor or consultant who performs work for us may have obligations to a third party that are in conflict with their obligations to us, and as a result such third party may claim an ownership interest in the intellectual property arising out of work performed for us. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending 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 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;
- the success or lack of success with regards to the Advisory Committee meeting convened as a part of our FDR related to our NDA seeking marketing approval for tenapanor for the Hyperphosphatemia Indication, and announcements of regulatory decisions regarding our NDA;
- announcements regarding any potential receipt from Nasdaq of notice regarding lack of compliance with the listing requirements of Nasdaq or a de-listing of our common stock;
- results of regulatory inspections of our facilities or those of our contract manufacturing organizations, or specific label restrictions or patient populations for XPHOZAH's use, if approved, or changes or delays in the regulatory review process;
- announcements regarding whether XPHOZAH, if approved, alone or with other oral only medications, will be included in the bundled prospective payment system for the treatment of ESRD patients, and the time and manner in which such transition is achieved;
- announcements relating to our current or future collaboration partnerships;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our product label, our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our approved products or our product candidates;
- the success of our testing and clinical trials;
- failure to meet any of our projected timelines or goals with regard to the commercial launch of IBSRELA, or the clinical development and commercialization of any of our product candidates;
- the success of our efforts to acquire or license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- the success of our efforts to obtain adequate intellectual property protection for our product candidates;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;

- FDA or other U.S. or foreign regulatory actions affecting us or our industry or other healthcare reform measures in the United States;
- 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 United States 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 would 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 will devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.

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

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002 ("Section 404") and the related rules of the Securities and Exchange Commission ("SEC") which 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 United States, presidential elections, other political influences and inflationary pressures. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including the current inflationary environment and rising interest rates. For example, the 2008 global financial crisis caused extreme volatility and disruptions in the capital and credit markets. 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 United States 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 person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnities, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Additionally, the terms of our loan and security agreements 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.

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the European Union and ratified a trade and cooperation agreement governing its future relationship with the European Union. The agreement, which is being applied provisionally from January 1, 2021, until it is ratified by the European Parliament and the Council of the European Union, addresses trade, economic arrangements, law enforcement, judicial cooperation and a governance framework including procedures for dispute resolution, among other things. Because the agreement merely sets forth a framework in many respects and will require complex additional bilateral negotiations between the United Kingdom and the European Union as both parties continue to work on the rules for implementation, significant political and economic uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal.

These developments, or the perception that any related developments could occur, have had and may continue to have a material adverse effect on global economic conditions and financial markets, and may significantly reduce global market liquidity, restrict the ability of key market participants to operate in certain financial markets or restrict our access to capital. Any of these factors could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our common stock.

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

Effective February 23, 2022, we entered into a loan and security agreement pursuant to which the Lenders agreed to provide us a loan facility for up to $50.0 million. Covenants in the loan and security agreement limit our ability to pay dividends or make other distributions. For additional information refer to "NOTE 8. BORROWING" in the notes to our condensed financial statements in Part I, Item 1, *Notes to Condensed Financial Statements*, of this Quarterly Report on Form 10-Q.

Unregistered Sales of Equity Securities

None.

Use of Proceeds

Not applicable.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

The 2022 Loan Agreement with SLR Investment Corp. provides us the right to borrow an additional $22.5 million on or prior to July 25, 2023; provided that (i) we have achieved certain product revenue milestone targets described in the 2022 Loan Agreement and (ii) that we have received approval by the FDA for our NDA for the Hyperphosphatemia Indication by a particular date. On August 1, 2022, we entered into an amendment to the 2022 Loan Agreement to extend the date for approval of our NDA for the Hyperphosphatemia Indication from December 31, 2022 to March 31, 2023.

ITEM 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.1†	Royalty and Sales Milestone Interest Acquisition Agreement dated June 29, 2022, by and between Ardelyx, Inc. and Healthcare Royalty Partners IV, L.P.				X
10.2	First Amendment to the Loan and Security Agreement dated August 1, 2022, by and between Ardelyx, Inc. and SLR Investment Corp.				X
10.3#	Second Amended and Restated Non-Employee Director Compensation Program				X
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following financial statements, formatted in Inline Extensible Business Reporting Language (XBRL): (i) Condensed Balance Sheets as of June 30, 2022 and December 31, 2021, (ii) Condensed Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2022 and 2021, (iii) Condensed Statements of Cash Flows for the three and six months ended June 30, 2022 and 2021, and (iv) Notes to Unaudited Condensed Financial Statements.				X
104	Cover Page Interactive Data File, formatted in Inline XBRL and contained in Exhibit 101.				

† 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 Securities and Exchange Commission upon request.

# Indicates management contract or management or non-employee director compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Ardelyx, Inc.

Date: August 4, 2022

By: /s/ Robert Felsch

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

Exhibit 10.1

Certain confidential information contained in this document, marked by [***], has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

EXECUTION COPY

ROYALTY AND SALES MILESTONE INTEREST ACQUISITION AGREEMENT

Dated as of June 29, 2022

between

Ardelyx, Inc.

and

HealthCare Royalty Partners IV, L.P.

TABLE OF CONTENTS

Certain confidential information contained in this document, marked by [***], has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

EXHIBITS

Exhibit A – License Agreement
Exhibit B – Form of Assignment

This **ROYALTY AND SALES MILESTONE INTEREST ACQUISITION AGREEMENT** is made and entered into as of June 29, 2022 by and between Ardelyx, Inc., a corporation organized under the laws of the State of Delaware, and HealthCare Royalty Partners IV, L.P., a limited partnership organized under the laws of the State of Delaware (this "Agreement").

RECITALS

WHEREAS, Seller (this and other capitalized terms used in these Recitals shall have the meanings provided in ARTICLE I below) and Kyowa Kirin Co., Ltd. (formerly known as Kyowa Hakko Kirin Co., Ltd.), a company organized under the laws of Japan, have entered into that certain License Agreement, dated as of November 27, 2017, with respect to the Product, a true, correct and complete copy of which, together with all amendments, supplements, restatements or other modifications thereto, is attached hereto as Exhibit A;

WHEREAS, pursuant to the License Agreement, subject to the terms and conditions set forth therein, Seller has been and remains entitled to receive the Royalty Interest; and

WHEREAS, Seller wishes to sell, assign, convey and transfer to Buyer, and Buyer wishes to accept the sale, assignment, conveyance, and transfer from Seller of, the right to receive all payments in respect of the Royalty Interest, upon and subject to the terms and conditions hereinafter set forth;

NOW, THEREFORE, in consideration of the mutual covenants, agreements representations and warranties set forth herein, the Parties agree as follows:

ARTICLE I

DEFINITIONS

Section 1.01. Definitions.

The following terms, as used herein, shall have the following meanings:

"Acquisition" means, with respect to Seller, the acquisition by any Person, in a single transaction or in a series of related transactions, of (a) assets of Seller which constitute all or substantially all of the assets of Seller, (b) at least a majority of the Voting Stock of Seller or (c) all of Seller's assets, rights and obligations regarding the Product or the Lead Licensed Compound, in each case whether or not involving a merger or consolidation with such other Person.

"Additional Patents" means the Patents listed in Exhibit C to the License Agreement, and any Patents issuing after the Effective Date in the Territory claiming priority to any such Patents listed on Exhibit C to the License Agreement.

"Affiliate" shall mean any Person that controls, is controlled by, or is under common control with another Person. For purposes of this definition, "control" shall mean (a) in the case of corporate entities, direct or indirect ownership of at least [***] of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct

or indirect ownership of at least [***] of the equity interest with the power to direct the management and policies of such non-corporate entities.

"Agreement" has the meaning given in the preamble hereto.

"Amendment Number 2 of the License Agreement" means Amendment Number 2 of the License Agreement, dated as of April 11, 2022, by and between Seller and the Licensee.

"API" means active pharmaceutical ingredient, which is also commonly referred to as drug substance. For the avoidance of doubt, API shall include any prodrug form.

"Ardelyx [***] Patents" means all Patents that [***] (i) inventions that [***] of a Licensed Compound or a Licensed Product, (ii) [***] for a Licensed Product or Licensed Compound, or (iii) [***] a Licensed Product in the Field. Ardelyx [***] Patents specifically excludes Excluded Patents.

"Ardelyx Controlled Patents" means, collectively, Licensed Patents, Ardelyx [***] Patents and Joint Patents, in each case, to the extent such Patents are subject to the License Agreement.

"Ardelyx Sole Invention Patent" means any Patent claiming Sole Program Know-How owned solely by Seller or its Affiliates, in each case, to the extent such Patents are subject to the License Agreement.

"Assignment" shall mean the Bill of Sale pursuant to which Seller shall assign, convey and transfer to Buyer, Seller's rights and interests in and to the Purchased Assets, which Bill of Sale shall be substantially in the form of Exhibit B.

"Back-up Manufacturing Agreement" means any separate manufacturing and supply agreement, between Seller and a contract manufacturing organization under which Seller acquires or intends to acquire API for delivery to Licensee under the Manufacturing and Supply Agreement for Development; Interim Commercial Supply Letter or Supply Agreement for Commercial, as may be amended, supplemented, restated or otherwise modified or replaced from time to time.

"Backup Licensed Compounds" means (i) any compound, other than the Lead Licensed Compound, that is claimed by the Compound Patent(s) and (ii) any [***] of any such compound described in clause (i) that Seller or its Affiliates may Develop during the term of the License Agreement.

"Bankruptcy Law" means Title 11 of the United States Code entitled "Bankruptcy" and all other liquidation, conservatorship, bankruptcy, assignment for the benefit of creditors, moratorium, rearrangement, receivership, insolvency, reorganization, or similar debtor relief laws of the United States or other applicable jurisdictions (domestic or foreign) from time to time in effect affecting the rights of creditors generally.

"Business Day" shall mean any day other than a Saturday, a Sunday, any day which is a legal holiday under the laws of the State of New York or in Japan, or any day on which banking institutions located in the State of New York or in Japan are required by law or other governmental action to close.

"Buyer" shall mean HealthCare Royalty Partners IV, L.P., a limited partnership organized under the laws of the State of Delaware.

"Buyer Indemnified Party" shall mean each of Buyer and its Affiliates and any of their respective partners, directors, managers, members, officers, employees and agents.

"Capital Stock" of any Person shall mean any and all shares, interests, ownership interest units, rights to purchase, warrants, options, participations or other equivalents of or interests in (however designated) equity of such Person, including any preferred stock, but excluding any debt securities convertible into such equity.

"Claim" shall mean any claim, demand, action or proceeding (including any investigation by any Governmental Authority).

"Clinical Trials" means any clinical study of a pharmaceutical product on human subjects to assess the dosing, safety and/or efficacy of such pharmaceutical product, including but not limited to phase 1 clinical trials, phase 2 clinical trials and phase 3 clinical trials and, if imposed by the Regulatory Authorities as a condition to Regulatory Approval, phase 4 clinical trials. For the avoidance of doubt, post-marketing surveillance clinical studies are not Clinical Trials.

"Closing" has the meaning set forth in Section 6.01(a).

"Closing Amount" shall mean $10,000,000.

"Closing Date" shall mean the date of this Agreement, which is the date all of the conditions set forth in ARTICLE VI are fulfilled or waived in writing by the applicable Party, as set forth in such ARTICLE VI.

"Collateral" has the meaning set forth in Section 2.01(b).

"Combination Product" means any prescription pharmaceutical product which comprises two (2) or more APIs, at least one (1) of which is the Lead Licensed Compound, that is sold either as a fixed dose or as separate doses in a single package.

"Commercialization" or "Commercialize" means, with respect to a Product or a Combination Product, any and all activities directed to the marketing, promotion, distribution, offering for sale, and sale of such Product or Combination Product in the Territory, and interacting with Regulatory Authorities regarding the foregoing.

"Commercially Reasonable Efforts" means, with respect to the efforts to be expended, or considerations to be undertaken, by [***].

"Competitive Product" shall mean any [***].

"Competitor" shall have the meaning provide in Schedule 8.03.

"Compound Patents" means the Patents listed in Exhibit B to the License Agreement, and any Patents issuing after the Effective Date in the Territory claiming priority to any such Patents listed on Exhibit B to the License Agreement.

"Confidential Information" means any and all information, whether communicated orally or in any physical form, including without limitation, financial and all other information which Disclosing Party or its authorized Representatives provide to the Receiving Party, together with such portions of analyses, compilations, studies, or other documents, prepared by or for the Receiving Party and its Representatives, which contain or are derived from information provided by Disclosing Party, and shall include the terms of the Transaction Documents. Without limiting the foregoing, information shall be deemed to be provided by Disclosing Party to the extent it is learned or derived by Receiving Party or Receiving Party's Representatives (a) from any inspection, examination or other review of books, records, contracts, other documentation or operations of Disclosing Party, (b) from communications with authorized Representatives of Disclosing Party or (c) created, developed, gathered, prepared or otherwise derived by Receiving Party while in discussions with Disclosing Party. However, Confidential Information does not include any information which Receiving Party can demonstrate (i) is or becomes part of the public domain through no fault of Receiving Party or its Representatives, (ii) was known by Receiving Party on a non-confidential basis prior to disclosure, or (iii) was independently developed by Persons who were not given access to the Confidential Information disclosed to Receiving Party by Disclosing Party. For the avoidance of doubt, Confidential Information shall include all Evaluation Material (as defined in the Confidentiality Agreement) previously disclosed by Seller to Buyer under the Confidentiality Agreement.

"Confidentiality Agreement" means that certain Confidentiality Agreement by and between HealthCare Royalty Management, LLC and Seller, dated as of December 7, 2020.

"Contract" shall mean any agreement, contract, obligation, or undertaking.

"Control" means, with respect to an item of Know-How, Patent or other Intellectual Property Rights, the ability and authority of a Party or its Affiliates, whether arising by ownership, possession, or pursuant to a license or sublicense, to grant licenses, sublicenses, or other rights to the other Party under or to such item of Know-How, Patent or Intellectual Property Rights as provided for in the License Agreement without breaching the terms of any agreement between such Party and any Third Party.

"Deposit Agreement" means the deposit account control agreement entered into by the Depositary Bank, Buyer and the Seller, which shall be in form and substance reasonably acceptable to Buyer and Seller, as amended, supplemented or otherwise modified from time to time and any replacements thereof.

"Depositary Bank" means such bank or other financial institution approved by Buyer and Seller, including any successor Depositary Bank appointed pursuant to Section 2.05.

"Development" means all internal and external research, development and regulatory activities regarding a Lead Licensed Compound and Product, as the case may be. This includes (a) research, preclinical testing, toxicology, route of synthesis, non-clinical activities, formulation and clinical studies of a Lead Licensed Compound and a Product; and (b) preparation, submission, review, and development of data or information for the purpose of submission to a governmental authority to obtain authorization to conduct Clinical Trials and Regulatory Approval of a Product. "Development" shall include development and regulatory activities for additional forms, formulations, or indications for a Product after Regulatory Approval of such Product, including clinical trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after a Regulatory Approval which was mandated by the

applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved indication. "Develop", "Developing" and "Developed" shall be construed accordingly.

"Development Quality Assurance Agreement" means that certain Quality Agreement, dated as of June 10, 2020, by and between the Seller and Licensee, as may be amended, supplemented, restated or otherwise modified or replaced from time to time.

"Disclosing Party" means, with respect to any Confidential Information, the Party disclosing the Confidential Information to the other Party.

"Dispute" shall mean any opposition, interference proceeding, reexamination proceeding, cancellation proceeding, re-issue proceeding, invalidation proceeding, inter parties review proceeding, injunction, claim, lawsuit, proceeding, hearing, investigation, complaint, arbitration, mediation, demand, decree, dispute or disagreement; provided, however, that Dispute shall not include any exchanges between Seller and/or Licensee and the Japan Patent Office relating to the examination of patent applications included in the Ardelyx Controlled Patents or the Licensee Controlled Patents.

"Effective Date" means November 27, 2017.

"Event of Default" means the occurrence of one or more of the following:

(a) any [***];

(b) Seller fails to [***];

(c) Seller fails to[***];

(d) Seller shall be in breach of or in default under [***], and such breach or default would reasonably be likely to cause a Material Adverse Effect;

(e) the occurrence of a [***]; or

(f) the occurrence of [***].

