# 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 March 31, 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

Johnnission me number: 001-3040



ARDELYX, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

26-1303944

(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 Sec	tion 12(b) of the Act:											
Title of eac	]	Trading Symbol(s)	Name of each exchange on which registered									
Common Stock, par	Common Stock, par value \$0.0001			The Nasdaq G	Global Market							
Indicate by check mark whether the such shorter period that the registran	0 ()	· ·	5	rities Exchange Act of 1934 during th for the past 90 days. Yes 🛛 No [	_							
5	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 definitions of "large accelerated filer	0 0	-		aller reporting company, or an emerg Rule 12b-2 of the Exchange Act.	ing growth company. See the							
Large acceler	ated filer	$\boxtimes$		Accelerated filer								
Non-accelerat	ed filer			Smaller reporting company								
				Emerging growth company								
If an emerging growth company, ind standards provided pursuant to Section	5	° _	to use the extended transition period	l for complying with any new or revis	sed financial accounting							
* *												

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 May 2, 2022, was 144,598,863.

# 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<sup>®</sup> (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<sup>®</sup>, 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 a limited operating history, 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 to achieve our goals, including our goals of commercializing IBSRELA, and preparing for and participating 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 ("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 XPHOZAH for the Hyperphosphatemia Indication, and 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 XPHOZAH for the Hyperphosphatemia Indication, the expense and time required to do so could adversely impact our ability to successfully commercialize XPHOZAH for such 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 no prior 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<sup>®</sup>, IBSRELA<sup>®</sup>, and XPHOZAH<sup>®</sup> are trademarks of Ardelyx. All other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

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# PART I. FINANCIAL INFORMATION

# ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2022		December 31, 2021
	 (Unaudited)		
Assets			
Current assets:			
Cash and cash equivalents	\$ 47,077	\$	72,428
Short-term investments	42,627		44,261
Accounts receivable	4,394		502
Inventory	3,487		—
Prepaid expenses and other current assets	 16,640		16,458
Total current assets	114,225		133,649
Right-of-use assets	11,910		12,752
Property and equipment, net	2,045		2,362
Other assets	 1,228		1,150
Total assets	\$ 129,408	\$	149,913
Liabilities and stockholders' equity		-	
Current liabilities:			
Accounts payable	\$ 5,030	\$	4,277
Accrued compensation and benefits	6,304		5,422
Current portion of long-term debt	26,139		32,264
Current portion of operating lease liability	3,592		3,492
Accrued expenses and other current liabilities	6,778		7,366
Total current liabilities	47,843		52,821
Operating lease liability, net of current portion	8,812		9,748
Deferred revenue, non-current	 8,563		4,727
Total liabilities	65,218		67,296
Commitments and contingencies (Note 13)			
Stockholders' equity:			
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; no shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively.	_		_
Common stock, \$0.0001 par value; 300,000,000 shares authorized; 136,330,360 and 130,182,535 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively.	14		13
Additional paid-in capital	805,265		795,540
Accumulated deficit	(741,001)		(712,930)
Accumulated other comprehensive loss	(88)		(6)
Total stockholders' equity	 64,190	_	82,617
Total liabilities and stockholders' equity	\$ 129,408	\$	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 I	Ended	March 31,
	 2022		2021
Revenues:			
Product sales, net	\$ 450	\$	_
Product supply revenue	14		126
Licensing revenue	4		5,002
Collaborative development revenue	 		1,454
Total revenues	 468		6,582
Operating expenses:			
Cost of revenue	85		1,000
Research and development	8,851		20,456
Selling, general and administrative	 19,339		17,131
Total operating expenses	28,275		38,587
Loss from operations	(27,807)		(32,005)
Interest expense	(746)		(1,100)
Other income (expense), net	 484		(49)
Loss before provision for income taxes	(28,069)		(33,154)
Provision for income taxes	 2		1
Net loss	\$ (28,071)	\$	(33,155)
Net loss per common share, basic and diluted	\$ (0.21)	\$	(0.34)
Shares used in computing net loss per share - basic and diluted	130,934,795		97,179,241
Comprehensive loss:			
Net loss	\$ (28,071)	\$	(33,155)
Unrealized losses on available-for-sale securities	(82)		(3)
Comprehensive loss	\$ (28,153)	\$	(33,158)
		_	

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

# ARDELYX, INC. CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY For the Three Months ended March 31, 2022 and 2021 (Unaudited) (in thousands, except shares)

	Three Months Ended March 31, 2022											
	Common Stock			Additional				Accumulated Other			Total	
	Shares		Amount		Paid-In Capital		Accumulated Deficit		Comprehensive Income		Stockholders' Equity	
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	113,469		_		_		_				_	
Issuance of common stock in at the market offering	5,907,256		1		5,920		_		_		5,921	
Stock-based compensation	_				3,722		_		_		3,722	
Unrealized losses on available-for-sale securities	_		_		_		_		(82)		(82)	
Net loss	_						(28,071)		_		(28,071)	
Balance as of March 31, 2022	136,330,360	\$	14	\$	805,265	\$	(741,001)	\$	(88)	\$	64,190	

	Three Months Ended March 31, 2021										
-	Commo	on Sto	Amount		Additional Paid-In Capital		Accumulated Deficit		Accumulated Other Comprehensive Income	S	Total tockholders' Equity
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	10,507		_		20		_		_		20
Issuance of common stock upon vesting of restricted stock units	35,100		_				_		_		_
Issuance of common stock in at the market offering	4,940,787		1		34,271						34,272
Stock-based compensation	_		_		3,087		_		_		3,087
Unrealized losses on available-for-sale securities	_		_		_		_		(3)		(3)
Net loss	—		—				(33,155)		—		(33,155)
Balance as of March 31, 2021	98,688,577	\$	10	\$	718,728	\$	(587,920)	\$	(7)	\$	130,811

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

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

(in tiousanus)		Three Months Ended March 31,					
		2022		2021			
Operating activities							
Net loss	\$	(28,071)	\$	(33,155)			
Adjustments to reconcile net loss to net cash used in operating activities:							
Depreciation expense		232		422			
Amortization of deferred financing costs		169		157			
Amortization of deferred compensation for services		47		77			
Amortization of (discount) premium on investment securities		15		157			
Non-cash lease expense		842		607			
Stock-based compensation		3,722		3,087			
Change in derivative liabilities		15		36			
Debt refinancing costs		102		_			
Gain on sale of equipment		(710)					
Non-cash interest associated with debt discount accretion		109		70			
Changes in operating assets and liabilities:							
Accounts receivable		(3,892)		(5,783)			
Inventory		(3,487)					
Prepaid expenses and other assets		(307)		(13,662)			
Accounts payable		753		(248)			
Accrued compensation and benefits		882		(1,324)			
Operating lease liabilities		(836)		(721)			
Accrued and other liabilities		(1,041)		7,517			
Deferred revenue		3,836		(1,454)			
Net cash used in operating activities		(27,620)		(44,217)			
Investing activities							
Proceeds from maturities and redemptions of investments		27,300		35,370			
Purchases of investments		(25,763)		(32,107)			
Proceeds from sale of equipment		795		_			
Purchases of property and equipment				(778)			
Net cash provided by investing activities		2,332	-	2,485			
Financing activities							
Proceeds from 2022 Loan, net of issuance costs		26,971					
Repayment of 2018 Loan, net of settlement costs		(33,038)					
Proceeds from issuance of common stock in at the market offering, net of issuance costs		5,921		34,272			
Proceeds from issuance of common stock under equity incentive and stock purchase plans		83		498			
Net cash provided by (used in) financing activities		(63)		34,770			
Net decrease in cash and cash equivalents		(25,351)		(6,962)			
Cash and cash equivalents at beginning of period		72,428		91,032			
Cash and cash equivalents at end of period	\$	47,077	\$	84,070			
Supplementary disclosure of cash flow information:	<u> </u>	17,077	Ψ	01,070			
	\$	741	\$	963			
Cash paid for interest				903			
Cash paid for income taxes	\$	1	\$				
Supplementary disclosure of non-cash activities:							
Right-of-use assets obtained in exchange for lease obligations	<u>\$</u>		\$	450			
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 months ended March 31, 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 March 31, 2022, we had cash and investments of approximately \$89.7 million. We have incurred operating losses since inception and our accumulated deficit as of March 31, 2022 is \$741.0 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 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 months ended March 31, 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 March 31, 2022 our accounts receivable balance is comprised of \$3.8 million from our collaborators and \$0.6 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 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 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 specialty distributor sales to pharmacies, and available industry payor information.

Chargebacks: Chargebacks are discounts that occur when contracted purchasers purchase directly from our specialty distributors at a discounted price. The specialty distributor, in turn, charges back the difference between the price initially paid to us by the specialty distributor and the discounted price paid to the specialty distributor 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 specialty distributor chargebacks is estimated based on known chargeback rates, known sales to specialty distributors, and estimated utilization by types of contracted purchasers.

Discounts and Fees: Our payment terms are generally 30 to 60 days. Specialty distributors and specialty pharmacies are offered various forms of consideration, including service fees and prompt pay discounts for payment within a specified period. We expect these Customers will earn prompt pay discounts 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, 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 months ended March 31, 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 \$11.7 million as cost of revenue under the AZ Termination Agreement.

# **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 March 31, 2022 and December 31, 2021 are summarized below (in thousands):

		March 31, 2022									
				Gross U							
	Amo	Amortized Cost		Gains		Losses		Fair Value			
Cash and cash equivalents:											
Cash	\$	7,555	\$	—	\$		\$	7,555			
Money market funds		34,524		—		—		34,524			
Commercial paper		4,999				(1)		4,998			
Total cash and cash equivalents		47,078				(1)		47,077			
Short-term investments:											
Commercial paper	\$	28,409	\$	—	\$	(52)	\$	28,357			
U.S. government-sponsored agency bonds		10,777		—		(22)		10,755			
Corporate bonds		2,521		—		(10)		2,511			
Asset-backed securities		1,007				(3)		1,004			
Total short-term investments		42,714		_		(87)		42,627			
Total cash equivalents and investments	\$	89,792	\$	_	\$	(88)	\$	89,704			

	December 31, 2021									
				Gross U						
	Amo	rtized 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 March 31, 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 March 31, 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):

	March 31, 2022										
	]	Total Fair Value	Level 1		Level 2			Level 3			
Assets:											
Money market funds	\$	34,524	\$	34,524	\$	—	\$	—			
Commercial paper		33,355		—		33,355		—			
U.S. government-sponsored agency bonds		10,755		—		10,755		—			
Corporate bonds		2,511		—		2,511		—			
Asset-backed securities		1,004		—		1,004		—			
Total	\$	82,149	\$	34,524	\$	47,625	\$	—			
Liabilities:											
Derivative liability for exit fees	\$	1,088	\$		\$		\$	1,088			
Total	\$	1,088	\$	_	\$	_	\$	1,088			

	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 Exit Fee, as defined and discussed in Note 8, 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 March 31, 2022 and December 31, 2021, due to their short-term nature.