"Exchange Act" means the Securities Exchange Act of 1934 and the regulations promulgated thereunder.

"Excluded Liabilities and Obligations" means each liability or obligation of Seller or any of its Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter, whether known or unknown, and whether under the License Agreement, any Production Agreement, any Transaction Document or otherwise.

"Excluded Patents" means any Patents claiming aspects of Seller's proprietary platform technology known as Ardelyx Primary Enterocyte and Colonocyte Culture System.

"Excluded Taxes" has the meaning set forth in Section 8.05(e).

"Exploit" shall mean, with respect to a product such as the Product, the manufacture, use, sale, offer for sale (including marketing and promotion), importation, distribution or other commercialization; and "Exploitation" shall have the correlative meaning.

"Field" means the treatment of any cardiorenal diseases and conditions, but excluding cancer.

"Governmental Authority" shall mean any government, court, regulatory or administrative agency or commission, or other governmental authority, agency or instrumentality, whether foreign, federal, state or local, including any applicable Patent Office or any other government authority in any country. For the avoidance of doubt, Governmental Authorities include Regulatory Authorities.

"Indebtedness" of any Person means any indebtedness for borrowed money, obligation evidenced by a note, bond, debenture or similar instrument, or guarantee of any of the foregoing.

"Indemnified Taxes" has the meaning set forth in Section 8.05(e).

"Indemnity Threshold Amount" means [***].

"Insolvency Event" shall mean the occurrence of any of the following with respect to Seller:

a) (i) an involuntary proceeding shall be commenced or an involuntary petition shall be filed in a court of competent jurisdiction seeking (x) relief in respect of Seller or any material Subsidiary, or of a material part of the property of Seller or any material Subsidiary, under any Bankruptcy Law now or hereafter in effect, (y) the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for Seller or any material Subsidiary or for a material part of the property of Seller or any material Subsidiary or (z) the winding-up or liquidation of Seller or any Subsidiary, which proceeding or petition shall continue undismissed for 60 calendar days or (ii) an order of a court of competent jurisdiction approving or ordering any of the foregoing shall be entered;

b) Seller or any material Subsidiary shall (i) voluntarily commence any proceeding or file any petition seeking relief under any Bankruptcy Law now or hereafter in effect, (ii) apply for the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for Seller or any material Subsidiary or for a material part of the property of Seller or any material Subsidiary, (iii) fail to contest in a timely and appropriate manner any proceeding or the filing of any petition described in clause (a) of this definition, (iv) file an answer admitting the material allegations of a petition filed against it in any proceeding described in clause (i) of this definition, (v) make a general assignment for the benefit of creditors or (vi) wind up or liquidate (except as permitted under this Agreement);

c) Seller or any material Subsidiary shall take any action in furtherance of or for the purpose of effecting, or indicating its consent to, approval of, or acquiescence in, any of the acts set forth in clause (a) or (b) of this definition; or

d) Seller or any material Subsidiary shall become unable, admit in writing its inability, or fail generally, to pay its debts as they become due.

"Instruction to Payor" has the meaning set forth in Section 2.05(a).

"Intellectual Property Rights" means Patents, Trademarks, service marks, Know-How, trade names, registered designs, design rights, copyrights (including rights in computer software), domain names, database rights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.

"Interim Commercial Supply Letter" means that separate letter agreement entered into between Seller and Licensee as of March 4, 2021, as may be amended, supplemented, restated or otherwise modified or replaced from time to time.

"Investment Payment" has the meaning set forth in Section 2.03(b)(i).

"Investment Payment Conditions" shall mean (a) Buyer has received notice in accordance with Section 8.02 evidencing the achievement specified in Section 2.03(b)(i) with respect to the related Investment Payment, (b) Seller shall have complied in all material respects with its material covenants and obligations hereunder and under the Transaction Documents, (c) no Material Adverse Effect has occurred, (d) with respect to the Investment Payment described in Section 2.03(b)(i)(A) only, the representations and warranties made by Seller in ARTICLE III will be true as of the date of such Investment Payment, unless any of Schedules 3.03, 3.08(g), 3.08(n), 3.14(a), 3.14(b), 3.15(c), 3.15(e), 3.15(f), 3.15(p), 3.15(q), 3.15(r) or 3.15(t) have been amended or supplemented since the Closing Date, and such amendment or supplement to such Schedule could reasonably be expected to have a Material Adverse Effect, and (e) there is no event or circumstance that, upon notice or the passage of time, or both, would constitute or give rise to any breach or default in the performance of the Seller under this Agreement.

"Investment Return Amount" means [***].

"Joint Know-How" means any inventions and Know-How that are invented jointly by employees or independent contractors of Seller or Licensee.

"Joint Patent" means any Patent claiming any invention within the Joint Know-How.

"Know-How" means all inventions, discoveries, data, information (including scientific, technical or regulatory information), trade secrets, processes, means, methods, practices, formulae, instructions, procedures, techniques, materials, technology, results, analyses, designs, drawings, computer programs, apparatuses, specifications, technical assistance, laboratory, nonclinical and clinical data (including laboratory notes and notebooks), and other material or know-how, in written, electronic or any other form, whether or not confidential, proprietary or patentable, including without limitation: development technology; biology, chemistry, pharmacology, toxicology, drug stability, Manufacturing and formulation, test procedures, synthesis, purification and isolation techniques, quality control data and information, methodologies and techniques; information regarding clinical and nonclinical safety and efficacy studies, including study designs and protocols, marketing studies, absorption, distribution, metabolism and excretion studies; assays and biological methodology.

"Knowledge of Seller" shall mean, with respect to Seller, as applicable, the knowledge of [***] and any successors to such persons with similar responsibilities, regardless of title, relating to a particular matter without any obligation to inquire or otherwise investigate relating to a

particular matter; provided, however, that such persons shall be deemed to have knowledge, if, in the prudent exercise of his or her duties and responsibilities in the ordinary course of business, such person should have known of such matter.

"Law" shall mean, collectively, all U.S. or non-U.S. federal, state, provincial, territorial, municipal or local statute, treaty, rule, regulation, ordinance, code or administrative or judicial precedent or authority, and all applicable administrative orders, directed duties, requests, licenses, authorizations and permits of, and agreements with, any Governmental Authority (including any Regulatory Authority), or any similar provision having the force or effect of law.

"Lead Licensed Compound" means the compound tenapanor, as further described on Exhibit A to the License Agreement, and any [***] of such compound.

"License Agreement" shall mean that certain License Agreement, dated as of November 27, 2017, by and between Seller, as licensor, and Licensee, as licensee, with respect to the Product, as amended by Amendment Number 1 of the License Agreement dated June 23, 2020, and Amendment Number 2 of the License Agreement, and as may be amended, supplemented, restated or otherwise modified from time to time, subject to Buyer's rights under Section 5.07(e).

"License Termination" means the termination of the License Agreement under Section 11.02, Section 11.03 or Section 11.04 of the License Agreement.

"Licensed Compounds" means the Lead Licensed Compound and any and all Backup Licensed Compounds.

"Licensed Patents" means (a) the Compound Patents, (b) the Additional Patents, and (c) all Ardelyx Sole Invention Patents; provided that in the case of (b) and (c) above, such Patents claim any inventions necessary or useful for the Exploitation of the Licensed Compounds and/or Licensed Products pursuant to the terms and conditions of the License Agreement. Licensed Patents exclude Ardelyx [***] Patents and the Excluded Patents.

"Licensed Product" means any and all pharmaceutical preparations, compositions and formulations in forms suitable for human applications containing a Licensed Compound as an active ingredient.

"Licensee" shall mean Kyowa Kirin Co., Ltd. (formerly known as Kyowa Hakko Kirin Co., Ltd.), a company organized under the laws of Japan.

"Licensee [***] Patents" means all Patents (a) that [***]; provided, that, such Patents claim (i) inventions that [***] a Licensed Compound or a Licensed Product, (ii) [***] for a Licensed Product or Licensed Compound, or (iii) is [***] a Licensed Product.

"Licensee Controlled Patents" means, collectively, Licensee Sole Invention Patents and Licensee [***] Patents.

"Licensee Instruction" shall mean the written instruction from Seller to Licensee, substantially in the form set forth in Exhibit C.

"Licensee Sole Invention Patent" means any Patent claiming Sole Program Know-How owned solely by Licensee to the extent such Patents are subject to the License Agreement.

"Liens" shall mean any lien, hypothecation, charge, security agreement, security interest, mortgage, pledge or any other encumbrance, right or claim of any Person of any kind whatsoever whether choate or inchoate, filed or unfiled, noticed or unnoticed, recorded or unrecorded, contingent or non-contingent, material or non-material, known or unknown.

"Lockbox Account" means the "deposit account" (as defined in Article 9 of the UCC), investment account or other account in which funds are held or invested to or for the credit or account of any Party, established and maintained at any Depositary Bank solely for the purpose of receiving remittance of Royalty Interest Payments and disbursement thereof as provided herein, and any successor Lockbox Account entered into in accordance with Section 2.05.

"Losses" means any and all direct or indirect liabilities, claims, actions, damages, losses or expenses, including interest, penalties, and reasonable lawyers' fees and disbursements. In calculating Losses, the legal duty to mitigate on the part of the Party suffering the Loss shall be taken into account.

"Manufacture" or "Manufacturing" means activities in connection with the synthesis, manufacture, processing, formulating, testing (including, without limitation quality control, quality assurance, lot release testing, and development of any relevant analytical methods), bulk packaging or storage and delivery of Licensed Compound or Licensed Product.

"Manufacturing and Supply Agreement for Development" means that separate manufacturing and supply agreement effective as of April 9, 2018 between Seller and Licensee, as amended, supplemented, restated or otherwise modified from time to time.

"Material Adverse Effect" shall mean [***].

"Milestone Payments" means any amounts due, paid or payable for achievement of the Milestones, including any interest payable pursuant to Section 6.03 of the License Agreement, without any deduction or set-off of any kind, including any deduction or set-off under the License Agreement.

"Milestones" means the sales related milestones captioned as "Milestone Payment[s]" pursuant to Section 6.03(a) of the License Agreement.

"Net Sales" has the meaning set forth in the License Agreement (whether or not the License Agreement remains in effect).

"New Arrangement" has the meaning set forth in Section 5.02(b).

"Party" shall mean Seller or Buyer as the context indicates and "Parties" shall mean Seller and Buyer.

"Patent Office" shall mean the respective patent office in any jurisdiction, including the United States Patent and Trademark Office, the European Patent Organisation, the Japan Patent Office and any comparable foreign patent office, for any Ardelyx Controlled Patents or Licensee Controlled Patents.

"Patents" shall mean (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either

from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)), and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

"Permitted Liens" shall mean the Liens described on Schedule 1.01 hereto.

"Person" means any individual, sole proprietorship, corporation, partnership, association, joint-stock company, trust, unincorporated organization, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

"PMDA" means the Pharmaceuticals and Medical Devices Agency in Japan or any successor thereto.

"Product" shall mean any pharmaceutical product, drug product, preparation, formulation or dosage form that has the Lead Licensed Compound as at least one API.

"Production Agreements" means each of the Back-Up Manufacturing Agreement, the Manufacturing and Supply Development Agreement, the Interim Commercial Supply Letter and the Development Quality Assurance Agreement as may be amended, supplemented, restated or otherwise modified or replaced from time to time.

"Purchased Assets" shall mean (a) the Royalty Interest and (b) all proceeds (as defined under the UCC) of any of the foregoing.

"Receiving Party" means, with respect to any Confidential Information disclosed by a Party hereto, the other Party which is receiving such Confidential Information.

"Regulatory Approval" means any and all approvals (including without limitation pricing and reimbursement approvals), product or establishment licenses, registrations, or authorizations of any regional, federal, state, or local Regulatory Health Authority, department, bureau, or other governmental entity, necessary to commercially distribute, sell or market a Licensed Product in a regulatory jurisdiction, including, where applicable, (a) pricing or reimbursement approval in such jurisdiction, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), (c) labeling approval and (d) technical, medical and scientific licenses.

"Regulatory Authority" means any court or government body, whether national, supra-national, federal, state, local, foreign or provincial, including any political subdivision thereof, including any department, commission, board, bureau, agency, or other regulatory or administrative governmental authority or instrumentality, and further including any quasi-governmental Person or entity exercising the functions of any of these.

"Regulatory Health Authority" means any applicable national (for example the PMDA), supra-national, regional, state, provincial or local regulatory health authority, department, bureau, commission, council, or other government entity regulating or otherwise exercising authority with respect to the Exploitation of Licensed Compounds or Licensed Products in the Territory pursuant to the terms and conditions of the License Agreement, including any such entity involved in the granting of Regulatory Approval for pharmaceutical products.

"Representative" means, with respect to any Person, directors, officers, employees, agents, co-investors, advisors, potential investors, underwriters, rating agencies, permitted assignees, transferees or successors-in-interest, sources of financing and trustees of such Person (other than competitors of Buyer and its Affiliates).

"Royalties" means (a) any amounts due, paid or payable to Seller pursuant to Section 6.04 of the License Agreement on and after the Closing Date and (b) any amounts payable to Seller as a result of Net Sales of the Licensed Product in the Field and in the Territory pursuant to any New Arrangement; provided, that the amount due to Buyer under any New Arrangement shall not exceed the amount that would have been due Buyer under Section 6.04 and 6.03(a) of the License Agreement, in each case of clauses (a) and (b), without any deduction or set-off of any kind, other than as set forth in clause (b). Without limiting the foregoing, if the License Agreement is terminated and Seller or its Affiliates Commercialize the Product in the Territory pursuant to Section 5.02(b), any amounts received by or on behalf of Seller or its Affiliates (or its or their licensees) for such Commercialization less any such amounts that are allocated to the cost of manufacturing and supplying the Product, or which are intended to reimburse Seller, its Affiliates or licensees for expenses incurred outside of the scope of the calculation of Net Sales, which are itemized by Seller in each royalty report to the extent such expenses are being taken as a deduction from net sales for which royalties are payable, shall be treated as "Net Sales" subject to the same royalty rate set forth in Section 6.04 of the License Agreement, and the product of such net sales times such royalty rate shall be Royalties hereunder.

"Royalty Interest" shall mean (a) the Royalties, (b) the Milestone Payments arising after the Closing Date, (c) any payments made in lieu of the Royalties or the Milestone Payments or in satisfaction of the obligation to pay the Royalties or the Milestone Payments, including any amounts payable to Buyer pursuant to Section 5.16 in satisfaction of the obligation to pay Royalties or the Milestone Payments; provided, that (i) such amounts payable under this subsection (c) as a result of enforcement of the License Agreement pursuant to Section 5.16 shall include any damages, penalties, fees or expenses payable in connection with the enforcement of the License Agreement pursuant to Section 5.16, to the extent such damages, penalties, fees or expenses relate to amounts otherwise due under Sections 6.03 or 6.04 of the License Agreement, and (ii) the amounts due under this subsection (c) shall not include duplication of any corresponding Royalty Interest Payments or Milestone Payments, and (d) all amounts payable by Licensee (or other licensee pursuant to a New Arrangement) pursuant to Section 365(n) of the Bankruptcy Law in the event of rejection of the License Agreement (or other licensee agreement pursuant to a New Arrangement). For the avoidance of doubt, the Royalty Interest shall not include the Excluded Liabilities and Obligations.

"Royalty Interest Payment" shall mean the payment of the Royalty Interest.

"Royalty Reports" means, with respect to each calendar quarter, the report (including any certifications in respect thereof) required to be prepared and delivered pursuant to Section 6.07 of the License Agreement.

"SEC" means the U.S. Securities and Exchange Commission.

"Seller" shall mean Ardelyx, Inc., a corporation organized under the laws of the State of Delaware.

"Seller Indemnified Party" shall mean each of Seller, its Affiliates and any of their respective partners, directors, managers, officers, employees and agents.

"Set-Off" means any right of set-off, counterclaim, credit, reduction or deduction by contract or otherwise.

"Sole Program Know-How" means all inventions and other Know-How invented by employees or independent contractors of Seller or Licensee in such Party's performance of the License Agreement.

"Sublicensee" means any Person that is not a distributor or an Affiliate of the Licensee who is granted a sublicense under the License Agreement by the Licensee or its Affiliate.

"Subsidiary" means, with respect to any Person, at any time, any entity of which more than fifty percent (50%) of the outstanding Voting Stock or other equity interest entitled ordinarily to vote in the election of the directors or other governing body (however designated) is at the time beneficially owned or controlled directly or indirectly by such Person, by one or more such entities or by such Person and one or more such entities. Unless otherwise indicated herein, "Subsidiary" shall refer a "Subsidiary" of Seller.

"Supply Agreement for Commercial" means that separate manufacturing and supply agreement, between Seller and the Licensee to be entered into pursuant to Section 5.01(c) of the License Agreement, providing for the manufacture of the Lead Licensed Compound and Product, as may be amended, supplemented, restated or otherwise modified or replaced from time to time.

"Termination Date" has the meaning set forth in Section 7.01.

"Territory" shall mean Japan.

"Third Party" shall mean any Person other than Seller or Buyer or their respective Affiliates.

"Third Party Patent Rights" shall mean, with respect to any Third Party, any and all issued patents and pending patent applications as of the date of this Agreement, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, and renewals, all letters patent granted thereon, and all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms (including regulatory extensions), and all supplementary protection certificates, together with any foreign counterparts thereof anywhere in the world, of such Third Party.

"Trademark" means any registered trademark, application for registration thereof, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

"Transaction Documents" shall mean, collectively, this Agreement, the Assignment, the Deposit Agreement and the Instruction to Payor.

"UCC" shall mean the Uniform Commercial Code (or any similar or equivalent legislation) as in effect in any applicable jurisdiction.

"Use" shall include the use, manufacture, marketing, sale, offer for sale, importation, distribution or commercialization.

"Voting Stock" shall mean Capital Stock issued by a company, or equivalent interests in any other Person, the holders of which are ordinarily, in the absence of contingencies, entitled to vote for the election of directors (or persons performing similar functions) of such Person, even if the right so to vote has been suspended by the happening of such contingency.

ARTICLE II

ASSIGNMENT OF THE PURCHASED ASSETS

Section 1.01. Assignment.

(a) Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, Seller shall assign, transfer and convey to Buyer, free and clear of all Liens (other than any Permitted Liens or Liens in favor of Buyer) and subject to the conditions set forth in ARTICLE VI and the other provisions of this Agreement, the Purchased Assets, and Buyer shall accept such assignment, transfer and conveyance from Seller. Such assignment, transfer and conveyance shall be evidenced by the execution and delivery of the Assignment by Seller in accordance with Section 6.02.

(b) It is the intention of the Parties hereto that the assignment, transfer and conveyance contemplated by this Agreement be, and is, a true, complete, absolute and irrevocable assignment, transfer and conveyance by Seller to Buyer of all of Seller's right, title and interest in and to the Purchased Assets, free and clear of all Liens (other than any Liens in favor of Buyer). Neither Seller nor Buyer intends the transactions contemplated by this Agreement to be, for any purpose (other than financial accounting purposes), characterized as a loan from Buyer to Seller or a pledge, a security interest, a financing transaction or a borrowing. Each of Seller and Buyer hereby waives, to the maximum extent permitted by applicable Law, subject to Section 2.02, any right to contest or otherwise assert that this Agreement does not constitute a true, complete, absolute and irrevocable assignment, transfer and conveyance by Seller to Buyer of all of Seller's right, title and interest in and to the Purchased Assets under applicable Law, which waiver shall, to the maximum extent permitted by applicable Law, be enforceable against Seller in any bankruptcy or insolvency proceeding relating to Seller. Not in derogation of the foregoing statement of the intent of the Parties hereto in this regard and for the purposes of providing additional assurance to Buyer (i) Seller does hereby grant to Buyer as security for the payment of amounts to Buyer equal to the Royalty Interests as they become due and payable, a security interest in and to (x) all right, title and interest of Seller, in, to and under the Royalty Interests; and (y) any "proceeds" (as such term is defined in the UCC) of the items set forth

in clauses (x) and (y) hereof (collectively, the "Collateral"), and Seller does hereby authorize Buyer, from and after the Closing, to file such financing statements (and continuation statements with respect to such financing statements when applicable) in such manner and such jurisdictions as are necessary or appropriate to perfect such security interest and (ii) upon the occurrence of the Termination Date, Buyer shall, at the sole cost and expense of Seller, release its Liens in the Collateral (and execute and deliver any termination or release documents reasonably requested by Seller in connection therewith) and all rights, title and interests, in, to and under the Collateral shall revert to Seller. Notwithstanding the foregoing, the Collateral does not include rights held under a license or other agreement that are not assignable by their terms without the consent of the licensor or counterparty thereof (but only to the extent such restriction on assignment is effective under Section 9-406, 9-407, 9-408 or 9-409 of the UCC (or any successor provision or provisions) of any relevant jurisdiction or any other applicable law (including the Bankruptcy Code) or principles of equity).

Section 1.02. Royalty Interest Payments.

(c) Effective as of the execution and delivery of the Assignment at the Closing and subject to the terms of Section 2.04, Seller and Buyer agree that Buyer shall have all right, title, interest in and to the Purchased Assets, and is entitled to receive all Royalty Interest Payments payable to Seller under the License Agreement.

(d) [reserved]

(e) Buyer shall be entitled to receive 100% of the Royalty Interest Payments from the Closing Date through the Termination Date.

Section 1.01. Payments to Seller.

(f) Subject to the terms and conditions set forth herein, Buyer shall pay Seller the Closing Amount by wire transfer of immediately available funds as directed by Seller promptly at the Closing, but in any event, within one (1) Business Day of the Closing Date.

(g) Investment Payments.

(i) Following the Closing, Buyer shall, subject to the conditions set forth below and subject to Section 2.03(b)(iii), make the following one-time payments (each, an "Investment Payment") to Seller:

(A) upon approval of a new drug application for the Lead Licensed Compound for application in the Field by the PMDA, Buyer shall make a payment to Seller of $5,000,000; and

(B) a payment to Seller of $5,000,000 if Licensee's Net Sales exceed [***] for the calendar year 2025.

(i) The Investment Payment provided in Section 2.03(b)(i)(A) shall be due and payable promptly, but in any event within ten (10) Business Days after the date that the Investment Payment Conditions for such Investment Payment have been met, by wire transfer of immediately available funds as directed by Seller. Buyer agrees to retain in the Lockbox Account any Royalty Interest Payments paid to Seller from Licensee in the first quarter of 2026 relating to Licensee achieving the Net Sales milestone set forth in Section 2.03(b)(i)(B). Upon deposit of such amounts, Buyer shall direct the Depository Bank to pay to Seller the Investment Payment then due Seller pursuant to Section 2.03(b)(i)(B) within five (5) Business Days of the date on which the related Investment Payment Condition has been met. In the event amounts deposited into the Lockbox Account are insufficient to pay the full amount of such Investment Payment, Buyer shall direct the Depository Bank to pay any subsequent deposits into the Lockbox Account to Seller, to be applied towards such Investment Payment Amount, until the aggregate amounts so paid to Seller equal $5,000,000. If such Investment Payment is not earned by Seller for the calendar year 2025, Buyer may direct the Depository Bank to pay Royalty Interests Payments on deposit in the Lockbox Account to Buyer.

(ii) Buyer shall have the right to deduct from any Investment Payment the amount of any Losses resulting from Seller's breach of any representation or warranty set forth in ARTICLE III as of the date on which such representation or warranty is made or any covenant set forth in ARTICLE V in accordance with this Section 2.03(b). In the event that Buyer makes a good faith determination that it is entitled to Set-Off (and of the amount thereof) from any Investment Payment, Buyer shall notify Seller, in reasonable detail, of the basis of Buyer's claim to a right of Set-Off (and the amount thereof) within thirty (30) days after the date that the Investment Payment Conditions for such Investment Payment have been met. In the event that Seller disagrees, either with respect to the basis of the claim or the amount in controversy, then such dispute shall be escalated to the senior leadership of the Parties for resolution in good faith (which senior leadership shall be the Chief Executive Officer of Seller and the Chief Executive Officer of Buyer), within thirty (30) days of the date on which such dispute is referred to them If the senior leadership, notwithstanding their good faith efforts, is unable to resolve such dispute within such thirty (30) day period, then Buyer may make such Set-Off. For the avoidance of doubt, (a) Buyer's exercise of the foregoing right of Set-Off will not limit Buyer's right to pursue any other available remedies in law or equity, including as set forth in Section 8.04 and (b) Seller retains its right to challenge such Set-Off and does not waive its right, nor shall its right be limited by this Section 2.03 to pursue any remedy in law or equity. The prevailing party in the final resolution of any dispute regarding such Set-Off will be entitled to recover from the other party all of its reasonable and documented out-of-pocket costs and expenses arising from such proceedings (including attorneys' fees incurred both before and through the completion of such proceedings).

Section 1.01. No Assumption.

Notwithstanding any provision in this Agreement or any other Transaction Document or writing to the contrary, subject to Section 2.02, Buyer is accepting the purchase and assignment of only the Purchased Assets and is not assuming any Excluded Liabilities and Obligations. All Excluded Liabilities and Obligations shall be retained by and remain obligations and liabilities solely of Seller or its Affiliates.

Section 1.02. Lockbox Account

(a) Seller shall, on or prior to the date that is sixty (60) days following the Closing, enter into a Deposit Agreement with the Depositary Bank with respect to the Lockbox Account. Seller shall deliver instructions to Licensee (the "Instruction to Payor") with respect to any Royalty Interest Payments (which instruction shall be in form and substance reasonably satisfactory to Buyer) to remit such Royalty Interest Payments to the Lockbox Account. To the extent any such Royalty Interest Payments are paid directly to Seller, Seller shall remit to Buyer all such amounts within fifteen (15) Business Days of Knowledge of Seller of such receipt of any such funds.

(b) Buyer shall have the right to exercise all of its rights and remedies under this Agreement including, without limitation, directing the Depositary Bank to transfer all of the funds in the Lockbox Account to Buyer.

(c) Seller shall have no right to terminate the Lockbox Account without Buyer's prior written consent; provided that, without Buyer's consent to the change of location of such accounts (provided such location is in the United States), Seller shall have the right from time to time to establish a replacement Lockbox Account with a replacement Depositary Bank, provided that such replacement Depositary Bank entered into a Deposit Agreement with respect to such replacement accounts effective no later than the date of replacement. For purposes of this Agreement, any reference to the "Lockbox Account", "Depositary Bank" and "Deposit Agreement" shall refer to such replacement Lockbox Account, Depositary Bank, or Deposit Agreement, as the context requires.

ARTICLE III

REPRESENTATIONS AND WARRANTIES OF SELLER

Seller hereby represents and warrants to Buyer that the following representations are true and complete as of the Closing Date and with respect to those representations and warranties that reference a Schedule, subject to such Schedule as amended and updated by Seller (with a copy of such amendment or update to Buyer) as of the date such representation and warranty is being made as of:

Section 1.02. Organization.

Each of Seller and its Subsidiaries are duly organized and validly existing and in good standing under the laws of its and their respective jurisdictions of formation. Each of Seller and its Subsidiaries have all corporate powers and all licenses, authorizations, consents and approvals

required to carry on its and their business as now conducted and as proposed to be conducted in connection with the transactions contemplated by the Transaction Documents and the License Agreement, except where the failure to be so licensed, authorized or qualified has not and would not reasonably be expected to have a Material Adverse Effect. Each of Seller and its Subsidiaries is duly qualified to do business and is in good standing in every jurisdiction in which the failure to so qualify or be in good standing would result in a Material Adverse Effect. Seller has no Subsidiaries, other than those listed in Schedule 3.01, with the jurisdiction of formation listed after the name of each such Subsidiary.

Section 1.03. Authorizations; Enforceability.

(a) Seller has all necessary corporate power and authority to enter into, execute and deliver this Agreement and the other Transaction Documents and to perform all of the obligations to be performed by it hereunder and thereunder and to consummate the transactions contemplated hereunder and thereunder. None of the execution and delivery by Seller of the Transaction Documents, the performance by Seller of any of the obligations to be performed by it hereunder or thereunder, or the consummation by Seller of any of the transactions contemplated hereby or thereby, will require any notice to, action, approval or consent by, or in respect of, or filing or registration with, any Governmental Authority or other Person, except those that have already been obtained and copies of which have been provided to Buyer, and filings necessary to perfect Liens created by the Transaction Documents.

(b) Once signed, the Transaction Documents will have been duly authorized, executed and delivered by Seller and each Transaction Document will then constitute the valid and binding obligation of Seller, enforceable against Seller in accordance with their respective terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or general equitable principles.

Section 1.03. Litigation.

Schedule 3.03 sets forth each (i) Dispute pending or, to the Knowledge of Seller, threatened against Seller or its Subsidiaries, (ii) inquiry of any Governmental Authority pending or, to the Knowledge of Seller, threatened against Seller or its Subsidiaries, or (iii) to the Knowledge of Seller with respect to the following clauses (x) and (y), (x) Dispute pending or threatened against Licensee, or (y) inquiry of any Governmental Authority pending or threatened against Licensee which, in each instance of clauses (i), (ii) and (iii), if adversely determined, whether individually or in the aggregate, could reasonably be expected to have a Material Adverse Effect.

Section 1.04. Compliance with Laws.

Seller and its Subsidiaries are not in material violation of, and have not materially violated any, applicable Law, judgment, order, writ, decree, permit or license entered by any Governmental Authority and, to the Knowledge of Seller, are not under investigation with respect to any applicable Law, and have not been threatened in writing to be charged with, or been given written notice of any, material violation of any applicable Law relating to the Product or the License Agreement. Except as would not, whether individually or in the aggregate,

reasonably be expected to have a Material Adverse Effect, Seller and its Subsidiaries are not in violation of, and have not violated any, applicable Law, judgment, order, writ, decree, permit or license entered by any Governmental Authority and, to the Knowledge of Seller, are not under investigation with respect to any applicable Law, and have not been threatened in writing to be charged with, or been given written notice of any, violation of any applicable Law.

Section 1.05. Conflicts.

(c) Neither the execution and delivery by Seller of any of the Transaction Documents nor the performance or consummation of the transactions contemplated thereby (including, without limitation, the assignment to Buyer of the Royalty Interest) to be performed or consummated by Seller will: (i) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, in any material respects any provisions of: (A) any Law, or any judgment, order, writ, decree, permit or license of any Governmental Authority, in any case, applicable to the Royalty Interest; or (B) any material contract, agreement, commitment or instrument to which Seller is a party; (ii) except for the filing of the UCC-1 financing statements required hereunder (or pursuant to Section 2.01(b)), require any notification to, filing with, or consent of, any Person or Governmental Authority that has not already been obtained, a copy of which has been provided to Buyer; (iii) give rise to any right of termination, cancellation or acceleration of any right or obligation of Seller or any other Person as such right or obligation relates to the Royalty Interest or the Royalty Interest Payments; or (iv) result in the creation or imposition of any Lien on the Royalty Interest or the Royalty Interest Payments (other than Liens in favor of Buyer).

(d) Seller has not granted, nor agreed to grant to any Person other than Buyer, nor does there exist, any Lien granted by Seller on the Royalty Interest. No Subsidiary has granted, nor agreed to grant to any Person other than Buyer, nor does there exist, any Lien on any such Subsidiary's rights to receive Royalty Interest Payments.

(e) None of Seller, any Subsidiary nor any of their respective property is subject to any judgment, order, writ or decree of any Governmental Authority which could reasonably be expected to result in a Material Adverse Effect.

(f) Neither Seller nor its Subsidiaries are party to any contract, agreement, commitment or instrument for which Seller or any of its Subsidiaries are in breach which could reasonably be expected to result in a Material Adverse Effect.

Section 1.01. Ownership.