#### Fair Value of Debt

The interest rate of our term loan facility approximates the rate at which we could obtain alternative financing. Therefore, the carrying amount of the term loan facility approximated its fair value at March 31, 2022 and December 31, 2021.

### **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):

	March 31, 2022
Raw materials	\$ 460
Work in process	2,507
Finished goods	520
Total	\$ 3,487

### NOTE 5. PRODUCT REVENUE, NET

We received approval from the 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 U.S. We began selling IBSRELA in the U.S. in March 2022. We recorded net revenue for IBSRELA of \$0.5 million during the three months ended March 31, 2022.

Sales to Cardinal Health, AmerisourceBergen Drug Corporation, and McKesson Corporation made up 17.9%, 17.1%, and 15.4% of our gross product revenue during the three months ended March 31, 2022.

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

	unts and gebacks	Rebates	Other Fees, Copay and Returns	Total
Balance as of December 31, 2021	\$ 	\$ _	\$ _	\$ _
Activity related to 2022 sales	24	40	90	154
Balance as of March 31, 2022	\$ 24	\$ 40	\$ 90	\$ 154

There were no product sales or gross-to-net accruals during the three months ended March 31, 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 term of the 2019 KKC Agreement commenced on the Effective Date and ends 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 have no material future obligations under the 2019 KKC Agreement and recorded no revenue under the 2019 KKC Agreement during the three months ended March 31, 2022. During the three months ended March 31, 2021, we recognized \$1.5 million 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.

In addition to the up-front license fee received of \$30.0 million, we may be entitled to receive up to \$55.0 million in total development milestones, of which \$10.0 million has been received and recognized as revenue as of March 31, 2022, and approximately ¥8.5 billion for commercialization milestones, or approximately \$69.7 million at the currency exchange rate on March 31, 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. The variable consideration related to the remaining development milestone payments has not been included in the transaction price as these were fully constrained at March 31, 2022.

As discussed in *Note 14 - Subsequent events*, on April 11, 2022, we entered into a second amendment (the "Amendment") to the 2017 KKC Agreement. Under the terms of the Amendment, the parties 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 consideration for the reduction in the royalty rate, KKC has agreed to pay us up to an additional U.S. \$40.0 million payable in two tranches, with the first payment due following KKC's filing with the Japanese Ministry Health, Labour and Welfare (MHLW) 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.



During the three months ended March 31, 2022 we recognized no licensing revenue upon the achievement of development milestones. During the three months ended March 31, 2021, we recognized \$5.0 million licensing revenue upon the initiation of phase 3 clinical studies by KKC in Japan to evaluate tenapanor for hyperphosphatemia. During the three months ended March 31, 2022, we recognized \$14 thousand 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 months ended March 31, 2021, we recognized \$0.1 million 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. We also have recorded certain unbilled prepayments from KKC for the manufacturing of tenapanor drug product reflected within prepaid and other current assets. Both amounts are reflected within our deferred revenue, non-current on our condensed balance sheet as of March 31, 2022. The prepayment is reflected within prepaid and other current assets and deferred revenue, non-current on our condensed balance sheet as of March 31, 2022.

### 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. We assessed these arrangements in accordance with ASC 606 and concluded that the contract counterparty, Fosun Pharma, is a customer. Under the terms of the Fosun Agreement, we received \$12.0 million in upfront license fees which was recognized as revenue when the agreement was executed. Based on management's assessment, we determined that the license and the manufacturing supply services represented the material performance obligations at the inception of the agreement, and as such, each of the performance obligations is distinct.

We may be entitled to additional development and commercialization milestones of up to \$110.0 million, 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 March 31, 2022.

We have recorded no revenue during the three months ended March 31, 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. We assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Knight, is a customer. Based on management's assessment, we determined that the license and the manufacturing supply services represented the material performance obligations at the inception of the agreement, and as such, each of the performance obligations is distinct. Under the terms of the agreement, we received a \$2.3 million nonrefundable, one-time upfront payment in March 2018 and are eligible to receive additional development and commercialization milestone payments worth up to \$17.8 million. 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 March 31, 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 March 31, 2022, to date in aggregate, we have recognized \$11.7 million of the \$75.0 million, which has been recorded as cost of revenue, and have paid AstraZeneca \$11.6 million. During the three months ended March 31, 2022 we recognized and recorded as cost of revenue \$0.1 million related to the AstraZeneca Termination Agreement. During the three months ended March 31, 2021 we recognized \$1.0 million 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 March 31, 2021 current deferred revenue balance is attributable entirely to the 2019 KKC Agreement and the non-current deferred revenue balances at March 31, 2022 and 2021 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			(1,454)
Balance at March 31,	\$ 	\$	2,723
Deferred revenue - non-current	2022	2021	
Deferred revenue - non-current Balance at January 1,	\$ <b>2022</b> 4,727	\$ 2021	
	\$ -	\$ 2021	 2,947
Balance at January 1,	\$ 4,727	\$ 2021	 2,947 

# **NOTE 7. 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 8. 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 Investments 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"). 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 onemonth 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. 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 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 March 31, 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 March 31, 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	(1,399)
Less: Unaccreted value of final fee	(1,324)
Long-term debt	26,139
Less: Current portion of long-term debt	(26,139)
Long-term debt, net of current portion	\$ _

### NOTE 8. 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.

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.

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 months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,				
	 2022	2021			
Beginning balance	\$ 698	\$ 1,37	76		
2022 Exit Fee addition at fair value	375	-	_		
Changes in estimated fair value	15	3	36		
Ending balance	\$ 1,088	\$ 1,41	12		

### **NOTE 9. 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 as of March 31, 2022 and December 31, 2021 (dollars in thousands):

Facilities	March 31, 2022	Decembe	er 31, 2021
Right-of-use assets	\$ 11,910	\$	12,752
Current portion of lease liabilities	3,592		3,492
Operating lease liability, net of current portion	 8,812		9,748
Total	\$ 12,404	\$	13,240
Weighted-average remaining life (years)	3.2		3.4
Weighted-average discount rate	6.9 %		6.9 %

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

	,	Three Months Ended March 31,				
		2022		2021		
Operating lease expense	\$	1,064	\$	673		
Cash paid for operating lease	\$	1,058	\$	1,565		

The following table summarizes our undiscounted cash payment obligations for our operating lease liabilities as of March 31, 2022 (in thousands):

Remainder of 2022	\$ 3,234
2023	4,440
2024	4,589
2025	1,321
2026	252
Total undiscounted operating lease payments	 13,836
Imputed interest expenses	(1,432)
Total operating lease liabilities	 12,404
Less: Current portion of operating lease liability	(3,592)
Operating lease liability, net of current portion	\$ 8,812

#### NOTE 10. 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 three months ended March 31, 2021 we sold 4.9 million shares and received gross proceeds of \$35.0 million at a weighted average sales price of approximately \$7.09 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 three months ended March 31, 2022 we sold 5.9 million shares and received gross proceeds of \$6.0 million at a weighted average sales price of approximately \$1.02 per share under the 2021 Open Market Sales Agreement.

We sold 8.3 million shares of our common stock pursuant to the 2021 Open Market Sales Agreement which were settled between the dates of April 1, 2022 through April 27, 2022 for gross proceeds of \$9.0 million at a weighted average sales price of approximately \$1.09 per share. We did not sell any additional shares of our common stock after April 25, 2022 and through the date of filing this Quarterly Report on Form 10-Q.

# NOTE 11. 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 Month	Three Months Ended March 31,			
	2022	2022			
Research and development	\$ 1,2	4 \$	1,092		
Selling, general and administrative	2,50	8	1,995		
Total	\$ 3,7	2 \$	3,087		

As of March 31, 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	\$ 14,865	3.0
RSU grants	\$ 4,894	1.3
ESPP	\$ 53	0.8

### **Stock Options**

A summary of our stock option activity and related information for the three months ended March 31, 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	3,535	\$ 0.98
Options exercised	—	\$ —
Options forfeited or canceled	(1,006)	\$ 7.18
Balance at March 31, 2022	12,946	\$ 5.34
Exercisable at March 31, 2022	6,476	\$ 7.16

### **Restricted Stock Units**

A summary of our RSUs activity and related information for the three months ended March 31, 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	1,120	\$ 0.98
Vested	(113)	\$ 3.62
Forfeited	(88)	\$ 2.02
Non-vested restricted stock units at March 31, 2022	4,448	\$ 1.73

### **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 three months ended March 31, 2022, we issued no shares of our common stock to members of the board of directors in accordance with the program.

#### NOTE 12. 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 three months ended March 31, 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 Month	Three Months Ended March 3							
Numerator:	2022		2021						
Net loss	\$ (28,07	.) \$	(33,155)						
Denominator:									
Weighted average common shares outstanding - basic and diluted	130,93	5	97,179						
Net loss per share - basic and diluted	\$ (0.2	) \$	(0.34)						

For the three months ended March 31, 2022, the total number of securities that could potentially dilute basic net loss per share in the future that were not included in the computation of diluted net loss per share because the effect would have been antidilutive was 13.3 million.

For the three months ended March 31, 2021, the total number of securities that could potentially dilute basic net loss per share in the future that were not included in the computation of diluted net loss per share because the effect would have been antidilutive was 13.0 million.

# NOTE 13. 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 March 31, 2022 or 2021.

### NOTE 14. SUBSEQUENT EVENTS

On April 11, 2022, we entered into a second amendment (the "Amendment") to the 2017 KKC Agreement. Under the terms of the Amendment, the parties 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 consideration for the reduction in the royalty rate, KKC has agreed to pay us up to an additional U.S. \$40.0 million payable in two tranches, with the first payment due following KKC's filing with the Japanese Ministry Health, Labour and Welfare (MHLW) 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.

# 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. 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<sup>®</sup> (tenapanor) in March 2022. As of March 31, 2022, we had an accumulated deficit of \$741.0 million.

We expect to continue to incur substantial operating losses for the foreseeable future as we commercialize IBSRELA, seek to gain approval for XPHOZAH<sup>®</sup> (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 Product Pipeline**

#### **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 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.

In preparation for our commercial launch of IBSRELA, we have 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.

We have established commercial agreements with Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. ("Fosun Pharma") in China and Knight Therapeutics, Inc. ("Knight") in Canada for IBSRELA for IBS-C. Knight is currently marketing IBSRELA in Canada.