Other than the rights of Buyer upon the consummation of the transactions contemplated in the Transaction Documents including delivery of the Assignment, Seller is the sole holder of, the License Agreement and of all of the Purchased Assets, free and clear of any and all Liens (other than any Liens in favor of Buyer). Seller has full right and power to assign and convey the Purchased Assets as contemplated by this Agreement. Seller has not transferred, sold, conveyed, assigned, or otherwise disposed of, or agreed to transfer, sell, convey, assign, or otherwise dispose of any portion of the License Agreement or the Purchased Assets other than as contemplated by this Agreement. Upon delivery to Buyer of the executed Assignment, no

Person other than Buyer shall have any right to receive the Royalty Interest payable under the License Agreement. Upon delivery to Buyer of the executed Assignment, Seller shall have sold, transferred, conveyed and assigned to Buyer, and Seller shall have done everything which is required to be done by Seller to cause Buyer to acquire all of Seller's rights, interests and obligations arising on or after the Closing Date under the License Agreement and the Purchased Assets, free and clear of any Liens (other than any Liens in favor of Buyer), but subject to the further provisions of this Agreement. Seller is legally competent to execute this Agreement and the other Transaction Documents and upon such execution by Seller, the obligations of Seller hereunder and thereunder shall constitute the legally binding and enforceable obligations of Seller, subject to bankruptcy, insolvency, reorganization, moratorium, ad hoc representative appointment, conciliation, safeguard proceedings, judicial receivership, or other laws affecting creditors' rights generally or general equitable principles.

Section 1.02. Subordination.

Seller has not caused, by any means, Seller's Royalty Interest to be subordinated to the rights of any creditor of Licensee or any other Person. In addition, Seller has not caused, and to the Knowledge of Seller no other Person has caused, the claims and rights of Buyer created by any Transaction Document in and to the Purchased Assets to be subordinated to any creditor of Licensee or any other Person; provided, however, that Seller makes no representation as to whether Buyer (or any Person acting on behalf of Buyer) has caused any such subordination.

Section 1.03. License Agreement.

(g) Exhibit A hereto contains a true and complete copy of the License Agreement (including, without limitation, all amendments, supplements and other modifications or restatements thereto) as of the Closing Date. To the Knowledge of Seller, other than the Royalty Interest for the calendar quarter (or portion thereof) ended immediately preceding the Closing Date, if any, there are no unpaid Royalty Interests that have become due or are overdue, and none are expected to become overdue as of the Closing Date, in each case subject to the terms of the License Agreement.

(h) Seller is not in breach of the License Agreement which could have a Material Adverse Effect. To the Knowledge of Seller, no circumstances or grounds exist that would give rise (i) to a claim by Licensee of a breach of the License Agreement or any other agreement, in each case, which could have a Material Adverse Effect, or (ii) to a right of rescission, termination, revision, setoff, or any other rights, in, to or under the Purchased Assets. Seller has no unfulfilled obligations in respect of the License Agreement or the Purchased Assets that were required to be fulfilled on or prior to the Closing Date, the lack of completion of which would have a Material Adverse Effect.

(i) To the Knowledge of Seller, Licensee is not in breach of or in default under the License Agreement which could have a Material Adverse Effect. To the Knowledge of Seller, Licensee has no obligations unfulfilled in respect of the License Agreement that were required to be fulfilled that could reasonably be expected to have a Material Adverse Effect.

(j) Seller has the full right, power and authority to grant all rights and interests granted to Buyer in this Agreement.

(k) To the Knowledge of Seller, no circumstance or grounds exist, that would invalidate, reduce or eliminate, in whole or in part, the enforceability or scope of the Purchased Assets, including, without limitation, Seller's right to payments made in respect of Royalty Interests.

(l) To the Knowledge of Seller (i) no Person is in breach of the License Agreement, (ii) nothing has occurred and no condition exists that would permit either party thereto to terminate the License Agreement for cause and (iii) Seller has not received any notice of termination for convenience from the Licensee under Section 11.02(b) of the License Agreement. To the Knowledge of Seller, the License Agreement is valid and binding on each other party thereto in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium, ad hoc representative appointment, conciliation, safeguard proceedings, judicial receivership, or other laws affecting creditors' rights generally or general equitable principles, and is in full force and effect.

(m) Except as set forth on Schedule 3.08(g), (i) to the Knowledge of Seller, Licensee has not entered into any sublicense under the License Agreement, and (ii) Seller has not consented to Licensee entering into any sublicense under the License Agreement.

(n) To the Knowledge of the Seller, Licensee has not exercised any right of rescission, offset, counterclaim or defense, with respect to the License Agreement or provided notice to Seller that it planned to do any of the foregoing. To the Knowledge of Seller, nothing has occurred and no condition exists that would permit Licensee to exercise any right of rescission, offset, counterclaim or defense, with respect to the License Agreement.

(o) Licensee has not provided Seller with notice of termination of the License Agreement nor any notice that it plans to terminate the License Agreement.

(p) All payments due and payable by Seller or, to the Knowledge of Seller, the Licensee, under the License Agreement have been timely paid.

(q) There have been no claims for indemnification made under Article XII of the License Agreement by any Indemnified Party (as defined in the License Agreement).

(r) The Seller has not:

(i) forgiven, released, delayed, postponed or compromised any payment in respect of the Royalty Interest;

(ii) waived, amended, cancelled or terminated, exercised or to the Knowledge of Seller failed to exercise, any material rights constituting or relating to the Purchased Assets;

(iii) except as set forth in Exhibit A, amended, modified, restated, cancelled, supplemented, terminated or waived any provision of the License Agreement, or granted any consent thereunder, or agreed to do any of the foregoing;

(iv) exercised any right of rescission, offset, counterclaim or defense, upon or with respect to the Purchased Assets, or agreed to do or suffer to exist any of the foregoing;

(v) sold, leased, pledged, licensed, transferred or assigned (or attempted to do any of the foregoing) all or any portion of the Purchased Assets, except in favor of Buyer pursuant to the Transaction Documents;

(vi) received any advance payments on the Royalty Interest; it being understood that the transaction contemplated by Amendment Number 2 to the License Agreement does not constitute advance payments on the Royalty Interests.

(s) No credit is owed to or claimed by Licensee with respect to Royalty Interest Payments.

(t) Except as set forth on Schedule 3.08(n), the License Agreement constitutes the only agreement (i) to which Seller is a party relating to the Royalty Interests, (ii) which relate to Seller's entitlement to the Purchased Assets or (iii) which relate to the Development or Commercialization of the Product in the Territory.

Section 1.06. Production Agreements.

(u) Except as set forth on Schedule 3.09(a), the License Agreement and the Production Agreements constitute the only agreements to which the Seller is a party (i) relating to the Royalty Interests, (ii) which relate to Seller's entitlement to the Purchased Assets, or (iii) which relate to the right to Develop and Commercialize the Product in the Field in the Territory.

(v) Seller is not in breach of any Production Agreement which could have a Material Adverse Effect. No circumstances or grounds exist that would give rise to a claim by Licensee of a breach of the Manufacturing and Supply Agreement for Development, the Interim Commercial Supply Letter or the Development Quality Assurance Agreement. Seller has no unfulfilled obligations in respect of any Production Agreement, the lack of which would be reasonably likely to have a Material Adverse Effect or could give rise to a right of set-off against the Royalty Interest Payments.

(w) To the Knowledge of Seller, Licensee is not in breach of or in default under the Manufacturing and Supply Agreement for Development, the Interim Commercial Supply Letter or the Development Quality Assurance Agreement, in any case, which could have a Material Adverse Effect. To the Knowledge of Seller, Licensee has no unfulfilled obligations in respect of the Manufacturing and Supply Agreement for Development, the Interim Commercial Supply Letter or the Development Quality Assurance Agreement that were required to be fulfilled.

(x) To the Knowledge of Seller, no Person is in breach of any Production Agreement which could have a Material Adverse Effect and nothing has occurred and no condition exists that would permit any other party thereto to terminate any Production Agreement. To the Knowledge of Seller, each of the Production Agreements is valid and binding on each other party thereto in accordance with its terms, subject to bankruptcy, insolvency, reorganization, moratorium, ad hoc representative appointment, conciliation, safeguard proceedings, judicial receivership, or other laws affecting creditors' rights generally or general equitable principles, and is in full force and effect.

(y) Licensee has not exercised any right of rescission, offset, counterclaim or defense, with respect to the Manufacturing and Supply Agreement for Development, the Interim Commercial Supply Letter or the Development Quality Assurance Agreement or provided notice to Seller that it planned to do any of the foregoing. To the Knowledge of Seller, nothing has occurred and no condition exists that would permit Licensee to exercise any right of rescission, offset, counterclaim or defense, with respect to the Manufacturing and Supply Agreement for Development, the Interim Commercial Supply Letter or the Development Quality Assurance Agreement.

(z) Licensee has not provided Seller with notice of termination of the Manufacturing and Supply Agreement for Development, the Interim Commercial Supply Letter or the Development Quality Assurance Agreement nor any notice that it plans to terminate the Manufacturing and Supply Agreement for Development, the Interim Commercial Supply Letter or the Development Quality Assurance Agreement.

(aa) All payments due and payable by the Seller or the Licensee under any Production Agreement to which they are a party have been timely paid.

(ab) There have been no claims for indemnification made under Article XII of the License Agreement by Seller or Licensee under the Manufacturing and Supply Agreement for Development, the Interim Commercial Supply Letter or the Development Quality Assurance Agreement.

(ac) The [***] set forth in Schedule 3.09(j) (the "[***]), is [***], as applicable, and to the Knowledge of Seller, is accurate and complete in all material respects; provided that Seller does not represent or warrant that any [***] is accurate. To the Knowledge of Seller, Seller will be able to [***] as set forth therein.

(ad) Seller has not:

(vii) forgiven, released, delayed, postponed or compromised any payment in respect of any Production Agreement which could have a Material Adverse Effect;

(viii) waived, amended, cancelled or terminated, exercised or to the Knowledge of Seller failed to exercise, any material rights constituting or relating to any Production Agreement which could have a Material Adverse Effect;

(ix) amended, modified, restated, cancelled, supplemented, terminated or waived any provision of any Production Agreement, or granted any consent thereunder, or agreed to do any of the foregoing which could have a Material Adverse Effect;

(x) exercised any right of rescission, offset, counterclaim or defense, upon or with respect to any Production Agreement, or agreed to do or suffer to exist any of the foregoing which could have a Material Adverse Effect; or

(xi) sold, leased, pledged, licensed, transferred or assigned (or attempted to do any of the foregoing) all or any portion of any Production Agreement.

Section 1.10. Net Sales; Milestones.

(ae) Schedule 3.10(a) hereto sets forth a true and complete list of all Net Sales of the Product provided by Licensee pursuant to Section 6.07 of the License Agreement and, to the Knowledge of Seller, payable by Licensee to Seller, through but excluding the Closing Date. Seller has provided to Buyer a copy of the Royalty Reports delivered to Seller as of the Closing. Buyer is aware that payments may differ in the future and that past payments made are no guarantee for future payments to be made.

(af) Schedule 3.10(b) hereto sets forth a true and complete list of all milestone payments provided by Licensee pursuant to Section 6.03 of the License Agreement and, to the Knowledge of Seller, payable by Licensee to Seller, through but excluding the Closing Date.

Section 1.11. Broker's Fees.

Neither Seller nor its Affiliates have taken any action that would entitle any Person to any commission or broker's fee in connection with the transactions contemplated by the Transaction Documents.

Section 1.12. Information.

All Seller's written information heretofore or herein supplied by or on behalf of Seller to Buyer is accurate and complete in all material respects, and none of such information, when taken together with all other information furnished and information available through Seller's SEC filings, contains any untrue statement of a material fact or omits to state any material fact necessary to make such information not materially misleading in light of the circumstances under which made. To the Knowledge of Seller, there is no fact or circumstance that could reasonably be expected to have a Material Adverse Effect that has not been expressly disclosed in this Agreement, in the other Transaction Documents, in any of Seller's SEC filings, or in any other documents, certificates and statements furnished to Buyer for use in connection with the transactions contemplated hereby. Notwithstanding the above, Seller makes no representation or warranty with respect to the [***] or any other [***].

Section 1.13. Insolvency Event; Material Adverse Effect.

No Insolvency Event has occurred regarding Seller. To the Knowledge of Seller, no event has occurred and no condition exists that could reasonably be expected to result in a Material Adverse Effect.

Section 1.14. Indebtedness and Liens.

(ag) Set forth on Schedule 3.14(a) is a complete and correct list of all Indebtedness of Seller and each of its Subsidiaries outstanding.

(ah) Set forth on Schedule 3.14(b) is a complete and correct list of all Liens granted by Seller and each of its Subsidiaries with respect to their respective property.

Section 1.1. Intellectual Property Rights.

(ai) Schedule 3.15(a) sets forth under the caption, "Ardelyx Controlled Patents," the following for each Ardelyx Controlled Patent: (i) the application number; (ii) the title of the application or patent, if any, (iii) the patent or registration number, if any; and (iv) the scheduled initial expiration date of such Ardelyx Controlled Patents, including a notation if such scheduled expiration date includes a term extension.

(aj) Schedule 3.15(a) includes a complete and accurate list of all Patents Controlled by Seller in the Territory that are necessary or useful to Exploit the Licensed Product in accordance with the terms of the License Agreement.

(ak) Except as set forth on Schedule 3.15(c), to the Knowledge of Seller, there have not been, nor are there, any Disputes relating to Seller's or its Subsidiaries' rights in the Ardelyx Controlled Patents or related Intellectual Property Rights. To the Knowledge of Seller, there have not been, nor are there, any Disputes relating to Licensee's rights in the Ardelyx Controlled Patents or related Intellectual Property Rights.

(al) To the Knowledge of Seller, neither Seller nor its Subsidiaries has received, and to the Knowledge of Seller, Licensee has not received, any opinion of counsel that any of the Ardelyx Controlled Patents are invalid or unenforceable. To the Knowledge of Seller, neither Seller nor its Subsidiaries has received, and to the Knowledge of Seller, Licensee has not received, any notice of any claim by any Third Party challenging the validity, inventorship, ownership or enforceability of any of the Ardelyx Controlled Patents.

(am) Except as set forth on Schedule 3.15(e), to the Knowledge of Seller, there is at least one valid claim in each of the Ardelyx Controlled Patents that would be infringed by Licensee's Exploitation of the Product in the Territory but for Licensee's license under the License Agreement to such Ardelyx Controlled Patents.

(an) Except as set forth on Schedule 3.15(f), there are no pending, decided or settled Disputes, and to the Knowledge of Seller, no such Dispute has been threatened

that could (i) impact the validity, enforceability, scope, inventorship or ownership of any of the claims of the Ardelyx Controlled Patents, or (ii) otherwise impact whether any claim within the Ardelyx Controlled Patents or Licensee Controlled Patents is a valid claim.

(ao) The term for which consideration is to be paid pursuant to the License Agreement as is set forth in Section 6.04(d) on Exhibit A of Amendment Number 2 of the License Agreement has not been amended or revised since the date thereof.

(ap) To the Knowledge of Seller, each of the Ardelyx Controlled Patents correctly identifies each and every inventor of the claims thereof as determined in accordance with the laws of Japan. To the Knowledge of Seller, there is not any Person who is or claims to be an inventor of any of the Ardelyx Controlled Patents who is not a named inventor thereof. Seller and its Subsidiaries have not, and to the Knowledge of Seller, Licensee has not, received any notice from any Person who is or claims to be an inventor of any of the Ardelyx Controlled Patents who is not a named inventor thereof.

(aq) To the Knowledge of Seller, each Person who has or has had any rights in or to the Ardelyx Controlled Patents, including each inventor named on the Ardelyx Controlled Patents, has executed a Contract assigning his, her or its entire right, title and interest in and to such Ardelyx Controlled Patents and the inventions embodied, described or claimed therein, to Seller and each such Contract has been, duly recorded at the Japan Patent Office where such recordation has been required as of the Closing Date.

(ar) To the Knowledge of Seller, maintenance fees, annuities or other like payments with respect to any Ardelyx Controlled Patents required to be paid as of the Closing Date have been paid.

(as) To the Knowledge of Seller, no issued Ardelyx Controlled Patent has lapsed, expired or otherwise been terminated. Except as set forth on Schedule 3.15(k), to the Knowledge of Seller, no Ardelyx Controlled Patent applications have lapsed, expired, been abandoned or otherwise been terminated, other than by operation of law.

(at) To the Knowledge of Seller, none of the conception, development and reduction to practice of the inventions claimed in the Ardelyx Controlled Patents has constituted or involved the misappropriation of trade secrets or other rights or property of any Third Party.

(au) To the Knowledge of Seller, Seller and its Subsidiaries have not, and to the Knowledge of Seller, Licensee has not, filed any disclaimer, other than a terminal disclaimer, or made or permitted any other voluntary reduction in the scope of any Ardelyx Controlled Patents.

(av) To the Knowledge of Seller, Seller and its Subsidiaries have not, and to the Knowledge of Seller, no other Person has, undertaken or omitted to undertake any acts, and to the Knowledge of Seller no circumstances or grounds exist, that would void, invalidate, reduce or eliminate, in whole or in part, the enforceability

of claims specifically covering the Lead Licensed Compound within any issued Ardelyx Controlled Patent.

(aw) [Reserved].

(ax) Except as set forth on Schedule 3.15(p), to the Knowledge of Seller, no Third Party Patent Right has been, or is, or will be, infringed by Licensee's Exploitation of the Product in accordance with the terms of the License Agreement. To the Knowledge of Seller, there are no patent rights that Licensee does not have the right to use that would limit or prohibit in any material respect Licensee's Exploitation of the Product in accordance with the terms of the License Agreement. To the Knowledge of Seller, neither Seller nor Licensee has received any notice of any claim by any Third Party asserting that Licensee's Exploitation of the Product infringes such Third Party's Patent Rights.

(ay) Except as set forth on Schedule 3.15(q), to the Knowledge of Seller, there are no pending, published patent applications owned by any Third Party, which Licensee does not have the right to use, which if issued, would limit or prohibit in any material respect Licensee's Exploitation of the Product in accordance with the License Agreement.

(az) Except as set forth on Schedule 3.15(r), to the Knowledge of Seller, no Third Party is infringing any of the issued Ardelyx Controlled Patents. Seller has not, and to the Knowledge of Seller, Licensee has not, put any Third Party on notice of any of the issued Ardelyx Controlled Patents.

(ba) [Reserved].

(bb) Except as set forth on Schedule 3.15(t), to the Knowledge of Seller, there are no Disputes between Licensee and a Third Party relating to Licensee's Exploitation of the Product in accordance with the terms of the License Agreement. Seller has not received notice of any such Dispute, and to the Knowledge of Seller, there exists no circumstances or grounds upon which any such claims could be reasonably asserted. To the Knowledge of Seller, the Ardelyx Controlled Patents are not subject to any outstanding injunction, judgment or other decree, ruling, charge settlement or other disposition of any Dispute which could reasonably be expected to have a Material Adverse Effect.

(bc) To the Knowledge of Seller, no individual associated with the filing and prosecution of the Ardelyx Controlled Patents failed to comply in all material respects with all applicable duties of candor and good faith in dealing with any Patent Office, including the duty to disclose to the Japanese Patent Office all information known to be material to patentability where such duty to disclose is required.

(bd) Except as set forth on Schedule Section 3.15(v), to the Knowledge of Seller, no validity concerns, or prior art have been raised in connection with any Patents outside of the Territory which specifically claim the compound tenapanor which, if raised in connection with the Ardelyx Controlled Patents, could reasonably be

expected to impact the validity of any claims in the issued Ardelyx Controlled Patents which specifically claim the compound tenapanor.

Section 1.15. Compliance.

To the Knowledge of Seller, all applications, submissions, information and data related to the Product submitted or utilized as the basis for any request to any Regulatory Authority by or on behalf of Licensee relating to the Product were true and correct in all material respects as of the date of such submission or request, and any material updates, changes, corrections or modifications to such applications, submissions, information or data required under applicable Law were submitted to the necessary Regulatory Authorities, or were corrected by subsequent submission to the applicable Regulatory Authority. To the Knowledge of Seller, Licensee has not committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for any Governmental Authority to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," or similar policies set forth in any applicable Laws.

Section 1.16. Exploitation; Material Information.

(be) To the Knowledge of Seller, Licensee is neither (i) considering terminating the Exploitation of the Product, nor (ii) considering manufacturing, selling, offering for sale (including marketing and promotion), importation, distribution or other commercialization of a Competitive Product that would compete with the Product during the term of this Agreement in the Territory.

(bf) [Reserved]

(bg) To the Knowledge of Seller, Licensee is neither contemplating nor planning to commence any case, proceeding or other action relating to Licensee's bankruptcy, insolvency, liquidation or dissolution or reorganization by any of the foregoing means.

Section 1.2. Taxes.

No deduction or withholding for or on account of any tax has been made, or was required to have been made, from any payment to Seller under the License Agreement and, other than with respect to Japanese tax withholding, Seller was not required to claim any treaty benefits in order to avoid such withholding.

ARTICLE IV

REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer hereby represents and warrants to Seller that the following representations are true and complete as of the Closing Date, except as otherwise indicated:

Section 1.07. Organization.

Buyer is a limited partnership formed and validly existing under the laws of the State of Delaware, and has all limited partnership powers and all licenses, authorizations, consents and

approvals required to carry on its business as now conducted and as proposed to be conducted in connection with the transactions contemplated by the Transaction Documents.

Section 1.08. Authorization.

Buyer has all necessary limited partnership power and authority to enter into, execute and deliver this Agreement and the other Transaction Documents and to perform all of the obligations to be performed by it hereunder and thereunder and to consummate the transactions contemplated hereunder and thereunder. Once signed, the Transaction Documents will have been duly authorized, executed and delivered by Buyer and each Transaction Document will then constitute the valid and binding obligation of Buyer, enforceable against Buyer in accordance with their respective terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or general equitable principles.

Section 1.09. Broker's Fees.

None of Buyer or its Affiliates has taken any action that would entitle any Person to any commission or broker's fee in connection with the transactions contemplated by the Transaction Documents.

Section 1.010. Conflicts.

Neither the execution and delivery of this Agreement or any other Transaction Document nor the performance or consummation of the transactions contemplated hereby or thereby will: (i) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, in any material respects, any provisions of: (A) any Law, or any judgment, order, writ, decree, permit or license of any Governmental Authority, to which Buyer or any of its assets or properties may be subject or bound; or (B) any contract, agreement, commitment or instrument to which Buyer is a party or by which Buyer or any of its assets or properties is bound or committed; (ii) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, any provisions of the organizational or constitutional documents of Buyer; or (iii) require any notification to, filing with, or consent of, any Person or Governmental Authority.

ARTICLE V

COVENANTS

During the term of this Agreement, the following covenants shall apply:

Section 1.04. Consents and Waivers.

Seller and Buyer shall use commercially reasonable efforts to obtain and maintain any required consents, acknowledgements, certificates or waivers so that the transactions contemplated by this Agreement or any other Transaction Document may be consummated and shall not result in any default or breach or termination of the License Agreement.

Section 1.05. Compliance.

(a) The Seller shall comply with and fulfill, in all material respects, all of Seller's obligations under the License Agreement and each Production Agreement.

(b) In the event the License Agreement is terminated for any reason whatsoever prior to its expiration pursuant to Section 11.01 of the License Agreement, Seller shall use Commercially Reasonable Efforts, at its sole cost and expense, to locate and secure a replacement licensee to Develop and Commercialize the Product in the Territory; provided that [***] (the "New Arrangement"), and Seller agrees to use Commercially Reasonable Efforts to negotiate substantially similar obligations and liabilities as it currently has under the License Agreement (such New Arrangement shall, for purposes of the assignment of the Purchased Assets hereunder, be deemed to constitute the "License Agreement" hereunder and shall be subject to the terms and conditions hereof and of the other Transaction Documents) and Seller shall [***]. If Seller is not able to enter into a New Arrangement pursuant to the terms of this Section 5.02(b), despite using Commercially Reasonable Efforts, then [***] Seller or its Affiliates shall, [***]. The Parties will work together in good faith, if necessary, to amend this Agreement and the Transaction Documents, as appropriate, in order to address any alternative or differing provisions in a New Arrangement entered into pursuant to this Section 5.02(b) or to address Seller or its Affiliates performing the obligations of Licensee under the License Agreement, as applicable. Without limiting the foregoing, if the License Agreement is terminated and Seller or its Affiliates [***], shall be treated as "Net Sales" subject to the specified royalty rates set forth in the applicable provision of Section 6.04 of Amendment Number 2 of the License Agreement, and the product of such net sales times such royalty rate for the corresponding royalty periods for which such royalty rates apply shall be Royalties hereunder, and Seller shall pay Purchaser an amount equal to any milestone payments that would otherwise have been payable under Section 6.03 of the License Agreement related to the Commercialize the Product in the Territory.

Section 1.011. Confidentiality; Public Announcement; SEC Filings.

(c) Except as expressly authorized in this Agreement or the other Transaction Documents or except with the prior written consent of the Disclosing Party, the Receiving Party hereby agrees that (i) it will use the Confidential Information of the Disclosing Party solely for the purpose of the transactions contemplated by this Agreement and the other Transaction Documents and exercising its rights and remedies and performing its obligations hereunder and thereunder; (ii) it will keep confidential the Confidential Information of the Disclosing Party; and (iii) it will not furnish or disclose to any Person any Confidential Information of the Disclosing Party.

(d) Notwithstanding anything to the contrary set forth in this Agreement or any other Transaction Document, the Receiving Party may, without the consent of the Disclosing Party, but with prior written notice to the Disclosing Party, furnish or disclose Confidential Information of the Disclosing Party to (i) the Receiving

Party's Affiliates and their respective Representatives, actual or potential financing sources, investors or co-investors and permitted assignees, transferees or successors-in-interest under Section 8.03, in each such case, who need to know such information in order to provide or evaluate the provision of financing to the Receiving Party or any of its Affiliates or to assist the Receiving Party in evaluating the transactions contemplated by this Agreement and the other Transaction Documents or in exercising its rights and remedies and performing its obligations hereunder and thereunder and who are, prior to such furnishing or disclosure, informed of the confidentiality and non-use obligations contained in this Section 5.03 and who are bound by written or professional confidentiality and non-use obligations no less stringent than those contained in this Section 5.03; and (ii) permitted assignees, transferees or successors-in-interest under Section 8.03, in each such case, who need to know such information in connection with such actual or potential assignment, sale or transfer, including, following any such assignment, sale or transfer, in order to exercise their rights and remedies and perform their obligations under this Agreement and the other Transaction Documents and who are, prior to such furnishing or disclosure, informed of the confidentiality and non-use obligations contained in this Section 5.03 and who are bound by written or professional confidentiality and non-use obligations no less stringent than those contained in this Section 5.03. Each Party hereby acknowledges that the United States federal and state securities laws prohibit any Person that has material, non-public information about a company from purchasing or selling securities of such a company or from communicating such information to any other Person under circumstances in which it is reasonably foreseeable that such Person is likely to purchase or sell such securities.

(e) In the event that the Receiving Party, its Affiliates or any of their respective Representatives is required by applicable Law, applicable stock exchange rules or legal or judicial process (including by deposition, interrogatory, request for documents, subpoena, civil investigative demand or similar process) to furnish or disclose any portion of the Confidential Information of the Disclosing Party, the Receiving Party shall, to the extent legally permitted, provide the Disclosing Party, as promptly as practicable, with written notice of the existence of, and terms and circumstances relating to, such requirement, so that the Disclosing Party may seek, at its expense, a protective order or other appropriate remedy (and, if the Disclosing Party seeks such an order, the Receiving Party, such Affiliates or such Representatives, as the case may be, shall provide, at their expense, such cooperation as such Disclosing Party shall reasonably require). Subject to the foregoing, the Receiving Party, such Affiliates or such Representatives, as the case may be, may disclose that portion (and only that portion) of the Confidential Information of the Disclosing Party that is legally required to be disclosed; provided, however, that the Receiving Party, such Affiliates or such Representatives, as the case may be, shall exercise reasonable efforts (at their expense) to preserve the confidentiality of the Confidential Information of the Disclosing Party, including by obtaining reliable assurance that confidential treatment will be accorded any such Confidential Information disclosed. Notwithstanding anything to the contrary contained in this Agreement or any of the other Transaction Documents, in the event that the Receiving Party or any of its Affiliates receives a request from an authorized representative of a U.S. or foreign tax authority for a copy of this Agreement or any of the other

Transaction Documents, the Receiving Party or such Affiliate, as the case may be, may provide a copy hereof or thereof to such tax authority representative without advance notice to, or the consent of, the Disclosing Party; provided, however, that the Receiving Party shall, to the extent legally permitted, provide the Disclosing Party with written notice of such disclosure as soon as practicable. Notwithstanding the above, the Parties acknowledge and agree that this Agreement is a material contract of Seller that will be required to be disclosed to the Securities and Exchange Commission pursuant to the Exchange Act. Seller will be permitted to file this Agreement with the Securities and Exchange Commission in its entirety or with confidential treatment of certain terms and conditions of this Agreement, as determined by Seller in its sole discretion.

(f) Notwithstanding anything to the contrary contained in this Agreement or any of the other Transaction Documents, the Receiving Party may disclose the Confidential Information of the Disclosing Party, including this Agreement, the other Transaction Documents and the terms and conditions hereof and thereof, to the extent necessary in connection with the enforcement of its rights and remedies hereunder or thereunder or as required to perfect the Receiving Party's rights hereunder or thereunder; provided that, the Receiving Party shall only disclose that portion of the Confidential Information that its counsel advises that it is legally required to disclose and will exercise commercially reasonable efforts to ensure that confidential treatment will be accorded to that portion of the Confidential Information that is being disclosed, including requesting confidential treatment of information in the Transaction Documents. In any event, Receiving Party will not oppose action by Disclosing Party to obtain an appropriate protective order or other reliable assurance, at its own expense, that confidential treatment will be accorded the Confidential Information in the event that confidential treatment cannot be obtained by the Receiving Party.

(g) Each Party shall have the right to issue a press release with respect to the transactions contemplated by this Agreement or any other Transaction Document, provided that the form of such press release is substantially similar to that set forth on Section 5.03(e). Following the initial press release, the Parties shall be permitted to make additional public disclosures regarding the transactions contemplated by this Agreement or any other Transaction Document, provided that such additional public disclosures are consistent with such initial disclosure or as may be necessary to correct any facts or circumstances that have changed since the initial disclosure. In addition, each Party shall be permitted to provide any public disclosure regarding the transactions contemplated by this Agreement or any other Transaction Document if and to the extent that any such release or disclosure is required by applicable Law, by the rules and regulations of any applicable stock exchange or by any Governmental Authority of competent jurisdiction.

(h) Except with respect to Buyer's internal communications or private communications with its Representatives, Buyer shall not, and shall cause its Representatives, its Affiliates and its Affiliates' Representatives not to make use of the name, nickname, trademark, logo, service mark, trade dress or other name, term, mark or symbol identifying or associated with Seller without Seller's prior written consent to the specific use in question; provided that, the consent of Seller

shall not be required with respect to publication of Seller's name and logos in Buyer's promotional materials, including without limitation the websites for Buyer and its Affiliates, if such publication is made in accordance with the format set forth on Schedule 5.03(f) and Buyer does not make any such publication until after Seller files this Agreement in compliance with United States securities laws.

(i) Each of Seller and Buyer hereby (i) agree that, notwithstanding the terms thereof, the Confidentiality Agreement is hereby terminated and (ii) acknowledge that this Agreement shall supersede such Confidentiality Agreement with respect to the treatment of Confidential Information by the Parties (including, without limitation, with regard to Confidential Information previously provided pursuant to such Confidentiality Agreement).

(j) Buyer further agrees to (a) comply with the terms of Article VII of the License Agreement with respect to any Confidential Information (as defined in the License Agreement) of Licensee and (b) to keep confidential and not publish or otherwise disclose or use for any purpose other than to conduct its activities under this Agreement any Confidential Information of Licensee, unless such disclosure falls within the exceptions set forth in Section 7.02 or 7.04 of the License Agreement, in which case Buyer agrees to make any such limited permitted disclosure in strict compliance with the requirements set forth in Article VII of the License Agreement.