### 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 has 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 intends to direct the Division of Cardiology and Nephrology to bring the XPHOZAH NDA to the Advisory Committee, and to provide a response to our appeal within thirty (30) days after the conclusion of the Advisory Committee meeting. There can be no assurances that the Advisory Committee will recommend approval of our NDA for XPHOZAH, or that if approval is recommended, that such approval 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 our launch of IBSRELA and preparations for the Advisory Committee for XPHOZAH.

### **RDX020 Program: Small molecule for Treating Metabolic Acidosis**

We have an ongoing discovery program targeting the inhibition of bicarbonate exchange inhibitor 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 agreement with Knight, we received a \$2.3 million nonrefundable, one-time upfront payment in March 2018 and are eligible to receive additional development and commercialization milestone payments worth up to \$17.8 million. We are also eligible to receive royalties throughout the term of the agreement, and a transfer price for manufacturing services.

KKC has exclusive rights for the development, commercialization and distribution of tenapanor in Japan for cardiorenal indications. In April 2021, we announced that KKC had commenced four phase 3 clinical trials in Japan evaluating tenapanor for hyperphosphatemia. The phase 3 clinical trials consist of a multi-center, randomized, double-blind, placebo-controlled, parallel-group comparative study; a phosphate binder-combination parallel-group comparative study; an open-label, single-arm study evaluating hyperphosphatemia patients on peritoneal dialysis; and a long-term study evaluating serum phosphorus in patients who switch from one or more phosphate binders to tenapanor. 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 milestones, of which \$10.0 million has been received and recognized as revenue as of March 31, 2022, and approximately ¥8.5 billion for commercialization milestones, or approximately \$69.7 million at the currency exchange rate on March 31, 2022, as well as royalties on net sales throughout the term of the agreement.

As discussed in *Note 14 - Subsequent events*, on April 11, 2022, we entered into a second amendment (the "Amendment") to the 2017 KKC Agreement. Under the terms of the Amendment, the parties 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 consideration for the reduction in the royalty rate, KKC has agreed to pay us up to an additional U.S. \$40.0 million payable in two tranches, with the first payment due following KKC's filing with the Japanese Ministry Health, Labour and Welfare (MHLW) 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 for the development, commercialization and distribution of tenapanor in China for both hyperphosphatemia and IBS-C. Under the terms of the Fosun Agreement, we received \$12.0 million in upfront license, and we may be entitled to additional development and commercialization milestones of up to \$110.0 million, 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 three months ended March 31, 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 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 (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 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 Our estimates for payor mix are guided by payor information received from specialty pharmacies, expected utilization for specialty distributor sales to pharmacies, and available industry payor information.



Chargebacks: Chargebacks are discounts that occur when contracted purchasers purchase directly from our specialty distributors at a discounted price. The specialty distributor, in turn, charges back the difference between the price initially paid to us by the specialty distributor and the discounted price paid to the specialty distributor 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 specialty distributor chargebacks is estimated based on known chargeback rates, known sales to specialty distributors, and estimated utilization by types of contracted purchasers.

Discounts and Fees: Our payment terms are generally 30 to 60 days. Specialty distributors and specialty pharmacies are offered various forms of consideration, including service fees and prompt pay discounts for payment within a specified period. We expect these Customers will earn prompt pay discounts 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, accrued expenses and other current liabilities on the condensed balance sheets.

## **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 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 months ended March 31, 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 months ended March 31, 2022 would have been \$9 thousand higher, if we had not previously expensed certain material and production costs with respect to the units sold. As of March 31, 2022, we had approximately \$32.3 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 \$11.7 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 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 months ended March 31, 2022 and 2021

### Revenue

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

	Three Months Ended March 31,					Change 2022 vs. 2021		
	2022 2021			\$	%			
Product sales, net	\$	450	\$	_	\$	450	(a)	
Product supply revenue		14		126		(112)	(88.9)%	
Licensing revenue		4		5,002		(4,998)	(99.9)%	
Collaborative development revenue		—		1,454		(1,454)	(100.0)%	
Total revenues	\$	468	\$	6,582	\$	(6,114)	(92.9)%	

(a) Percent change is not meaningful.

The decrease to total revenues during the three months ended March 31, 2022 is primarily attributable to a \$5.0 million milestone that was earned during the prior year upon the initiation of phase 3 clinical studies by KKC in Japan to evaluate tenapanor for hyperphosphatemia 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 three months ended March 31, 2022. Partially offsetting these decreases was recognition of \$0.5 million of product sales, net for initial 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):

	Th	Three Months Ended March 31,				Change 2022 vs. 2021			
		2022		2021		\$	%		
Cost of revenue	\$	85	\$	1,000	\$	(915)	(91.5)%		
Research and development		8,851		20,456		(11,605)	(56.7)%		
Selling, general and administrative		19,339		17,131		2,208	12.9 %		
Total operating expenses	\$	28,275	\$	38,587	\$	(10,312)	(26.7)%		

### Cost of revenue

The decrease in cost of revenue for the three months ended March 31, 2022 was primarily attributable to \$1.0 million payment due to AstraZeneca under the AZ Termination Agreement related to the development milestone we earned upon the initiation by KKC of phase 3 clinical studies in Japan to evaluate tenapanor for hyperphosphatemia during the three months ended March 31, 2021, compared to \$0.1 million due to AstraZeneca during the three months ended March 31, 2022, we incurred cost of revenue from initial 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 March 31,					Change 2022 vs. 2021			
	2022 2021			\$	%				
External R&D expenses	\$	2,940	\$	11,508	\$	(8,568)	(74.5)%		
Employee-related expenses		4,177		7,220		(3,043)	(42.1)%		
Facilities, equipment and depreciation expenses		1,114		1,284		(170)	(13.2)%		
Other		620		444		176	39.6 %		
Total research and development expenses	\$	8,851	\$	20,456	\$	(11,605)	(56.7)%		

The decrease in our external R&D expenses for the three months ended March 31, 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 months ended March 31, 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 increase in general and administrative expenses for the three months ended March 31, 2022 was primarily due to increased costs associated with building and staffing our commercial infrastructure and teams as we prepared for the U.S. launch of IBSRELA. The increase consisted of headcount and related personnel costs and an increase in external spending for disease awareness initiatives, commercial infrastructure and strategy.

### Other Income, net

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

	Three Months Ended March 31,					Change 2022 vs. 2021			
		2022		2021		\$	%		
Interest expense	\$	(746)	\$	(1,100)	\$	354	(32.2)%		
Other income (expense), net		484		(49)		533	(1,087.8)%		
Total other income, net	\$	(262)	\$	(1,149)	\$	887	(77.2)%		

#### **Interest Expense**

The decrease in interest expense for the three months ended March 31, 2022 was primarily due to lower principal outstanding on our loan payable.

### Other Expense, net

The increase in other income (expense), net for the three months ended March 31, 2022 primarily resulted from sales of certain lab equipment and supplies for a net gain of \$0.7 million. The gain was partially offset by \$0.1 million expense incurred upon the settlement of our 2018 Loan, as well as higher unrealized foreign currency exchange losses.



### Liquidity and Capital Resources

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

	Mar	ch 31, 2022	Dece	ember 31, 2021	Change \$		Change %
Cash and cash equivalents	\$	47,077	\$	72,428	\$	(25,351)	(35)%
Short-term investments		42,627		44,261		(1,634)	(4)%
Total liquid funds	\$	89,704	\$	116,689	\$	(26,985)	(23)%

As of March 31, 2022, we had cash, cash equivalents and investments totaling \$89.7 million compared to \$116.7 million as of December 31, 2021. We have incurred operating losses since inception and our accumulated deficit as of March 31, 2022 is \$741.0 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 May 5, 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, 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 three months ended March 31, 2021 we sold 4.9 million shares and received gross proceeds of \$35.0 million at a weighted average sales price of approximately \$7.09 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 three months ended March 31, 2022 we sold 5.9 million shares and received gross proceeds of \$6.0 million at a weighted average sales price of approximately \$1.02 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. 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. Our primary uses of cash have been to fund operating expenses, primarily research and development expenditures and pre-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 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.

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):

	Three Months	Ended				
	2022 2021				Change \$	Change %
Net cash used in operating activities	\$ (27,620)	\$	(44,217)	\$	16,597	(38)%
Net cash provided by investing activities	2,332		2,485		(153)	(6)%
Net cash provided by (used in) financing activities	(63)		34,770		(34,833)	(100)%
Net decrease in cash and cash equivalents	\$ (25,351)	\$	(6,962)	\$	(18,389)	264 %

### **Cash Flows from Operating Activities**

Net cash used in operating activities during the three months ended March 31, 2022 decreased by \$16.6 million primarily as a result of changes to our operating assets and liabilities as we built and staffed our commercial infrastructure and teams in preparation for the U.S. launch of tenapanor. In addition to the changes in our operating assets and liabilities, our net loss was \$5.1 million less than during the three months ended March 31, 2021.

### **Cash Flows from Investing Activities**

Net cash provided by investing activities decreased by \$0.2 million due to the timing of our investment maturities and purchases, as well as \$0.8 million proceeds from sale of laboratory equipment and supplies during the three months ended March 31, 2022.

### **Cash Flows from Financing Activities**

Net cash provided by financing activities decreased by \$34.8 million primarily due to net proceeds from issuance of our common stock pursuant to the at the market offerings of \$34.3 million during the three months ended March 31, 2021 compared to \$5.9 million during the three months ended March 31, 2022. In addition, during the three months ended March 31, 2022, we received net proceeds of \$27.0 million pursuant to the 2022 Loan Agreement and repaid \$33.0 million, net of settlement costs, to repay the 2018 Loan.

### **Off-Balance Sheet Arrangements**

As of March 31, 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 a decrease in interest rates would have any material negative impact on the fair value of our cash equivalents.

As of March 31, 2022, we had cash, cash equivalents and investments of \$89.7 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 AAAm/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 months ended March 31, 2022. As of March 31, 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 March 31, 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 March 31, 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 March 31, 2022, our disclosure controls and procedures were effective at a reasonable assurance level.

### Changes in Internal Control Over Financial Reporting

During the three months ended March 31, 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 seeks 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. The court has not yet ruled on those motions. Once the court appoints a lead plaintiff and lead counsel, the parties will negotiate and submit a

proposed schedule for 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 March 31, 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 March 31, 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 a limited operating history, 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 are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused substantially all of our efforts on our research and development activities, including developing tenapanor and developing our proprietary drug discovery and design platform. We began selling our first product, IBSRELA<sup>®</sup> (tenapanor) for the treatment of irritable bowel syndrome with constipation ("IBS-C") in March 2022, 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 March 31, 2022, we had an accumulated deficit of \$741.0 million.