Section 1.04. Further Assurances.

(k) Subject to the terms and conditions of this Agreement, each of Buyer and Seller will use commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary under applicable Laws to consummate the transactions contemplated by this Agreement and any other Transaction Document. Buyer and Seller agree to execute and deliver such other documents, certificates, agreements and other writings (including any financing statement filings, other documents, certificates or agreements requested by Buyer) and to take such other actions as may be reasonably necessary to carry out and effectuate all of the provisions of this Agreement and any other Transaction Document, to consummate the transactions contemplated by this Agreement and any other Transaction Document and to vest in Buyer all of Seller's rights and obligations (whether joint, several or joint and several) to the Purchased Assets, free and clear of all Liens except any Permitted Liens or Liens created in favor of Buyer. Seller shall take all actions and do, all things necessary to pay off, satisfy and release any Permitted Liens.

(l) Except for Disputes between the Parties, each of Buyer and Seller shall cooperate and provide assistance as reasonably requested by the other Party (and at no expense to the requesting Party unless the requesting Party is obligated to indemnify the other Party pursuant to the requesting Party's indemnification obligations provided for in this Agreement) in connection with any litigation, arbitration or other proceeding (whether threatened, existing, initiated, or contemplated prior to, on or after the date hereof) to which any Party or any of its officers, directors, shareholders, agents or employees is or may become a party or is or may become otherwise directly or indirectly affected or as to which any such

Persons have a direct or indirect interests, in each case relating to this Agreement or any other Transaction Document, and the Purchased Assets, the License Agreement, or the transactions described herein or therein, and, without limiting the generality of the preceding provision, shall provide promptly to the other Party copies of all correspondence, reports, notices or other information sent by or on behalf of such Party to, or received by or on behalf of such Party from, Licensee, in any case relating to the License Agreement; it being understood that a Party's failure to provide such information shall not limit any otherwise applicable indemnification obligations under this Agreement of the other Party other than to the extent of any final non-appealable order of a court of competent jurisdiction finding that a Loss was incurred by such other Party as a result of such failure to provide such information. In particular, with respect to the immediately preceding sentence, Seller shall, upon request of Buyer, be available and fully cooperate with and support Buyer in connection with the License Agreement and its performance, at reasonable times and, unless otherwise set forth in this Agreement. Notwithstanding anything in this Section 5.04(b) to the contrary, at no time shall either Buyer or Seller be required to provide any attorney-client privileged information.

(m) Seller and its Subsidiaries shall obtain Buyer's prior written consent prior to delivering any notice or correspondence to Licensee alleging any material breach or material default of any representation, warranty or covenant (or otherwise) by Licensee or its Subsidiaries under the License Agreement.

Section 1.012. Notice by Seller.

Seller shall provide Buyer with written notice as promptly as practicable (and in any event within five (5) Business Days) after obtaining actual knowledge of any of the following:

(n) any Event of Default;

(o) the occurrence of an Insolvency Event with respect to Seller or the occurrence of any equivalent event with respect to Licensee;

(p) any material breach or material default, or alleged material breach or material default, of any representation, warranty or covenant by Licensee or its Subsidiaries or Seller or its Subsidiaries under the License Agreement or any Production Agreement;

(q) that Seller shall be unable to provide the supply of API set forth in the Manufacturing and Supply Agreement for Development or the Interim Commercial Supply Letter in any material respect;

(r) any written notice, report or other communication, together with copies of the same, received from or on behalf of the Licensee with respect to the License Agreement, any Production Agreement, the Royalty Interest, the Patent rights, or any of the Purchased Assets, in each case, to the extent regarding matters affecting the Purchased Assets that would, whether individually or in the aggregate, reasonably be expected to have a Material Adverse Effect;

(s) any written notice, report or other communication, together with copies of the same, sent to the Licensee by or on behalf of Seller with respect to the License Agreement, any Production Agreement, the Royalty Interest, the Patent rights, or any of the Purchased Assets, in each case, to the extent regarding matters affecting the Purchased Assets that would, whether individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and

(t) any change in, or amendment or alteration of, Seller's (a) legal name, (b) form or type of organization, or (c) jurisdiction of organization.

Section 1.06. Patent Rights.

(u) Seller shall, at its sole expense, take any and all commercially reasonable actions and prepare, execute, deliver and file any and all agreements, documents or instruments which are necessary or desirable to diligently prosecute and maintain the Licensed Patents, to the extent required to prevent a Material Adverse Effect.

(v) Seller shall, or shall permit Licensee to, at its sole expense, defend or assert the Licensed Patents against infringement by any other Persons, and against any claims of invalidity or unenforceability, in the Territory (including, without limitation, by bringing any legal action for infringement or defending any counterclaim of invalidity or action of a Third Party for declaratory judgment of non-infringement), to the extent required to prevent a Material Adverse Effect.

(w) Seller shall not disclaim or abandon, or fail to take any action necessary or desirable to prevent the disclaimer or abandonment of, any Licensed Patents, to the extent the disclaimer or abandonment of such Licensed Patent could reasonably be likely to have a Material Adverse Effect.

(x) Without limiting Seller's obligations under Section 5.06(a), Seller shall keep Buyer reasonably informed and shall promptly provide to Buyer any information of which Seller becomes aware that could reasonably be expected to have an effect on the prosecution, maintenance, defense or enforcement of any Licensed Patents, in a manner that could reasonably be expected to have a Material Adverse Effect. To the extent that Seller receives any material correspondence regarding the prosecution, maintenance, defense or enforcement of any such Licensed Patents, that could reasonably be expected to have a Material Adverse Effect, Seller will provide such correspondence to Buyer.

(y) In furtherance of Section 5.06(d), in the event of defense or enforcement of any Licensed Patent, Seller shall provide regular updates regarding the status of and strategy for such defense or enforcement activities, including with respect to infringement, validity, enforceability, any counterclaim or settlement; provided that, notwithstanding anything to the contrary contained herein, this provision is not deemed to grant Buyer any rights to (i) dictate or control any enforceability with respect to any Licensed Patent or (ii) information protected by attorney-client privilege or that would otherwise cause a conflict of interest.

(z) In the event that Seller becomes aware of any Third Party Claim, whether actual or threatened in writing, alleging that the manufacture, Commercialization or

other Exploitation of the Product may infringe or misappropriate intellectual property of a Third Party, Seller will notify Buyer, and will provide such information as Buyer may reasonably request.

(aa) In the event Seller becomes aware that any Third Party has filed a marketing authorization request for a generic version of the Lead Licensed Compound in the Territory or has otherwise initiated a Dispute alleging that a Generic does not infringe the Ardelyx Controlled Patents or Licensee Controlled Patents, in the Territory, or that the Ardelyx Controlled Patents or Licensee Controlled Patents (or any claims thereof) are invalid or unenforceable, in the Territory, Seller will notify Buyer, and will provide such information as Buyer may reasonably request.

Section 1.013. Negative Covenants.

Seller shall not, nor shall it permit any of its Subsidiaries to, without the prior written consent of Buyer:

(ab) forgive, release or reduce any amount, or delay or postpone any amount, owed to Seller or its Affiliates and relating to the Royalty Interest or the Royalty Interest Payments;

(ac) create, incur, assume or suffer to exist any Lien, upon or with respect to the Royalty Interest, the Licensee Agreement, the Ardelyx Controlled Patents (excluding any Ardelyx Controlled Patents that are Ardelyx Sole Invention Patents or Ardelyx [***] Patents, in each case, in jurisdictions outside of the Territory), the right to receive Royalty Interest Payments, or agree to do or suffer to exist any of the foregoing, except for any Permitted Liens and any Lien or agreements in favor of Buyer granted under or pursuant to this Agreement and the other Transaction Documents;

(ad) waive, amend, cancel or terminate, exercise or fail to exercise, any material rights constituting or relating to the Royalty Interest or other Purchased Assets;

(ae) grant or withhold any consent, exercise or waive any right or option or fail to exercise any right or option in respect of, affecting or relating to the Royalty Interest or other Purchased Assets in any manner that would (i) reasonably be expected to have a Material Adverse Effect or (ii) conflict with, or that would reasonably be expected to give rise to a material breach, material violation, termination or material default under the License Agreement;

(af) amend, modify, restate, cancel, supplement, terminate or waive any provision of the License Agreement or grant any consent thereunder, or agree to do any of the foregoing, in each case, in a manner that could adversely affect Buyer;

(ag) assign, in whole or in part, the License Agreement or any provision thereof or right thereunder other than pursuant to Section 8.03;

(ah) sell, lease, license, transfer or assign (or attempt to do any of the foregoing) all or any material portion of any of the Ardelyx Controlled Patents (excluding any Ardelyx Controlled Patents that are Ardelyx Sole Invention Patents or Ardelyx

[***] Patents, in each case, in jurisdictions outside of the Territory) other than pursuant to Section 8.03, or pursuant to a license outside of the Territory and/or Field; or

(ai) directly or indirectly, launch, license, sell, commercialize, distribute, assign or sell rights to any Competitive Product or intellectual property related to any Competitive Product which, in either case, would compete with the Product during the term of this Agreement in the Territory.

Section 1.01. Future Agreements.

Seller shall not enter into, nor shall it permit any of its Subsidiaries to enter into, any agreement that would reasonably be expected to result in a Material Adverse Effect without Buyer's prior written consent, which consent shall not be unreasonably withheld, delayed or conditioned by Buyer. For clarity, nothing in this Section 5.08, or otherwise in this Agreement shall restrict Seller from entering into an agreement for the development and commercialization of the Product in the Territory for irritable bowel syndrome with constipation; provided that any such agreement does not result in a breach of Seller's obligations under the License Agreement.

Section 1.02. Records; Access.

(aj) During the term of this Agreement and for a period of two (2) years thereafter, Seller shall keep and maintain proper books of record and account in which full, true and correct entries in conformity with GAAP and all requirements of applicable Law are made of all dealings and transactions as are adequate to correctly calculate and verify the accuracy of all reports and all Royalty Interest Payments.

(ak) During the term of this Agreement:

(xii) Buyer and its representatives shall have the right, from time to time during normal business hours and upon at least twenty (20) Business Days' prior written notice to Seller, but no more frequently than one (1) time per calendar year to visit the offices and properties of Seller and the Subsidiaries where books and records relating or pertaining to the Royalty Interest Payments, the Royalty Interest and the Purchased Assets are kept and maintained, to inspect and make extracts from and copies of such books and records, to discuss, with officers of Seller and the Subsidiaries, the business, operations, properties and financial and other condition of Seller and the Subsidiaries and to verifying the accuracy of the reports and the Royalty Interest Payments. In the event any inspection of such books and records reveals any underpayment of any Royalty Interest Payment in respect of any calendar quarter, Seller shall pay promptly (but in any event within five (5) Business Days thereafter) to Buyer (x) the amount of such underpayment; and (y) if such underpayment exceeds [***] of the Royalty Interest Payment that was required to be made in respect of such calendar quarter, the reasonable and documented out-of-pocket fees and expenses incurred by Buyer and its Affiliates in connection with such inspection (in all other cases, such fees and expenses will be borne by Buyer and its Affiliates).

(xiii) All information furnished or disclosed to Buyer or any of its representatives in connection with any inspection shall constitute Confidential Information of Seller and shall be subject to the provisions of Section 5.03.

(xiv) Subject to Section 5.03(h), Seller shall deliver to Buyer such information and data relating or pertaining to the Royalty Interest Payments, the Royalty Interest or the Purchased Assets as Buyer shall reasonably request, promptly upon such request.

(al) Seller shall on, on at least a quarterly basis, or more frequently if requested in writing by Buyer (such notice to be given at least ten (10) Business Days' in advance), cause such of the executive officers and employees of Seller as shall be reasonably identified by Buyer in such notice to meet (virtually or in person), or, at Buyer's option, to participate in a conference call with, Buyer for the purpose of discussing the Product and the Purchased Assets.

Section 1.10. Regulatory Approvals.

Seller shall, to the extent permitted under the License Agreement, take any and all commercially reasonable actions and prepare, execute, deliver and file any and all agreements, documents or instruments that are necessary to secure and maintain all Regulatory Approvals for the Product in the Territory, except where the failure to do so would not reasonably be expected to result in a Material Adverse Effect. To the extent permitted under the License Agreement, Seller shall not withdraw or abandon, or fail to take any action necessary to prevent the withdrawal or abandonment of, any such Regulatory Approval in the Territory once obtained, except where such withdrawal or abandonment would not reasonably be expected to result in a Material Adverse Effect. Notwithstanding the foregoing in this Section 5.10, Seller shall not consent to the withdrawal or abandonment of any Regulatory Approval for the Product in the Territory by Licensee unless Seller obtains Buyer's prior written consent.

Section 1.11. Misdirected Payments.

(am) Notwithstanding the terms of the Licensee Instruction, commencing on the Closing Date and at all times thereafter, if any portion of the Royalty Interest is paid to Seller (after giving effect to the adjustments set forth in Section 2.02(c)), including any payments remitted by Buyer to Seller plus any of Buyer's reasonable and documented out-of-pocket costs and expenses (including reasonable and documented attorneys' fees and expenses) incurred in enforcing Buyer's rights under this Agreement, any Transaction Document or the License Agreement, which are not otherwise reimbursed hereunder then (i) Seller shall hold such amount in trust for the benefit of Buyer in a segregated account, (ii) Seller shall have no right, title or interest whatsoever in such amount and shall not create or suffer to exist any Lien thereon and (iii) Seller promptly, and in any event no later than five (5) Business Days following the receipt by Seller of such amount, shall remit such amount to Buyer. The Seller shall notify Buyer of such wire transfer and provide reasonable details regarding the Royalty Interest Payment so received by Seller.

(an) If the Licensee exercises any set-off or deduction against any payment of the Royalty Interests, then Seller shall promptly (and in any event no later than five (5) Business Days) following payment of the Royalty Interest reduced by such set-off or deduction, make a true-up payment to Buyer such that Buyer receives the full amount of such Royalty Interest Payment that would have been payable to Buyer had such set-off or deduction not been exercised. After Seller makes the payment referred to in the first sentence of this Section 5.11(b), Seller shall be entitled to, and Buyer shall not be entitled to, any amounts recovered from the Licensee in respect of such set-off or deduction.

(ao) All remittances pursuant to this Section 5.11 shall be made (i) without set-off or deduction of any kind (except as required by applicable Law) and (ii) by wire transfer of immediately available funds to such account as Buyer designates in writing.

(ap) Any amounts payable by Seller under this Section 5.11 shall bear interest, to the extent not paid within thirty (30) days of demand therefore by Buyer at a per annum rate equal to [***].

Section 1.3. Licensee Instruction.

During the term of this Agreement, other than the Licensee Instruction, Seller shall not, without Buyer's prior written consent (which consent may be withheld or granted in Buyer's sole discretion), deliver any written instructions to Licensee redirecting the payment of the Royalty Interests.

Section 1.4. Seller's Commercially Reasonable Efforts and Judgment.

It is understood and agreed that, in determining whether Seller's efforts or judgments are "commercially reasonable" with respect to any covenant that specifically references such term in this Agreement, Seller shall be deemed to be acting or making a judgment in a commercially reasonable manner if Seller would reasonably be expected to act in the same manner if Seller had the sole right, title and interest in and to the Purchased Assets.

Section 1.5. Royalty Reports; Notices and Communications from Licensee.

(aq) Seller shall promptly (and in any event no later than five (5) Business Days) following the receipt by Seller from the Licensee of a Royalty Report furnish a copy of the same to Buyer. Except for the Licensee Instruction and notices and correspondence required to be given or made by Seller (i) under the License Agreement or (ii) by applicable Law, Seller shall not send any notice or correspondence to the Licensee relating to, affecting or involving, the Purchased Assets that would reasonably be expected to result in a Material Adverse Effect, except with the prior written consent of Buyer. Without limiting the foregoing, Seller shall, promptly (and in any event no later than five (5) Business Days) following the delivery thereof by Seller to the Licensee, furnish a copy of a written notice sent by Seller to the Licensee relating to, affecting or involving the Purchased Assets or that would reasonably be expected to result in a Material

Adverse Effect. Without limiting the foregoing, Seller shall, promptly (and in any event no later than five (5) Business Days) following the delivery thereof by Seller to the Licensee, furnish a copy of correspondence sent by Seller to the Licensee that would reasonably be expected to result in a Material Adverse Effect.

(ar) Seller shall promptly deliver (i) notices received by Seller from Licensee; and (ii) invoices provided by Seller to Licensee, in each case regarding the achievement of Milestones.

Section 1.12. Maintenance of License Agreement.

Within five (5) Business Days after becoming aware, by written notice, of Licensee's (A) intent to terminate the License Agreement, in whole or in part or (B) allegation of a breach or violation of or default, in each case in any material respect, under the License Agreement by Seller, Seller shall give written notice thereof to Buyer. Such notice shall (x) describe in reasonable detail such breach, default or termination event, (y) include a copy of any written notice received from Licensee with respect thereto, and (z) in the case of any breach or default or alleged breach or default by Seller, in each case of clauses (x), (y) and (z), in any material respect, describe in reasonable detail any corrective action Seller proposes to take in respect of such breach or default. In consultation with Buyer, Seller shall use Commercially Reasonable Efforts to cure any breach or default by it under the License Agreement, as applicable, and, in any case, shall give written notice to Buyer upon curing such breach or default. Seller shall pay the costs and expenses associated with all of the foregoing actions, including in connection with any Disputes related to any alleged breach or alleged default under the License Agreement.

Section 1.13. Enforcement of License Agreement and the Production Agreements (excluding the Back-up Manufacturing Agreements).

Seller will comply with the enforcement provisions set forth in Schedule 5.16.

Section 1.14. Audits.

(as) The Seller and Buyer shall consult with each other regarding the timing, manner and conduct of any review or audit of the Licensee's books and records pursuant to Section 8.06 of the License Agreement. For the avoidance of doubt, Seller shall not request an examination of the Licensee's records and books of account without the prior written consent of Buyer, such consent not to be unreasonably withheld, conditioned or delayed.

(at) Following consultation in accordance with Section 5.17(a), if requested in writing by Buyer, Seller shall to the extent permitted by Section 10.01 of the License Agreement, provide written notice to the Licensee to cause an inspection or audit to determine the correctness of any Royalty Interest Payments made under the License Agreement. Seller will promptly furnish to Buyer a true, correct and complete copy of any inspection or audit report prepared in connection with such an inspection or audit. If, following the completion of such inspection or audit, Seller is required to reimburse Licensee for overpayment of the Royalty Interests, then Buyer shall promptly upon request reimburse Seller, or, at Seller's request, Licensee on behalf of Seller, for the portion of such overpaid amount that was

actually paid to Buyer, and shall promptly (and in any event within two (2) Business Days) after making such payment provide documentation satisfactory to Seller evidencing that such payment was made. If, following the completion of such inspection or audit, Licensee is required to pay amounts representing an underpayment of the Royalty Interests during the applicable period of time, Buyer shall be paid from such amounts a portion equal to the amount by which the Royalty Interest was underpaid during the applicable period of time.

(au) All of the expenses of any inspection or audit requested by Buyer pursuant to this Section 5.17, including such fees and expenses of any public accounting firm engaged by Seller (and reasonably acceptable to Buyer) in connection with such an inspection or audit shall be paid by Buyer unless the amount of the overpayment or underpayment payable pursuant to Section 5.17(b) is greater than [***] of the total amount actually owed for the period audited, in which case Seller shall pay such fees and expenses.

Section 1.1. Post-Closing Obligations.

(av) [Reserved].

(aw) Notwithstanding any provision herein or in any other Transaction Document, as soon as practicable, Seller shall deliver to Licensee a duly executed copy of the Licensee Instruction. Within three (3) Business Days thereafter, Seller shall deliver to Buyer evidence reasonably satisfactory to Buyer confirming the delivery to and receipt by Licensee of the Licensee Instruction.

ARTICLE VI

THE CLOSING; CONDITIONS TO CLOSING

Section 1.01. Closing.

(a) Subject to the closing conditions set forth in Section 6.02, and unless otherwise mutually agreed by the Parties, the closing of the transactions contemplated under this Agreement (the "Closing") shall take place remotely via electronic delivery of the executed Transaction Documents and other deliverables, on the Closing Date.

(b) As soon as practicable (but in any event no later than one (1) Business Day after the Closing Date) Seller shall deliver to Buyer a receipt (which may be confirmation by electronic mail) for payment of the amount set forth in Section 2.03.

Section 1.02. Conditions Applicable to Buyer.

The obligations of Buyer to effect the Closing and pay the Closing Amount pursuant to Section 2.03 hereof, shall be subject to the satisfaction of the following conditions, as of the Closing Date, any of which may be waived in writing by Buyer in its sole discretion:

(a) All notices to, consents, approvals, authorizations and waivers from Third Parties and Governmental Authorities that are required for the consummation of the

transactions contemplated by this Agreement or any of the Transaction Documents shall have been obtained or provided for and shall remain in effect, in form and substance reasonably acceptable to Buyer.

(b) All of the Transaction Documents (including without limitation, the Assignment) shall have been executed and delivered by Seller to Buyer, and Buyer shall have received the same.

(c) Buyer shall have received an opinion of Latham & Watkins, LLP, counsel to Seller, in form and substance reasonably acceptable to Buyer.

(d) Buyer shall have received a certificate of an executive officer of Seller (the statements made in which shall be true and correct on and as of the Closing Date): (i) attaching copies, certified by such officer as true and complete, of (x) the organizational documents of Seller and (y) resolutions of the governing body of Seller authorizing and approving the execution, delivery and performance by Seller of the Transaction Documents and the transactions contemplated herein and therein; (ii) setting forth the incumbency of the officer or officers of Seller who have executed and delivered the Transaction Documents, including therein a signature specimen of each such officer or officers; and (iii) attaching a copy, certified by such officer as true and complete, of a good standing certificate of the appropriate Governmental Authority of Seller's jurisdiction of organization issued as of a recent date, stating that Seller is in good standing under the Applicable Laws of such jurisdiction.

(e) Buyer shall have received a certificate of an executive officer of Seller (the statements made in which shall be true and correct on and as of the date of such certificate) attesting that (i) the representations made by Seller in ARTICLE III will be true as of the Closing Date, and (ii) there is no event or circumstance that, upon notice or the passage of time, or both, would constitute or give rise to any breach or default in the performance of Seller under this Agreement.

(f) Searches of Uniform Commercial Code filings in the jurisdictions where a filing would need to be made in order to perfect Purchaser's ownership of or security interest in the Purchased Assets, copies of the financing statements on file in such jurisdictions and evidence that no Liens exist on the Purchased Assets (apart from Liens created pursuant to this Agreement) have been completed, and copies of such search results provided to Buyer.

(g) UCC financing statements for each appropriate jurisdiction as is necessary, in Purchaser's sole discretion, to perfect Purchaser's ownership of and security interest in the Purchased Assets have been provided to Buyer.

(h) Payment of the amounts obligated to be paid by Seller to Purchaser under Section 8.12 have been made; provided that the condition set forth in this clause (g) will be satisfied by Purchaser's deduction of such amount from the Closing Payment.

ARTICLE VII

TERMINATION

Section 1.07. Termination.

This Agreement shall survive the expiration of any Licensed Patents and shall continue in full force and effect unless terminated on a date (such date, the "Termination Date") mutually agreed upon in writing by the Parties.

Section 1.08. Effects of Termination.

(a) The termination of this Agreement shall not release either Party of any obligation or liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination.

(b) Notwithstanding anything herein to the contrary, the termination of this Agreement shall be without prejudice to other remedies such Party may have at Law or in equity (including any enforcement of its rights under any of the Transaction Documents).

(c) ARTICLE I (Definitions) and Section 2.04 (No Assumption), Section 5.03 (Confidentiality; Public Announcement), Section 5.04(b) (Further Assurance) and Section 5.09(a) (Records), Section 5.17 (Audits), this Section 7.02 (Effects of Termination) and ARTICLE VIII (Miscellaneous) shall survive the termination of this Agreement. Except as otherwise provided in this Section 7.02 (Effects of Termination), all rights and obligations of the Parties under this Agreement shall terminate upon termination of this Agreement.

ARTICLE VIII

MISCELLANEOUS

Section 1.01. Survival.

Each representation and warranty of the Parties contained in the Transaction Documents will survive the Closing and continue in full force and effect, in each case, only as of the date such representation and warranty is made, until the Termination Date. Notwithstanding anything in this Agreement or implied by Law to the contrary, each covenant and obligation in the Transaction Documents or in any certificate delivered pursuant to the Transaction Documents will survive the Closing and continue in full force and effect until the Termination Date, subject to Section 7.02(c). Unless expressly waived pursuant to any Transaction Document, no representation, warranty, covenant, right or remedy available to any Person out of or in connection with any Transaction Document will be deemed waived by any action or inaction of that Person (including consummation of the Closing, any inspection or investigation, or the awareness of any fact or matter) at any time, whether before, on or after the Closing.

Section 1.02. Notices.

All notices, consents, waivers and communications hereunder given by any Party to the other shall be in writing (including electronic mail) and delivered personally, by electronic mail, by a recognized overnight courier, or by dispatching the same by certified or registered mail, return receipt requested, with postage prepaid, in each case addressed:

If to Buyer to:

HealthCare Royalty Partners IV, L.P.
300 Atlantic Street, 6th Floor
Stamford, CT 06901
Attention: [***]
Email: [***]

with a courtesy copy to (which shall not constitute notice):

HealthCare Royalty Partners IV, L.P.
300 Atlantic Street, 6th Floor
Stamford, CT 06901
Attention: [***]
Email: [***]

and

Cadwalader, Wickersham & Taft LLP
200 Liberty Street
New York, NY 10281
Attention: [***]
Email: [***]

If to Seller to:

Ardelyx, Inc.
34175 Ardenwood Blvd.
Fremont, CA 94555
Attention: [***]
Telephone: [***]
Email: [***]

with a courtesy copy to (which shall not constitute notice):

Ardelyx, Inc.
400 Fifth Avenue
Suite 210
Waltham, MA 02451
Attention: [***]

and

Latham & Watkins LLP

140 Scott Drive
Menlo Park, CA 94025-1008
Attention: [***].
Telephone: [***]
Email: [***]

or to such other address or addresses as Buyer or Seller may from time to time designate by notice as provided herein, except that notices of changes of address shall be effective only upon receipt. All such notices, consents, waivers and communications shall: (a) when posted by certified or registered mail, postage prepaid, return receipt requested, be effective five (5) Business Days after dispatch, (b) when sent by electronic mail, be effective upon receipt by the transmitting party of confirmation of complete transmission or return email or "read" receipt from the recipient, (c) when delivered by an internationally recognized overnight courier, be effective upon delivery (such date being evidenced by the courier's service records), or (d) when delivered in person, be effective upon delivery.

Section 1.03. Successors and Assigns.

The provisions of this Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and assigns. Seller shall not be entitled to assign any of its obligations or rights under the Transaction Documents without the prior written consent of Buyer; provided, however, such consent shall not be required in connection with an Acquisition, so long as the acquirer has delivered evidence, in form and substance reasonably satisfactory to Buyer, to Buyer that such Person has assumed all of Seller's rights and obligations under the Transaction Documents. Buyer may assign without the consent of Seller any of its rights or obligations under the Transaction Documents without restriction; provided that, so long as no Event of Default shall have occurred and be continuing, Buyer may not assign any of its rights and obligations under the Transaction Documents to any Competitor without the prior written consent of Seller. Any purported assignment in violation of this Section 8.03 shall be null and void.

Section 1.04. Indemnification.

(c) Seller hereby indemnifies and holds each Buyer Indemnified Party harmless from and against any and all Losses incurred or suffered by any Buyer Indemnified Party arising out of (i) any breach of any representation or warranty made by Seller in any of the Transaction Documents or in any certificate delivered pursuant to the Transaction Documents, (ii) any breach of or default under any covenant or agreement by Seller pursuant to any Transaction Document, the License Agreement or any Production Agreement, including any failure by Seller to satisfy any of the Excluded Liabilities and Obligations, (iii) any product liability claims or claims of infringement or misappropriation of any intellectual property rights of any Third Parties in respect of the Product, (iv) any Event of Default, (v) any Excluded Liabilities and Obligations, or (vi) any Losses suffered or incurred by any Buyer Indemnified Party as a result of the existence of any Permitted Liens. Notwithstanding the foregoing, such indemnification by Seller shall not apply with respect to any Losses to the extent resulting from the gross negligence, willful misconduct or bad faith of any Buyer Indemnified Party.

(d) Buyer hereby indemnifies and holds each Seller Indemnified Party harmless from and against any and all Losses incurred or suffered by a Seller Indemnified Party arising out of (i) any breach of any representation or warranty made by Buyer in any of the Transaction Documents or in any certificate delivered pursuant to the Transaction Documents or (ii) any breach of or default under any covenant or agreement by Buyer pursuant to any Transaction Document. Notwithstanding the foregoing, such indemnification by Buyer shall not apply with respect to any Losses to the extent resulting from the gross negligence, willful misconduct or bad faith of any Seller Indemnified Party.

(e) If any a Claim shall be brought or alleged against an indemnified party in respect of which indemnity is to be sought against an indemnifying party pursuant to the preceding paragraphs, the indemnified party shall, promptly after receipt of notice of the commencement of any such Claim, notify the indemnifying party in writing of the commencement of such Claim, enclosing a copy of all papers served, if any; provided, that the omission to so notify such indemnifying party will not relieve the indemnifying party from any liability that it may have to any indemnified party under the foregoing provisions of this Section 8.04 unless, and only to the extent that, such omission results in the forfeiture of, or has a material adverse effect on the exercise or prosecution of, substantive rights or defenses by the indemnifying party. In case any such Claim is brought against an indemnified party and it notifies the indemnifying party of the commencement thereof, the indemnifying party will be entitled to participate therein and, to the extent that it may wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party (who shall not, except with the consent of the indemnified party, be counsel to the indemnifying party), and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party will not be liable to such indemnified party under this Section 8.04 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof other than reasonable costs of investigation. In any such proceeding, an indemnified party shall have the right to retain its own counsel, but the reasonable and documented fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel, (ii) the indemnifying party has assumed the defense of such proceeding and has failed within a reasonable time to retain counsel reasonably satisfactory to such indemnified party or has failed to diligently conduct the defense of such Claim, (iii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential conflicts of interests between them based on the advice of such counsel; or (iv) the Claim relates to taxes or any criminal or regulatory enforcement Claim. The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any loss or liability by reason of such settlement or judgment. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened proceeding in respect of which any

indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement (i) includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such proceeding; (ii) provides for the payment by the indemnifying party of money as sole relief for the claimant; and (iii) involves no finding or admission of any violation of Law or the rights of any Person and has no effect on any other claims that have been made against the indemnified person.

(f) The only legal action that may be asserted by or on behalf of any Buyer Indemnified Party or Seller Indemnified Party with respect to any matter arising out of the transactions contemplated by this Agreement or the Transaction Documents shall be an action to enforce or to recover Losses as an indemnification claim pursuant to this Section 8.04. Without limiting the generality of the foregoing, no legal action based upon predecessor or successor liability, contribution, tort, strict liability or any statute, regulation or ordinance may be maintained by or on behalf of Buyer or any Buyer Indemnified Party or Seller or any Seller Indemnified Party, as applicable, with respect to any matter that is the subject of this Section 8.04.