We expect to continue to incur substantial operating losses for the foreseeable future as we commercialize IBSRELA, seek to gain approval for XPHOZAH<sup>®</sup> (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 to achieve our goals, including our goals of commercializing IBSRELA and preparing for and participating 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 and developing our proprietary drug discovery and design platform. 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 February 28, 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). Nasdag Listing Rule 5550(a)(2) requires that companies listed on the Nasdag Global Market maintain a minimum closing bid price of at least \$1.00 per share (the "Listing Requirement"). We received a letter from Nasdaq on March 31, 2022, indicating that the Company 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, and confirming that the Company will remain in compliance with this Listing Requirement as long as the closing bid price of its common stock does not fall below \$1.00 for thirty (30) consecutive business days. On April 8, 2022, the closing bid price of our common stock listed on Nasdaq was below \$1.00 per share, and there can be no assurances that we will continue to remain in compliance with the Listing Requirement. In the event that we are not able to remain in compliance with the Listing Requirement, there can be no assurances that we will be able to regain compliance with the Listing Requirement in the time frame that may be afforded us by Nasdaq. We are monitoring the bid price of our common stock and will consider options available to us, including the implementation of a reverse stock split, to maintain or regain, if required, compliance with the Listing Requirement. 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. There can be no assurances that our stockholders will approve the proposal, or that we will have other options available to maintain compliance with the Listing Requirement. If we fail to maintain 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 your ability to sell or purchase our common stock when you wish to do so. 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 to our second level of appeal to the Office of New Drugs ("OND"), Center for Drug Evaluation and Research (CDER), indicating that OND intends to direct the Division of Cardiology and Nephrology of OCHEN (the "Division") to bring the XPHOZAH NDA to the Advisory Committee (the "Interim Response"). There can be no assurances that any such Advisory Committee will recommend approval of our NDA for tenapanor for the Hyperphosphatemia Indication, or that if approval is recommended, that such approval 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. Our ability to generate revenue from product sales and achieve profitability depends on our ability to successfully commercialize IBSRELA; obtain approval by the FDA for the Hyperphosphatemia Indication; and the ability of our collaboration partners to obtain regulatory approval to market tenapanor in their respective territories. 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.

Our potential to achieve revenue from the commercialization of IBSRELA and the amount of such potential revenue 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.

### Our success is also dependent upon our ability to obtain 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.

Our success is also dependent upon our ability to obtain 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 intends to direct the Division to bring the XPHOZAH NDA to the Advisory Committee. We are currently awaiting further guidance from OND regarding the timing of the Advisory Committee meeting. 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 Advisory Committee will recommend approval of our NDA for tenapanor for the Hyperphosphatemia Indication, or that if approval is recommended, that such approval 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. To date, the most common adverse reactions reported in at least 2% of patients in IBSRELA-treated patients and at an incidence greater than placebo in the two Phase 3 trials include: diarrhea, abdominal distension, flatulence and dizziness. 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 these or other side effects 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 no prior 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 no prior 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. 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 our product candidates. We expect to experience pricing pressures in connection with the sale of IBSRELA, and if approved and commercialized, XPHOZAH, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We rely completely on third parties 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 manufactures 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 manufactures 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 our 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, 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 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

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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 a material disruption of our product development programs, and/or of our efforts to commercialize tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis or for another other related indication, if approved. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 have been notified from OND in an interim response to our second level appeal that OND will direct the Division to bring our NDA to an Advisory Committee, there can be no assurances that the Advisory Committee will recommend approval of our NDA for tenapanor for the Hyperphosphatemia Indication, or that if approval is recommended, that such approval 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. Business disruptions could include disruptions or restrictions on our ability to conduct our clinical trials, as planned, travel, as well as temporary closures of the facilities of our collaboration partners, suppliers or contract manufacturers. Any disruption of our clinical trial operations, collaboration partners, suppliers or contract manufacturers could adversely impact our operating results.

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.

## If we seek and obtain approval to commercialize our product candidates outside of the United States, manufacture our product candidates outside of the United States, or otherwise engage in business outside of the United States, 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 certain of our product candidates outside the United States or otherwise engage in business outside the United States, including entering into contractual agreements with third-parties. We currently utilize contract manufacturing organizations located outside of the United States to manufacture our active drug substance for tenapanor. 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.

Our development activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. 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 these hazardous materials. 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, fines or holds on clinical trials;
- 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. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to 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 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 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 regulatory approval of the products. 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 authorities do not pass a pre-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. In preparation for the commercial launch of IBSRELA, we have

implemented compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations regarding offlabel 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. If we are successful in commercializing any products, FDA and foreign regulatory agency regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be 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 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.

Following our commercial introduction of IBSRELA, and the regulatory approval by a foreign government and the commercial introduction of any either IBSRELA or XPHOZAH by our collaboration partner in such jurisdiction, 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. 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.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through



August 15, 2021. The executive order instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

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 will 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 the 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 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 must 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 be 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

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 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

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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.

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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 right, 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 to consider 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 delisting 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.

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### Our principal stockholders own a significant percentage of our stock and, together with our management, will be able to exert significant control over matters subject to stockholder approval.

Based on the number of shares outstanding as of March 31, 2022, our officers, directors and stockholders who hold at least 5% of our stock together beneficially own approximately 9.3% of our outstanding common stock. If these officers, directors, and principal stockholders or a group of our principal stockholders act together, they will be able to exert a significant degree of influence over our management and affairs and control matters requiring stockholder approval, including the election of directors, amendments to our organizational documents, and approval of any merger, sale of assets or other business combination transactions. The interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. For instance, officers, directors and principal stockholders, acting together, could cause us to enter into transactions or agreements that we would not otherwise consider. Similarly, this concentration of ownership may have the effect of delaying or preventing a change in control of our company otherwise favored by our other stockholders.

#### Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of March 31, 2022, we had approximately 136.3 million shares of common stock outstanding. Of those shares, approximately 9.0 million were held by current directors, executive officers and stockholders owning 5% or more of our outstanding common stock.

As of March 31, 2022, 4.4 million shares of common stock issuable upon vesting of outstanding restricted stock units and approximately 12.9 million shares of common stock issuable upon exercise of outstanding options were eligible for sale in the public market to the extent permitted by the provisions of the applicable vesting schedules, and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are issued and sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

### 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 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 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 7. 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

None.



#### ITEM 6. Exhibits

		Incorporated by Reference			
Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith
10.1	<u>Loan and Security Agreement dated February 23, 2022, by and between</u> <u>Ardelyx, Inc. and SLR Investment Corp.</u>				Х
10.2	<u>Exit Fee Agreement dated February 23, 2022, by and between Ardelyx, Inc.</u> and SLR Investment Corp.				Х
10.3††	<u>Amendment Number 2 to License Agreement, dated as of April 11, 2022, by</u> and among Ardelyx, Inc., and Kyowa Kirin Co., Ltd.	8-K	4/11/2022	10.1	
31.1	<u>Certification of Chief Executive Officer Pursuant to Section 302 of the</u> <u>Sarbanes-Oxley Act of 2002.</u>				Х
31.2	<u>Certification of Chief Financial Officer Pursuant to Section 302 of the</u> <u>Sarbanes-Oxley Act of 2002.</u>				Х
32.1	<u>Certification of Chief Executive Officer and Chief Financial Officer</u> <u>Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>				Х
101	The following financial statements, formatted in Inline Extensible Business Reporting Language (XBRL): (i) Condensed Balance Sheets as of March 31, 2022 and December 31, 2021, (ii) Condensed Statements of Operations and Comprehensive Loss for the three months ended March 31, 2022 and 2021, (iii) Condensed Statements of Cash Flows for the three months ended March 31, 2022 and 2021, and (iv) Notes to Unaudited Condensed Financial Statements.				Х
104	Cover Page Interactive Data File, formatted in Inline XBRL and contained in Exhibit 101.				

<sup>††</sup> Certain portions have been omitted pursuant to a confidential treatment request. Omitted information has been filed separately with the Securities and Exchange Commission.

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#### 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.

Date: May 5, 2022

Ardelyx, Inc.

By: /s/ Robert Felsch

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

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#### LOAN AND SECURITY AGREEMENT

**THIS LOAN AND SECURITY AGREEMENT** (as the same may be amended, restated, modified, or supplemented from time to time, this "**Agreement**") dated as of February 23, 2022 (the "**Effective Date**") 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 in such capacity, "**Collateral Agent**"), and the lenders listed on <u>Schedule 1.1</u> hereof or otherwise a party hereto from time to time including SLR (together with any other lenders party hereto, the "Lenders" and each, a "Lender"), and ARDELYX, INC., a Delaware corporation with offices located at 400 Fifth Avenue, Suite 210, Waltham, MA 02451 ("Borrower"), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

#### 1. DEFINITIONS AND OTHER TERMS

**1.1 Terms.** Capitalized terms used herein shall have the meanings set forth in <u>Section 1.4</u> to the extent defined therein. All other capitalized terms used but not defined herein shall have the meaning given to such terms in the Code. Any accounting term used but not defined herein shall be construed in accordance with GAAP and all calculations shall be made in accordance with GAAP. The term "financial statements" shall include the accompanying notes and schedules.

**1.2** Section References. Any section, subsection, schedule or exhibit references are to this Agreement unless otherwise specified.

**1.3 Divisions.** For all purposes under the Loan Documents, in connection with any division or plan of division under Delaware law (or any comparable event under a different jurisdiction's laws): (a) if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then it shall be deemed to have been transferred from the original Person to the subsequent Person, and (b) if any new Person comes into existence, such new Person shall be deemed to have been organized on the first date of its existence by the holders of its equity interests at such time.

**1.4 Definitions.** The following terms are defined in the Sections or subsections referenced opposite such terms:

"Agreement"	Preamble		
"Approved Lender"	Section 12.1		
"Borrower"	Preamble		
"Claims"	Section 12.2		
"Collateral Agent"	Preamble		
"Collateral Agent Report"	Exhibit B, Section 5		
"Communications"	Section 10		
"Connection Income Taxes"	Exhibit C, Section 1		
"Default Rate"	Section 2.3(b)		
"Effective Date"	Preamble		
"Event of Default"	Section 8		
"Excluded Taxes"	Exhibit C, Section 1		
"FATCA"	Exhibit C, Section 1		
"Good Faith Deposit"	Section 2.4(d)		
"Indemnified Person"	Section 12.2		
"Indemnified Taxes"	Exhibit C, Section 1		
"Lender" and "Lenders"	Preamble		
"Lender Transfer"	Section 12.1		

"New Subsidiary"	Section 6.10
"Non-Funding Lender"	Exhibit B, Section 10(c)(ii)
"Other Connection Taxes"	Exhibit C, Section 1
"Other Lender"	Exhibit B, Section 10(c)(ii)
"Other Taxes"	Exhibit C, Section 1
"Participant Register"	Section 12.1
"Perfection Certificate" and "Perfection Certificates"	Section 5.1
"Recipient"	Exhibit C, Section 1
"Register"	Section 12.1
"SLR"	Preamble
"Term A Loan"	Section 2.2(a)(i)
"Term B Loan"	Section 2.2(a)(ii)
"Term Loan"	Section 2.2(a)(ii)
"Termination Date"	Exhibit B, Section 8
"Transfer"	Section 7.1
"U.S. Tax Compliance Certificate"	Exhibit C, Section 7(b)(ii)(C)
"Withholding Agent"	Exhibit C, Section 1

In addition to the terms defined elsewhere in this Agreement, the following terms have the following meanings:

"Account" is any "account" as defined in the Code with such additions to such term as may hereafter be made under the Code, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"Account Debtor" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"ACH Letter" is an ACH debit authorization in the form of Exhibit G hereto.

"Acquisition Consideration" shall mean the purchase consideration for a Permitted Acquisition and all other payments, directly or indirectly, by Borrower or any of its Subsidiaries in exchange for, or as part of, or in connection with, a Permitted Acquisition, whether paid in cash or by exchange of equity interests or of properties or otherwise and whether payable at or prior to the consummation of a Permitted Acquisition or deferred for payment at any future time, whether or not any such future payment is subject to the occurrence of any contingency, and includes any and all payments representing the purchase price and any assumptions of Indebtedness, "earnouts" and other agreements to make any payment the amount of which is, or the terms of payment of which are, in any respect subject to or contingent upon the revenues, income, cash flow or profits (or the like) of any person or business; provided that any such future payment that is subject to a contingency shall be considered Acquisition Consideration only to the extent of the reserve, if any, required under GAAP (as determined at the time of the consummation of such Permitted Acquisition) to be established in respect thereof by the Borrower or any of its Subsidiaries.

"Affiliate" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

"Amortization Date" means April 1, 2024.

"Anti-Terrorism Laws" are any laws relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"**Applicable FDA Threshold**" means the greater of (a) One Million Dollars (\$1,000,000), and (b) as of any date of determination, ten percent (10%) of the Borrower's and its Subsidiaries' consolidated revenues for the trailing twelve months ending as of the last day of the month immediately prior to such date of determination.

"Applicable Rate" means a per annum interest rate equal to the greater of (a) one tenth percent (0.10%) and (b) the rate per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (the "Service") (or on any successor or substitute page of such Service, or any successor to or substitute for such Service, as determined by Collateral Agent in a manner consistent with other loans in Collateral Agent's portfolio) for a term of one month, which determination by Collateral Agent shall be conclusive in the absence of manifest error; provided that if, at any time, Lenders notify Collateral Agent that Lenders have determined that (x) Lenders are unable to determine or ascertain such rate, (y) the applicable regulator has made public statements to the effect that the rate published by the Service is no longer used for determining interest rates for loans or (z) by reason of circumstances affecting the foreign exchange and interbank markets generally, deposits in eurodollars in the applicable amounts or for the relative maturities are not being offered for such period, then the Applicable Rate shall be equal to an alternate benchmark rate and spread agreed between Collateral Agent and Borrowers (which may include SOFR, to the extent publicly available quotes of SOFR exist at the relevant time), giving due consideration to (i) market convention or (ii) selection, endorsement or recommendation by a Relevant Governmental Body. Such alternative benchmark rate and spread shall be binding unless the Required Lenders object within five (5) days following notification of such amendment.

"Approved Fund" is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.

"**Blocked Person**" is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"Borrower's Books" are Borrower's or any of its Subsidiaries' books and records including ledgers, federal and state tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Business Day" is any day that is not a Saturday, Sunday or a day on which commercial banks in New York, New York are required or authorized to be closed.

"**Cash Equivalents**" are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent, and (d) any money market or similar funds under Borrower's investment policy, as approved by Collateral Agent and the Lenders from time to time.

"**Code**" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"Collateral" is any and all properties, rights and assets of Borrower described on Exhibit A.

"Collateral Account" is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

"**Collateral Agent**" is SLR, not in its individual capacity, but solely in its capacity as collateral agent on behalf of and for the ratable benefit of the Secured Parties.

"Commitment Percentage" is set forth in <u>Schedule 1.1</u>, as amended from time to time.

"**Commodity Account**" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"Compliance Certificate" is that certain certificate in substantially the form attached hereto as Exhibit E.

"**Contingent Obligation**" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith in accordance with GAAP; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"**Control Agreement**" is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower or such Subsidiary, as applicable, and Collateral Agent pursuant to which Collateral Agent, for the ratable benefit of the Secured Parties, obtains "control" (within the meaning of the Code) over such Deposit Account, Securities Account, or Commodity Account.

"**Convertible Indebtedness**" means Indebtedness of the Borrower that is (i) either (A) Subordinated Debt or (B) unsecured Indebtedness that is not-cross defaulted to the Obligations and (ii) convertible into equity securities of the Borrower.

"**Copyrights**" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"Default" is any event that, with the giving of notice or passage of time or both, would constitute an Event of Default.

"**Deposit Account**" is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Disclosure Schedules**" the disclosure schedules to this Agreement, as amended or supplemented from time to time by Borrower with the written consent of the Required Lenders (or as supplemented by Borrower pursuant to the terms of the Loan Documents), delivered by Borrower to the Lenders.

"Dollars," "dollars" and "\$" each mean lawful money of the United States.

"Domestic Subsidiary" is any Subsidiary that is not a Foreign Subsidiary.

"Eligible Assignee" is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an "accredited investor" (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor's Rating Group and a rating of Baa2 or higher from Moody's Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Two Billion Five Hundred Million Dollars (\$2,500,000,000.00), and in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar taxes; provided that notwithstanding the foregoing, "Eligible Assignee" shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower's Affiliates or Subsidiaries or (ii) a direct competitor of Borrower, a vulture hedge fund or a distressed debt fund, each as determined by Collateral Agent in its reasonable discretion. Notwithstanding the foregoing, (x) in connection with any assignment made by a Lender as a result of a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any transfere of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obli

"Equipment" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made under the Code, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"ERISA" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"**Exigent Circumstance**" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

"Exit Fee Agreement" means that certain Exit Fee Agreement, dated as of the date hereof, by and among Collateral Agent, as agent, Lenders and Borrower, as amended, amended and restated, supplemented or otherwise modified from time to time.

"FDA" means the U.S. Food and Drug Administration or any successor thereto.

"**Fee Letter**" means that certain Fee Letter, dated the date hereof, by and among Collateral Agent, as agent, Lenders and Borrower, as amended, amended and restated, supplemented or otherwise modified from time to time.

"Foreign Subsidiary" is a Subsidiary that is not an entity organized under the laws of the United States or any state thereof or the District of Columbia.

"Funding Date" is any date on which a Term Loan is made to or on account of Borrower which shall be a Business Day.

"GAAP" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination; provided that for purposes of the defined term "Permitted Indebtedness," GAAP shall be GAAP as in effect on the Effective Date.

"General Intangibles" are all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

"Governmental Approval" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"Governmental Authority" is any federal, state, municipal, national or other government, governmental department, commission, board, bureau, court, agency or instrumentality or political subdivision thereof (including the FDA) or any entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to any government or any court, in each case whether associated with a state or locality of the United States, the United States, or a foreign government.

"Guarantor" is any Person providing a Guaranty in favor of Collateral Agent for the benefit of the Secured Parties (including without limitation pursuant to Section 6.10).

"Guaranty" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"Healthcare Laws" means all laws, rules and regulations relating to the provision or payment of health items and services applicable to the Borrower or its Subsidiaries, including, without limitation, (a) all federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)), the Civil False Claims Act (31 U.S.C. §3729 et seq.), the criminal false statements law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286, 287, 1347 and 1349, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.), any applicable state fraud and abuse prohibitions, including those that apply to all payors (governmental, commercial insurance and self-payors), the civil monetary penalty laws (42 U.S.C. § 1320a-7a), the exclusion laws (42 U.S.C. § 1320a-7), and any similar state laws or regulations, and (b) any laws relating to any governmental healthcare program, including, without

limitation, the Medicare statute (Title XVIII of the Social Security Act) and the Medicaid statute (Title XIX of the Social Security Act), each of (a) through (b) as may be amended from time to time.

# "Hyperphosphatemia" means elevated serum phosphorus.

"**Immaterial Subsidiary**" is any Foreign Subsidiary that holds assets worth less than One Hundred Thousand Dollars (\$100,000) in book value.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions or proceedings seeking reorganization, arrangement, or other relief.

"**Insolvent**" means not Solvent.

"Intellectual Property" means all of Borrower's or any of its Subsidiaries' right, title and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;

- (c) any and all source code;
- (d) any and all design rights which may be available to Borrower;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

"Internal Revenue Code" means the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder.

"**Inventory**" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

"IRS" means the United States Internal Revenue Service.

"**Key Person**" is each of Borrower's (i) Chief Executive Officer, who is Mike Raab as of the Effective Date and (ii) Chief Financial Officer, who is Justin Renz as of the Effective Date.

"Lender" is any one of the Lenders.

"**Lenders**" are the Persons identified on <u>Schedule 1.1</u> hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

"Lenders' Expenses" are (a) all reasonable audit fees and expenses, costs, and expenses (including reasonable attorneys' fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating and administering the Loan Documents, and (b) all fees and expenses (including attorneys' fees and expenses , as well as appraisal fees, fees incurred on account of lien searches, inspection fees) for defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

"Lien" is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"Loan Documents" are, collectively, this Agreement, the Fee Letter, the Exit Fee Agreement, each Control Agreement, the Perfection Certificates, the Disclosure Schedules, each Compliance Certificate, the ACH Letter, each Loan Payment Request Form, any Guarantees, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, any agreements creating or perfecting rights in the Collateral (including all insurance certificates and endorsements, landlord consents and bailee consents) and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent, as applicable, in connection with this Agreement; all as amended, restated, or otherwise modified.