(g) Losses shall be (i) calculated net of actual recoveries received by or on behalf of an indemnified party under insurance policies, risk sharing pools or similar arrangements (net of any actual collection costs and recoveries and deductibles) and (ii) reduced by any proceeds received from third parties, through indemnification, counterclaim or otherwise in compensation for the subject matter of an indemnification claim made hereunder. Notwithstanding the foregoing, any indemnified party may take any action against an indemnifying party to enforce or recover Losses pursuant to the indemnification obligations of the indemnifying party under this Section 8.04 without any requirement to take any action or exhaust any right or remedy against any other Person, provided that the indemnified party agrees that the indemnifying party shall then be subrogated to any and all other rights of the indemnified party to recovery to the extent of such indemnification paid by the indemnifying party (but excluding interest amounts and gross-up or other payments in respect of taxes). If any proceeds, benefits or recoveries are received by or on behalf an indemnified party with respect to Losses after an indemnifying party has made an indemnification payment to an indemnified party with respect thereto and receipt of such proceeds, benefits or recoveries prior to such payment would have reduced the amount of such indemnification payment if received prior to such payment, then such indemnified party shall hold such amounts in trust for the benefit of the indemnifying party and, within three (3) Business Days after receipt thereof, deliver such amounts (net of any applicable withholding tax) to the indemnifying party by wire transfer of immediately available funds as directed by the indemnifying party.

(h) Neither Party shall be obligated to indemnify Seller Indemnified Parties or Buyer Indemnified Parties, as applicable, with respect to any Losses as to which such Party is otherwise entitled to assert any claim for indemnification, pursuant to Section 8.04(a)(i) or Section 8.04(b)(i), as applicable, unless and until the aggregate amount of the Losses of Seller Indemnified Parties or Buyer Indemnified Parties in respect of Section 8.04(a)(i) or Section 8.04(b)(i), as applicable, exceed the Indemnity Threshold Amount; provided, however, that

thereafter the indemnifying party shall indemnify Buyer Indemnified Parties or Seller Indemnified Parties, as applicable, for all amounts including, for the avoidance of doubt, the Indemnity Threshold Amount; provided, further, that such foregoing limitation shall not apply to any Losses suffered by any indemnified party in connection with a Third Party Claim.

(i) Notwithstanding anything in this Agreement to the contrary, Seller shall not have any liability under Section 8.04(a) in excess of the sum of (i) the Closing Amount, (ii) all Investment Payments made by Buyer to Seller, and (iii) the applicable Investment Return Amount; provided that such foregoing limitation shall not apply to any Losses suffered by any Buyer Indemnified Party in connection with a Third Party Claim (other than any Losses to the extent resulting from the gross negligence, willful misconduct or bad faith of any Buyer Indemnified Party). Notwithstanding anything in this Agreement to the contrary, Buyer shall not have any liability under Section 8.04(b) in excess of the amount of Royalty Interest Payments received by Buyer pursuant to this Agreement.

Section 1.05. Independent Nature of Relationship; Taxes.

(a) The relationship between Seller, on the one hand, and Buyer, on the other hand, is solely that of assignor and assignee, and neither Buyer, on the one hand, nor Seller, on the other hand, has any fiduciary or other special relationship with the other or any of their respective Affiliates. For the avoidance of doubt, nothing in this Agreement shall be read to create any agency, partnership, association or joint venture of Seller (or any of its Affiliates) and Buyer (or any of its Affiliates) and each Party agrees not to refer to the other as a "partner" or the relationship as a "partnership" or "joint venture" or other kind of entity or legal form.

(b) Except as otherwise contemplated herein, no Party shall at any time obligate the other Party, or impose on such other Party any obligation, in any manner or respect to any Third Party.

(c) Seller and Buyer shall treat the transactions contemplated by the Transaction Documents as a sale of the Purchased Assets for all purposes (other than financial accounting purposes), including United States federal, state and local tax purposes.

(d) The Parties hereto agree not to take any position that is inconsistent with the provisions of this Section 8.05 on any tax return or in any audit or other administrative or judicial proceeding unless (i) the other Party to this Agreement has consented to such actions, or (ii) such inconsistent position is required by applicable Law. If a Governmental Authority conducts an inquiry of Seller or Buyer related to this Section 8.05, the Parties hereto shall cooperate with each other in responding to such inquiry in a reasonable manner consistent with this Section 8.05.

(e) The Parties shall use commercially reasonable efforts to ensure all payments to Buyer under this Agreement are made without any deduction or withholding for or on account of any tax, provided that if deduction or withholding is required from any payment under this Agreement, other than any deduction or withholding

in respect of (i) any tax that would not have been imposed (or would have been imposed but at a lower rate) but for any connection of Buyer with the jurisdiction of the applicable taxing authority (other than a connection arising solely from this Agreement or any transaction contemplated hereby); (ii) any tax that would not have been imposed (or would have been imposed but at a lower rate) but for any failure of Buyer to provide any applicable documentation permitting such payments to be made without (or at a reduced rate of) withholding that is reasonably requested by Seller and that Buyer is legally eligible to provide and (iii) any U.S. federal withholding tax (such taxes described in clauses (i) through (iii), "Excluded Taxes," and all such taxes other than Excluded Taxes, "Indemnified Taxes"), the sum payable shall be increased and paid by Seller or any of its Affiliates as necessary so that after all such deductions and withholdings have been made, Buyer receives an amount equal to the amount it would have received had no such deductions or withholding been made. Seller shall promptly notify Buyer in writing in the event that any deduction or withholding is effected or proposed by Seller or, to the Knowledge of Seller, any Governmental Authority, with respect to any such payments hereunder. On or prior to the Closing Date, Buyer shall deliver to Seller a duly executed Internal Revenue Service Form W-9.

(f) The Parties shall treat any Investment Payments pursuant to Section 2.03(b) and any indemnification payments pursuant to Section 8.04 (except to the extent treated as imputed interest pursuant to Sections 483 or 1274 of the Internal Revenue Code of 1986, as amended or otherwise) as adjustments to the purchase price of the Purchased Assets for all tax purposes to the extent permitted by applicable Law.

(g) Without limitation of Section 8.05(d) and (e), this Agreement is not intended to create a deemed partnership, association or joint venture between Buyer and any counterparty. Each Party agrees not to refer to the other as a "partner," or the relationship as a "partnership" or "joint venture."

Section 1.06. Entire Agreement.

This Agreement, together with the Exhibits and Schedules hereto (which are incorporated herein by reference), and the other Transaction Documents constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior agreements (including the Confidentiality Agreement), understandings and negotiations, both written and oral, between the Parties with respect to the subject matter of this Agreement. Neither this Agreement nor any provision hereof (other than Section 8.03 and Section 8.04), is intended to confer upon any Person other than the Parties any rights or remedies hereunder.

Section 1.07. Amendments; No Waivers.

(a) This Agreement or any term or provision hereof may not be amended, changed or modified except with the written consent of both Parties. No waiver of any right hereunder shall be effective unless such waiver is signed in writing by the Party against whom such waiver is sought to be enforced.

(b) No failure or delay by either Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege.

(c) No waiver or approval hereunder shall, except as may otherwise be stated in such waiver or approval, be applicable to subsequent transactions. No waiver or approval hereunder shall require any similar or dissimilar waiver or approval thereafter to be granted hereunder. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by applicable Law.

Section 1.08. Interpretation.

When a reference is made in this Agreement to Articles, Sections, Schedules or Exhibits, such reference shall be to an Article, Section, Schedule or Exhibit to this Agreement unless otherwise indicated. The words "include", "includes" and "including" when used herein shall be deemed in each case to be followed by the words "without limitation". Neither Party shall be or be deemed to be the drafter of this Agreement for the purposes of construing this Agreement against one Party or the other. The word "or" has the inclusive meaning represented by the phrase "or." References to an agreement or instrument mean such agreement or instrument as from time to time amended, supplemented, restated or otherwise modified in compliance with the terms thereunder. References to a Person are also to its permitted successors and assigns.

Section 1.09. Headings and Captions.

The headings and captions in this Agreement are for convenience and reference purposes only and shall not be considered a part of or affect the construction or interpretation of any provision of this Agreement.

Section 1.10. Counterparts; Effectiveness; Electronic Signatures.

This Agreement may be executed in two or more counterparts, each of which shall be an original, but all of which together shall constitute one and the same instrument. This Agreement shall become effective when each Party shall have received a counterpart hereof signed by the other Party. Any counterpart may be executed by facsimile, .pdf signature or other electronic signature and any such signature shall be deemed an original. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Agreement and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Buyer, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

Section 1.11. Severability.

If any provision of this Agreement is held to be invalid or unenforceable, the remaining provisions shall nevertheless be given full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree by a court of competent jurisdiction shall remain in full force and effect to the extent not held invalid or unenforceable. Upon such determination that a provision is invalid or unenforceable, the Parties shall negotiate in good faith to modify this Agreement as to effect the original intent of the Parties as closely as possible to the fullest extent permitted by applicable Law to the end that the transactions contemplated hereby are fulfilled to the extent possible.

Section 1.12. Expenses.

Each party will pay all of its own fees and expenses in connection with entering into and consummating the transactions contemplated by this Agreement; provided, that [***].

Section 1.13. Governing Law; Jurisdiction.

(a) This Agreement shall be governed by, and construed, interpreted and enforced in accordance with, the laws of the State of New York, USA without giving effect to the principles of conflicts of law thereof (other than Section 5-1401 of the General Obligations Law of the State of New York). Each Party unconditionally and irrevocably consents to the exclusive jurisdiction of the courts of the State of New York, USA located in the County of New York and the Federal district court for the Southern District of New York located in the County of New York with respect to any suit, action or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby. Each Party hereby further irrevocably waives any objection, including any objection to the laying of venue or based on the grounds of *forum non conveniens*, which it may now or hereafter have to the bringing of any action or proceeding in such jurisdiction in respect of any Transaction Document.

(b) Each Party hereby irrevocably consents to the service of process out of any of the courts referred to in Section 8.13(a) in any such suit, action or proceeding by the mailing of copies thereof by registered or certified mail, postage prepaid, to it at its address set forth in this Agreement. Each Party hereby irrevocably waives any objection to such service of process and further irrevocably waives and agrees not to plead or claim in any suit, action or proceeding commenced hereunder or under any other Transaction Document that service of process was in any way invalid or ineffective. Nothing herein shall affect the right of a Party to serve process on the other Party in any other manner permitted by law.

Section 1.6. Waiver of Jury Trial.

EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING, CLAIM OR COUNTERCLAIM ARISING OUT OF OR RELATING TO ANY TRANSACTION DOCUMENT OR THE TRANSACTIONS CONTEMPLATED UNDER ANY TRANSACTION DOCUMENT. THIS WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR

MODIFICATIONS TO ANY TRANSACTION DOCUMENT (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). THIS WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO ANY TRANSACTION DOCUMENT. EACH PARTY HERETO (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF THE OTHER PARTY HERETO HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT THE OTHER PARTY HERETO WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8.14.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed by their respective authorized officers as of the date first above written.

SELLER:	Ardelyx, Inc.
	By: /s/ Michael Raab
	Name: Michael Raab Title: CEO
BUYER:	HealthCare Royalty Partners IV, L.P.
	By: /s/ Clarke Futch
	Name: Clarke B. Futch Title: Chairman & CEO

Exhibit A
License Agreement

Incorporated by reference to Exhibit 10.35 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and Exhibit 10.1 of the Company's report on Form 8-K filed in April 11, 2022 filed with the Securities and Exchange Commission.

Exhibit 10.2

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "**Amendment**") is entered into as of August 1, 2022, by and among SLR INVESTMENT CORP., a Maryland corporation with an office located at 500 Park Avenue, 3rd Floor, New York, NY 10022 ("**SLR**"), as collateral agent (in such capacity, together with its successors and assigns, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 thereto or otherwise a party thereto from time to time including SLR in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and ARDELYX, INC., a Delaware corporation with offices located at 400 Fifth Avenue, Suite 210, Waltham, MA 02451 (the "**Borrower**").

A. Collateral Agent, Borrower and Lenders have entered into that certain Loan and Security Agreement dated as of February 23, 2022 (as amended, supplemented or otherwise modified from time to time, the "**Loan Agreement**") pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof; and

B. Borrower, Collateral Agent and the Required Lenders have agreed to amend the defined term "Term B Milestone", subject to, and in accordance with, the terms and conditions set forth herein, and in reliance upon the representations and warranties set forth herein.

Agreement

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

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

2. Amendment to Loan Agreement. The defined term "Term B Milestone" in Section 1.4 of the Loan Agreement is hereby amended by replacing the reference to December 31, 2022 with March 31, 2023.

3. Limitation of Amendment.

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

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

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

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

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

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

1.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not contravene (i) any material law or regulation binding on or affecting Borrower, (ii) any material contractual restriction with a Person binding on Borrower, (iii) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;

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

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

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

6. Effectiveness. This Amendment shall be deemed effective as of the date hereof upon the due execution of this Amendment by the parties thereto.

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

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

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

[*Balance of Page Intentionally Left Blank*]

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

BORROWER:

ARDELYX, INC.

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

COLLATERAL AGENT AND LENDER:

SLR INVESTMENT CORP.

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

LENDERS:

SLR SENIOR INVESTMENT CORP.
SCP PRIVATE CREDIT INCOME FUND SPV, LLC
SCP PRIVATE CREDIT INCOME BDC SPV LLC
SCP PRIVATE CORPORATE LENDING FUND SPV LLC
SCP SF DEBT FUND L.P.
SLR HC FUND SPV, LLC
SLR HC BDC LLC

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

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

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

1. Cash Compensation.

(a) Annual Retainers. Each Non-Employee Director shall be eligible to receive an annual retainer of $45,000 for service on the Board.

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

(i) Chairman of the Board. A Non-Employee Director serving as Chairman of the Board shall receive an additional annual retainer of $30,000 for such service.

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

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

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

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

(d) Election to Receive Stock in Lieu of Cash. After the first payment of Annual Retainers following the Effective Date, Non-Employee Directors shall have the ability to elect to receive the Annual Retainers in an award of stock in lieu of cash pursuant to an election form provided by the Company for such purpose. Non-Employee Directors must complete and deliver the election form to the Company no later than 15 days prior to the next annual meeting of the Company's stockholders. In the event that a Non-Employee Director makes an election to receive the Annual Retainers in an award of stock in lieu of cash, on the annual meeting of the Company's stockholders, he or she will automatically be granted that number of shares of fully vested Company common stock calculated by dividing the aggregate amount of the Annual Retainers by the Fair Market Value (as defined in the Equity Plan (as defined below)) of a share of Company common stock on the date of grant, rounded down to the nearest whole share. The stock awards shall be granted under and shall be subject to the terms and provisions of the Company's 2014 Equity Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "***Equity Plan***"). In the event of any inconsistency between the Equity Plan and this Program, the terms of this Program shall control.

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

(a) Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall be eligible to receive, on the date of such initial election or appointment, an option to purchase shares of the Company's common stock with a grant date fair value of $300,000, but with a maximum number of shares of 200,000 shares of the Company's common stock. The awards described in this Section 2(a) shall be referred to as "***Initial Awards***." No Non-Employee Director shall be granted more than one Initial Award.

(b) Subsequent Awards. A Non-Employee Director who (i) has been serving on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted, on the date of such annual meeting, an option to purchase shares of the Company's common stock with a grant date fair value of $150,000, but with a maximum number of shares of 100,000 shares of the Company's common stock. The awards described in this Section 2(b) shall be referred to as "***Subsequent Awards***." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

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

(d) Terms of Awards Granted to Non-Employee Directors

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

(ii) Vesting. Each Initial Award shall vest and become exercisable with respect to 1/36th of the shares subject to the Initial Award on each monthly anniversary of the date of grant, subject to the Non-Employee Director continuing in service on the Board through each such vesting

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

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

3. Reimbursements. The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of his or her duties to the Company in accordance with the Company's applicable expense reimbursement policies and procedures as in effect from time to time.

* * * * *

Exhibit 31.1

CERTIFICATION

I, Michael Raab, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 4, 2022

By: /s/ Michael Raab

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

Exhibit 31.2

CERTIFICATION

I, Justin Renz, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 4, 2022

By: /s/ Justin Renz

Justin Renz
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 Quartlery Report of Ardelyx, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Michael Raab, President and Chief Executive Officer of the Company, and Justin Renz, Chief Financial 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 4, 2022 By: /s/ Michael Raab

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

Date: August 4, 2022 By: /s/ Justin Renz

Justin Renz
Chief Financial Officer
(Principal Financial Officer)