#### "Loan Payment Request Form" is that certain form attached hereto as Exhibit D.

"**Material Adverse Change**" is (a) a material adverse change in the business, operations or financial condition of Borrower and its Subsidiaries, when taken as a whole; or (b) a material impairment of (i) the ability of Borrower and Guarantors to repay any portion of the Obligations, (ii) the legality, validity or enforceability of any Loan Document, (iii) the rights and remedies of Collateral Agent or Lenders under any Loan Document except as the result of the action or inaction of the Collateral Agent or Lenders or (iv) the validity, perfection or priority of any Lien in favor of Collateral Agent for the benefit of the Secured Parties on any of the Collateral except as the result of the action or inaction of the Collateral Agent or Lenders. For the avoidance of doubt, "Material Adverse Change" shall not include, in and of themselves, the non-occurrence of any of the events described under the "Term B Milestone".

"Material Agreement" is (i) as long as Borrower is a publicly reporting entity under the Securities Exchange Act of 1934, any license, agreement or other contractual arrangement required to be disclosed (including amendments thereto) under regulations promulgated under the Securities Act of 1933 or Securities Exchange Act of 1934, as each may be amended, or (ii) if Borrower is not such a publicly reporting entity, any license, agreement or other contractual arrangement whereby Borrower or any of its Subsidiaries is reasonably likely to be required to transfer, either in-kind or in cash, prior to the Maturity Date, assets or property valued (book or market) at more than One Million Dollars (\$1,000,000) per year.

### "Maturity Date" is, for each Term Loan, March 1, 2027.

"**Net Product Revenue**" means the revenue, determined in accordance with GAAP, from the sale of any products of Borrower or its Subsidiaries, inclusive of Borrower's share of sales generated indirectly through the sales of Borrower's products under any licensing or similar arrangement and which amounts are included in the net product revenue of Borrower in accordance with GAAP.

"**Obligations**" are all of Borrower's obligations to pay when due any debts, principal, interest, Lenders' Expenses, the Prepayment Premium, all fees under the Fee Letter, and any other amounts Borrower owes the Collateral Agent or the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents (other than the Exit Fee Agreement and any fees payable thereunder), and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent in connection with this Agreement and the other Loan Documents

(other than the Exit Fee Agreement), and the performance of Borrower's duties under the Loan Documents (other than the Exit Fee Agreement and any fees payable thereunder).

"OFAC" is the U.S. Department of Treasury Office of Foreign Assets Control.

**"OFAC Lists**" are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Patents**" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

**"Payment Date"** is the first (1<sup>st</sup>) calendar day of each calendar month, commencing on April 1, 2022.

"**Permitted Acquisition**" means any consensual transaction or series of related transactions for the direct or indirect (a) acquisition of all or substantially all of the property of any Person, or of any business or division of any Person, (b) acquisition of greater than ninety percent (90.0%) of the equity interests of any Person, and otherwise causing such person to become a Subsidiary of such Person, (c) merger or consolidation or any other combination with any Person or (d) the acquisition of any Intellectual Property and related ancillary rights or assets of any person, if each of the following conditions is met:

(i) no Default or Event of Default exists immediately prior thereto, and no Default or Event of Default would immediately result therefrom;

(ii) the Person, business or asset to be acquired (other than non-core assets, if any, with respect to such acquisition) shall be, or shall be engaged in, a business of the type that the Borrower is then permitted to be engaged in and the property acquired in connection with any such transaction shall be made subject to the Lien of the Loan Documents to the extent required in accordance with Section 6.10 and shall be free and clear of any Liens (other than Permitted Liens);

(iii) the Borrower shall be, after taking into account the payment of the Acquisition Consideration, in compliance with Section 7.13;

(iv) the Board of Directors or other governing body of the Person to be acquired shall not have indicated its opposition to the consummation of such acquisition (which opposition has not been publicly withdrawn);

(v) the Acquisition Consideration in respect of such acquisition is funded with cash or Permitted Investments of the Borrower or the proceeds of a cash equity contribution to any Borrower;

(vi) the Acquisition Consideration shall not exceed Five Million Dollars (\$5,000,000) in the aggregate for all such acquisitions, unless, in each case, funded with the proceeds of an equity contribution or convertible Indebtedness permitted hereunder received by the Borrower;

(vii) on a consolidated basis, the Borrower's and its Subsidiaries' rate of usage of cash and Cash Equivalents shall not increase as a result of such transaction by more than five percent (5%) over the forecasted rate of usage of cash and Cash Equivalents approved by the Lenders as of the Effective Date; provided that the amount of such increase shall be determined net of any proceeds of equity contributions over the succeeding twenty-four (24) months raised in connection with such acquisition; and

(viii) on or prior to the proposed date of consummation of such transaction, the Borrower shall have delivered to the Collateral Agent and the Lenders a certificate of a Responsible Officer of the Borrower certifying that such transaction complies with this definition.

# "Permitted Indebtedness" is:

- (a) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;
- (b) Indebtedness existing on the Effective Date and disclosed on the Disclosure Schedules;
- (c) Subordinated Debt;
- (d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;
- (e) unsecured Indebtedness in connection with credit cards incurred in the ordinary course of business;

(f) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Seven Hundred Fifty Thousand Dollars (\$750,000) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(g) Indebtedness consisting of the obligation to pay rent when due under real property leases entered into in the ordinary course of Borrower's business;

(h) other unsecured Indebtedness at any time not to exceed Three Hundred Seventy-Five Thousand Dollars (\$375,000) in the aggregate;

(i) reimbursement obligations in respect of letters of credit in the aggregate amount not to exceed (1) One Million Five Hundred Thousand Dollars (\$1,500,000) at any time for any letters of credit with a maturity date of six (6) months or less, and (2) Five Hundred Thousand Dollars (\$500,000) at any time for any letters of credit with a maturity date of six (6) months or more, in each case as incurred in the ordinary course of business;

(j) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business;

- business,
- time;

(k) Convertible Indebtedness in the aggregate amount not to exceed Two Hundred Million Dollars (\$200,000,000) at any

(l) Hedges and similar transactions with respect to currency risk entered into in the ordinary course of business and not for speculative purposes;

(m) Surety bonds and similar Indebtedness entered into in the ordinary course of business and in an amount not exceeding Two Hundred Fifty Thousand Dollars (\$250,000) outstanding at any time;

(n) "earnouts", purchase price adjustments, profit sharing arrangements, deferred purchase money amounts and similar payment obligations or continuing obligations of any nature of such Person arising out of purchase and sale contracts (including any indemnification and other similar obligations incurred in an acquisition), in each case subject to the limitations in the definition of "Permitted Acquisition";

(o) advances or deposits received in the ordinary course of business from customers or vendors;

(p) Indebtedness arising in connection with the financing of insurance premiums in an amount not exceeding Fifty Thousand Dollars (\$50,000) outstanding at any time;

(q) Indebtedness incurred in the Permitted Royalty Transaction; and

(r) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (q) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

#### "Permitted Investments" are:

(a) Investments disclosed on the Disclosure Schedules and existing on the Effective Date;

(b) (i) Investments consisting of cash and Cash Equivalents, and (ii) any Investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of Deposit Accounts in which Collateral Agent has a perfected Lien (subject to the terms of this Agreement) for the ratable benefit of the Secured Parties except as permitted in Section 6.6 hereof;

(e) Investments in connection with Permitted Indebtedness, Permitted Liens and with Transfers permitted by Section 7.1;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's board of directors; not to exceed Two Hundred Thousand Dollars (\$200,000) in the aggregate for (i) and (ii) in any fiscal year;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary;

(i) Investments in Subsidiaries that are Guarantors;

(j) Investments in Subsidiaries that are not Guarantors, the aggregate of which shall not exceed One Hundred Thousand Dollars (\$100,000) per fiscal year;

# (k) Permitted Acquisitions;

(1) Investments in joint ventures, corporate collaborations, or strategic alliances in the ordinary course of Borrower's business consisting of the licensing of technology (in compliance with the definition of "Permitted Licenses"), the development of technology or the providing of technical support and provided that the aggregate amount for cash consideration for all such Investments cannot exceed Two Hundred Fifty Thousand Dollars (\$250,000) per year and Seven Hundred Fifty Thousand Dollars (\$750,000) in the aggregate; and

(m) other Investments not to exceed One Hundred Thousand Dollars (\$100,000) in the aggregate outstanding at any time.

"Permitted Licenses" are (A) licenses of over-the-counter software that is commercially available to the public, (B) non-exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property, (C) exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, <u>provided</u>, that, with respect to each such license described in this clause (C), the license (i) constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property, (ii) is limited in territory with respect to a specific geographic country or region (i.e. Japan, Germany, northern China) outside of the United States, and (iii) Borrower has used commercially reasonable efforts to obtain the consent and acknowledgment of the counterparty to such license for the collateral assignment of such license to the Collateral Agent for the benefit of the Lenders, (D) exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries (excluding such Intellectual Property related to treatment of Hyperphosphatemia) in the United States entered into in the ordinary course of business, <u>provided</u>, that, with respect to each such license described in this clause (D), the license (i) constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property, (ii) Borrower has used commercially reasonable efforts to obtain the consent and acknowledgment of the counterparty to such license for the collateral assignment of such license to the Collateral Agent for the benefit of the Lenders, and (iii) Borrower shall have obtained the prior written consent of the Required Lenders to enter into such license, (E) exclusive licenses for the use in the United States of the Intellectual Property of Borrower or any of its Subsidiaries related to treatment of Hyperphosphatemia entered into in the ordinary course of business, provided, that, with respect to each such license described in this clause (E), the Borrower shall have obtained the prior written consent of the Required Lenders to enter into such license, and (F) licenses in connection with the Borrower's TGR5 and FXR programs.

#### "Permitted Liens" are:

(a) Liens existing on the Effective Date and disclosed on the Disclosure Schedules or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books in accordance with GAAP, provided that no notice of any such Lien has been filed or recorded in favor of the United States Treasury in accordance with the applicable provisions of the Internal Revenue Code;

(c) Liens securing Indebtedness permitted under clause (f) of the definition of "Permitted Indebtedness," provided that (i) such liens exist prior to the acquisition of, or attach

substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Two Hundred Fifty Thousand Dollars (\$250,000), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), <u>but</u> any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(a) hereof;

(i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;

(j) Liens on cash that stand as security for letter of credit reimbursement obligations and cash management obligations, together with such amount permitted under clause (k) of "Permitted Liens", in the aggregate amount not to exceed One Million Dollars (\$1,000,000);

(k) security deposits under real property leases that are made in the ordinary course of business, together with such amount permitted under clause (j) of "Permitted Liens", in the aggregate amount not to exceed One Million Dollars (\$1,000,000);

(l) to the extent constitution a Lien, escrow arrangements securing indemnification obligations associated with any Permitted Acquisition; and

# (m) Permitted Licenses.

"**Permitted Royalty Transaction**" means the purchase of a royalty interest of the Borrower's rights to research, develop and commercialize one of Borrower's products in Japan, <u>provided</u> that (i) the acquisition constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property, (ii) the transaction will be structured as a true sale with only precautionary security filings in the purchased royalty in the applicable jurisdiction, (iii) Borrower shall not grant a security interest in or lien on the underlying license agreement or any Intellectual Property and assets underlying the purchased royalty, (iv) Collateral Agent and Lenders will not be required to enter into an intercreditor or similar agreement, and (v) the royalty and sales milestone interest acquisition

agreement and related documents are otherwise in form and substance reasonably satisfactory, including the amount of the upfront cash proceeds received by Borrower, to Collateral Agent and the Required Lenders.

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Prepayment Premium**" is, with respect to any Term Loan subject to any prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise (including, but not limited to, upon the occurrence of a bankruptcy or insolvency event, an additional fee payable to the Lenders in amount equal to:

(i) for any prepayment made on or after the Effective Date through and including the first anniversary of the Effective Date, three percent (3.00%) of the principal amount of such Term Loan prepaid;

(ii) for any prepayment made after the date which is after the first anniversary of the Effective Date through and including the second anniversary of the Effective Date, two percent (2.00%) of the principal amount of such Term Loan prepaid; and

(iii) for any prepayment made after the date which is after the second anniversary of the Effective Date and prior to the Maturity Date, one percent (1.00%) of the principal amount of such Term Loan prepaid.

"**Pro Rata Share**" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

"Property" means any interest in any kind of property or asset, whether real, personal or mixed, and whether tangible or intangible.

"**Registered Organization**" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Registration**" means any registration, authorization, approval, license, permit, clearance, certificate, and exemption issued or allowed by the FDA (including, without limitation, new drug applications, abbreviated new drug applications, biologics license applications, investigational new drug applications, over-the-counter drug monograph, device pre-market approval applications, device pre-market notifications, investigational device exemptions, product recertifications, manufacturing approvals, registrations and authorizations, CE Marks, pricing and reimbursement approvals, labeling approvals or their foreign equivalent, controlled substance registrations, and wholesale distributor permits).

**"Regulatory Action**" means an administrative or regulatory enforcement action, proceeding, investigation or inspection, FDA Form 483 notice of inspectional observation, warning letter, untitled letter, other notice of violation letter, recall, seizure, Section 305 notice or other similar written communication, or consent decree, issued by the FDA.

"**Related Persons**" means, with respect to any Person, each Affiliate of such Person and each director, officer, employee, agent, trustee, representative, attorney, accountant and each insurance, environmental, legal, financial and other advisor and other consultants and agents of or to such Person or any of its Affiliates.

"**Relevant Governmental Body**" means the Federal Reserve Board, the Federal Reserve Bank of New York, and/or a committee officially endorsed or convened by the Federal Reserve Board and/or the Federal Reserve Bank of New York, or any successor thereto.

"**Required Lenders**" means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an "**Original Lender**") have not assigned or transferred any of their interests in their Term Loan other than to an Affiliate of such Lender, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six and two thirds percent (66.67%) of the aggregate outstanding principal balance of the Term Loan, Cause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender's interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

"**Requirement of Law**" is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"Responsible Officer" is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.

"Secured Parties" means the Collateral Agent and the Lenders.

"**Securities Account**" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**SOFR**" means the daily Secured Overnight Financing Rate provided by the Federal Reserve Bank of New York as the administrator of the benchmark (or a successor administrator) on the Federal Reserve Bank of New York's Website.

"**Solvent**" means, with respect to any Person, that (a) the fair salable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities, (b) such Person is not left with unreasonably small capital after giving effect to the transactions contemplated by this Agreement and the other Loan Documents, and (c) such Person is able to pay its debts (including trade debts) as they mature in the ordinary course.

"**Subordinated Debt**" is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Required Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor).

"**Subsidiary**" is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

"**Taxes**" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

**"Tenapanor**" is an inhibitor of NHE3 with the chemical name (S)-N,N'-(10,17-dioxo-3,6,21,24-tetraoxa-9,11,16,18-tetraazahexacosane-1,26-diyl)bis(3-((S)-6,8-dichloro-2-methyl-1,2,3,4 tetrahydroisoquinolin-4-yl)benzenesulfonamide) dihydrochloride.

"**Term B Draw Period**" is the period commencing on the date of the occurrence of the Term B Milestone and ending on July 25, 2023.

"**Term B Milestone**" is Collateral Agent's receipt of satisfactory evidence that Borrower (i) has received FDA approval of Tenapanor for use in certain patients with Hyperphosphatemia on or prior to

December 31, 2022 and (ii) has achieved a minimum of Thirty Million Dollars in Net Product Revenue calculated on a trailing six (6) month basis.

"**Term Loan Commitment**" is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on <u>Schedule 1.1</u>.

"Term Loan Commitments" means the aggregate amount of such commitments of all Lenders.

"**Trademarks**" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

## 2. LOANS AND TERMS OF PAYMENT

**2.1 Promise to Pay.** Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

#### 2.2 Term Loans.

(a) <u>Availability</u>. (i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Effective Date in an aggregate principal amount of Twenty-Seven Million Five Hundred Thousand Dollars (\$27,500,000) according to each Lender's Term A Loan Commitment as set forth on <u>Schedule 1.1</u> hereto (such term loans are hereinafter referred to singly as a "**Term A Loan**" and collectively as the "**Term A Loans**"). After repayment, no Term A Loan may be reborrowed.

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Term B Draw Period to make term loans to Borrower in an aggregate principal amount of Twenty-Two Million Five Hundred Thousand Dollars (\$22,500,000) and disbursed in a single advance according to each Lender's Term B Loan Commitment as set forth on <u>Schedule 1.1</u> hereto (such term loans are hereinafter referred to singly as a "**Term B Loan**" and collectively as the "**Term B Loans**"; each Term A Loan or Term B Loan is hereinafter referred to singly as a "**Term Loan**" and the Term A Loans and the Term B Loans are hereinafter referred to collectively as the "**Term Loans**"). After repayment, no Term B Loan may be re-borrowed.

(b) <u>Repayment</u>. Borrower shall make monthly payments of interest only commencing on the first (1<sup>st</sup>) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date after such Funding Date. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall (i) make monthly payments of interest, to each Lender in accordance with its Pro Rata Share, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon the effective rate of interest applicable to the Term Loan, as determined in Section 2.3(a) plus (ii) make consecutive equal monthly payments of principal to each Lender in accordance with its Pro Rata Share in accordance with their respective Pro Rata Shares, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon the effective rate of interest applicable to the Term Loan, as determined in Section 2.3(a) plus (ii) make consecutive equal monthly payments of principal to each Lender in accordance with its Pro Rata Share in accordance with their respective Pro Rata Shares, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (A) the respective principal amounts of such Lender's Term Loans outstanding, and (B) a repayment schedule equal to thirty-six (36) months. All unpaid principal and accrued and unpaid interest with respect to each such Term Loan is due and payable in full on the Maturity Date. The Term Loans may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) <u>Mandatory Prepayments</u>. If the Term Loans are accelerated (including, but not limited to, upon the occurrence of a bankruptcy or insolvency event (including the acceleration of claims by operation of law)), Borrower shall immediately pay to Lenders, payable to each Lender in accordance

with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) any fees payable under the Fee Letter by reason of such prepayment, (iii) the Prepayment Premium plus (iv) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate (if any) with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if any fees payable under the Fee Letter by reason of such prepayments had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to each Lender in accordance with the terms of the Fee Letter. The Prepayment Premium shall also be payable in the event the Obligations (and/or this Agreement) are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure or by any other means. EACH BORROWER AND GUARANTOR EXPRESSLY WAIVES (TO THE FULLEST EXTENT IT MAY LAWFULLY DO SO) THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE OR LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF THE FOREGOING PREPAYMENT PREMIUM IN CONNECTION WITH ANY SUCH ACCELERATION. Notwithstanding anything to the contrary contained herein, there shall be no Prepayment Premium due and payable by Borrower to the Lenders hereunder in connection with the voluntary prepayment by Borrower of all, but not less than all, of the outstanding Term Loans in connection with new loans made by either SLR or any Affiliate of SLR.

(d) <u>Permitted Prepayment of Term Loans</u>. Borrower shall have the option to prepay all, but not less than all, of the outstanding principal balance of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least five (5) Business Days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Shares, an amount equal to the sum of (A) the outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) any fees payable under the Fee Letter by reason of such prepayment, (C) the Prepayment Premium, plus (D) all other Obligations that are due and payable on such prepayment date, including any Lenders' Expenses and interest at the Default Rate (if any) with respect to any past due amounts.

#### 2.3 Payment of Interest on the Term Loans.

(a) <u>Interest Rate</u>. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Applicable Rate in effect from time to time *plus* 7.95%, which aggregate interest rate shall be determined by Collateral Agent in accordance with the definition of "Applicable Rate" on the third Business Day prior to the Funding Date of the applicable Term Loan and on the date occurring on the first Business Day of the month prior to each Payment Date occurring thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Except as set forth in Section 2.2(b), such interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full (or any payment is made hereunder).

(b) <u>Default Rate</u>. Immediately upon the occurrence and during the continuance of an Event of Default, all Obligations shall accrue interest at a fixed per annum rate equal to the rate that is otherwise applicable thereto plus four percentage points (4%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) <u>360-Day Year</u>. Interest shall be computed on the basis of a three hundred sixty (360) day year for the actual number of days elapsed.

(d) <u>Debit of Accounts</u>. Collateral Agent and each Lender may debit (or ACH) any deposit accounts, maintained by Borrower or any of its Subsidiaries for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off.

(e) <u>Payments</u>. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are

owed, at such Person's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 2:00 p.m. Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

**2.4** Fees. Borrower shall pay to Collateral Agent and/or Lenders (as applicable) the following fees, which shall be deemed fully-earned and non-refundable upon payment:

(a) <u>Fee Letter</u>. When due and payable under the terms of the Fee Letter, to Collateral Agent and each Lender, as applicable, the fees set forth in the Fee Letter.

(b) <u>Prepayment Premium</u>. The Prepayment Premium, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares. Borrower expressly agrees (to the fullest extent that each may lawfully do so) that: (i) the Prepayment Premium is reasonable and is the product of an arm's length transaction between sophisticated business people, ably represented by counsel; (ii) the Prepayment Premium shall be payable notwithstanding the then prevailing market rates at the time payment is made; (iii) there has been a course of conduct between Collateral Agent, Lenders and Borrower giving specific consideration in this transaction for such agreement to pay the Prepayment Premium and (iv) Borrower shall be estopped hereafter from claiming differently than as agreed to in this paragraph. Borrower expressly acknowledges that its agreement to pay the Prepayment Premium to Lenders as herein described is a material inducement to Lenders to provide the Term Loan Commitments and make the Term Loans.

(c) <u>Lenders' Expenses</u>. All Lenders' Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due.

(d) <u>Good Faith Deposit</u>. Borrower has paid to SLR a deposit of Fifty Thousand Dollars (\$50,000) (the "**Good Faith Deposit**"), to initiate Collateral Agent's and Lenders' due diligence review and documentation process. The Good Faith Deposit shall be utilized to pay Lenders' Expenses, with the remainder, if any, to pay a portion of the facility fee due in accordance with Section 1 of the Fee Letter.

**2.5 Taxes; Increased Costs.** Borrower, Collateral Agent and the Lenders each hereby agree to the terms and conditions set forth on <u>Exhibit C</u> attached hereto.

# 3. CONDITIONS OF LOANS

**3.1 Conditions Precedent to Initial Term Loan.** Each Lender's obligation to make a Term A Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

(a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;

(b) a completed Perfection Certificate for Borrower and each of its Subsidiaries and Disclosure Schedules for Borrower and each Guarantor;

(c) duly executed Control Agreements with respect to Collateral Accounts maintained by Borrower or any of its Subsidiaries to the extent required under Section 6.6;

(d) a duly executed Fee Letter;

(e) the Operating Documents and good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency) of Borrower's and such Subsidiaries' jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date;

(f) a certificate of Borrower in substantially the form of <u>Exhibit F</u> hereto executed by the Secretary of Borrower with appropriate insertions and attachments, including with respect to (i) the Operating Documents of such Person (which Certificate of Incorporation or Certificate of Formation of such Person shall be certified by the Secretary of State of the State of Delaware) and (ii) the resolutions adopted by such Person's board of directors or other governing body for the purpose of approving the transactions contemplated by the Loan Documents;

(g) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Term Loan, will be terminated or released;

(h) a duly executed legal opinion of counsel to Borrower dated the Effective Date;

(i) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, and, subject to Section 6.12, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Secured Parties;

(j) the duly executed Exit Fee Agreement;

(k) payment of the fees payable under the terms of the Fee Letter and Lenders' Expenses then due as specified in Section 2.4 hereof;

(l) a payoff letter in form and substance satisfactory to Agent and the Lenders evidencing the repayment in full and release of liens with respect to Borrower's existing Indebtedness; and

(m) a replacement Exit Fee Agreement related to Borrower's existing Indebtedness.

**3.2** Conditions Precedent to all Term Loans. The obligation of each Lender to extend each Term Loan, including the initial Term Loan, is subject to the following additional conditions precedent:

(a) receipt by Collateral Agent of an executed Loan Payment Request Form in the form of <u>Exhibit D</u> attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the Funding Date of each Term Loan; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the funding of such Term Loan;

(c) in such Lender's reasonable discretion, there has not been any Material Adverse Change;

(d) No Event of Default or Default, shall exist; and

(e) payment of the fees and Lenders' Expenses then due as specified in Section 2.4 hereof.

**3.3 Covenant to Deliver.** Borrower agrees to deliver to Collateral Agent and to the extent applicable the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to the funding of any Term Loan. Borrower expressly agrees that a Term Loan made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Term Loan in the absence of a required item shall be made in each Lender's sole discretion.

**3.4 Procedures for Borrowing.** Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan (other than the Term Loan funded on the Effective Date), Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 2:00 p.m. New York City time three (3) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to Collateral Agent by electronic mail or facsimile a completed Loan Payment Request Form executed by a Responsible Officer or his or her designee. The Collateral Agent may rely on any telephone notice given by a person whom Collateral Agent reasonably believes is a Responsible Officer or designee. On the Funding Date related to any Term Loan, each Lender shall credit and/or transfer (as applicable) to accounts designated by Borrower and agreed to by the Lenders, in an amount equal to its Term Loan Commitment in respect of such Term Loan.

# 4. CREATION OF SECURITY INTEREST

**4.1 Grant of Security Interest.** Borrower hereby grants Collateral Agent, for the ratable benefit of the Secured Parties, to secure the payment and performance in full of all of the Obligations in full and, until payment in cash of all Obligations (other than (a) inchoate indemnity obligations, and (b) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made), a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Secured Parties, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products and supporting obligations (as defined in the Code) in respect thereof. If Borrower shall acquire any commercial tort claim (as defined in the Code) in an amount greater than Fifty Thousand Dollars (\$50,000), Borrower shall grant to Collateral Agent, for the ratable benefit of the Secured Parties, a security interest therein and in the proceeds and products and supporting obligations (as defined in the Code) thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than (a) inchoate indemnity obligations, and (b) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than (a) inchoate indemnity obligations, and (b) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made) and at such time as the Lenders' obligation to extend Term Loans has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral (and enter into any documentation reasonably requested by Borrower) and all rights therein shall revert to Borrower.

**4.2** Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral (held for the ratable benefit of the Secured Parties), without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents; provided, however, that Borrower shall have no obligation to deliver to Collateral Agent share certificates with respect to its security interests in any Immaterial Subsidiary unless and until the first to occur of (a) an Event of Default or (b) the value of such Immaterial Subsidiary, on a book value, equals or exceeds One Hundred Thousand Dollars (\$100,000).

#### 5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

**5.1 Due Organization, Authorization: Power and Authority.** Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be so qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate and any updates or supplements thereto on, before or after the Effective Date (each a "**Perfection Certificate**" and collectively, the "**Perfection Certificates**"). Borrower represents and warrants that all the information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries is accurate and complete (other than clerical mistakes in addresses and other contact information).

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is, or they are, a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which Borrower, any of its Subsidiaries or any of their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

#### 5.2 Collateral.

(a) Borrower and each of its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith in respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein as required under this Agreement. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) The security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that, under applicable law, have priority over Collateral Agent's Lien.

(c) On the Effective Date, and except as disclosed on the Disclosure Schedules (i) the Collateral is not in the possession of any third party bailee, and (ii) no such third party bailee possesses components of the Collateral in excess of Five Hundred Thousand Dollars (\$500,000) in book value.

(d) All Inventory and Equipment is in all material respects of good and marketable quality, free from material defects.

(e) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Disclosure Schedules (which shall be updated within 45 days after the end of each fiscal quarter to reflect the consummation of any transaction not prohibited by this Agreement) or to be included in the next-delivered Compliance Certificate, neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other Material Agreement.

**5.3** Litigation. Except as disclosed on the Perfection Certificate or with respect to which Borrower has provided notice as required hereunder, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than Two Hundred Fifty Thousand Dollars (\$250,000).

**5.4 No Material Adverse Change; Financial Statements.** All consolidated financial statements for Borrower and its consolidated Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, and in all material respects the consolidated financial condition of Borrower and its consolidated Subsidiaries, and the consolidated results of operations of Borrower and its consolidated Subsidiaries. Since December 31, 2020, there has not been a Material Adverse Change.

**5.5 Solvency.** Borrower is Solvent. Borrower and each of its Subsidiaries, when taken as a whole, is Solvent.

**5.6 Regulatory Compliance.** Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

**5.7 Investments.** Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

**5.8** Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed all required tax returns and reports, each such tax return is true, correct and complete in all material respects, and Borrower and each of its Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries in an amount greater than Fifty Thousand Dollars (\$50,000), in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in accordance with the next sentence. Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted; (b) notifies Collateral Agent of the commencement of, and any material development in, the proceeding; and (c) maintains adequate reserves or other appropriate provisions on the books of such Borrower or Subsidiary, as applicable, in accordance with GAAP and which do not involve, in the reasonable

judgment of the Collateral Agent, any risk of the sale, forfeiture or loss of any material portion of the Collateral. Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower's or such Subsidiaries', prior tax years which could result in additional taxes becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

**5.9 Use of Proceeds.** Borrower shall use the proceeds of the Term Loans to repay existing Indebtedness, as working capital (including, without limitation, to fund Permitted Acquisitions) and to fund its general business requirements, and not for personal, family, household or agricultural purposes.

**5.10 Full Disclosure.** No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement, when taken as a whole, given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

### 5.11 Healthcare Regulatory Matters.

(a) Borrower and each Subsidiary is, and during the past three (3) years has been, in compliance with all applicable Healthcare Laws, except for such noncompliance, whether individually or in the aggregate, as could not reasonably be expected to have a Material Adverse Change. Without limiting the generality of the foregoing, during the past three (3) years, none of Borrower or its Subsidiaries has received written notice by a Governmental Authority of any violation (or of any investigation, audit, or other proceeding involving allegations of any violation) of any Healthcare Laws, which if determined or resolved adversely to the Borrower or any Subsidiary, could reasonably be expected to have a Material Adverse Change, and no such investigation, inspection, audit or other proceeding involving allegations of any such violation is, to Borrower's knowledge, threatened in writing or contemplated which could reasonably be expected to have a Material Adverse Change.

(b) Borrower and each Subsidiary, and its respective officers, directors, and employees are not and, during the past three (3) years, has not been, excluded, debarred, suspended or otherwise ineligible to participate in any governmental healthcare program where the same could reasonably be expected to have a Material Adverse Change, and no such action is pending or, to Borrower's knowledge, threatened in writing. None of the Borrower or its Subsidiaries: is a party to or has any reporting obligations under a corporate integrity agreement, deferred or non-prosecution agreement, monitoring agreement, consent decree, settlement order, or any similar agreement with any Governmental Authority.

### 6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

# 6.1 Government Compliance.

(a) Other than specifically permitted hereunder, maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations, including all Healthcare

Laws, to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Secured Parties, in all of the Collateral.

#### 6.2 Financial Statements, Reports, Certificates; Notices.

(a) Deliver to Collateral Agent:

(i) as soon as available, but no later than thirty (30) days after the last day of each month that is not a quarterend, a company prepared consolidated and, if prepared by Borrower or if reasonably requested by the Lenders, consolidating balance sheet, income statement and cash flow statement, in each case subject to year-end adjustments and the absence of footnotes, covering the consolidated operations of Borrower and its consolidated Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to the Collateral Agent;

(ii) as soon as available, but no later than forty-five (45) days after the last day of each fiscal quarter, a company prepared consolidated and, if prepared by Borrower or if reasonably requested by the Lenders, consolidating balance sheet, income statement and cash flow statement, in each case subject to year-end adjustments and the absence of footnotes, covering the consolidated operations of Borrower and its consolidated Subsidiaries for such fiscal quarter certified by a Responsible Officer and in a form reasonably acceptable to the Collateral Agent;

(iii) as soon as available, but no later than ninety (90) days after the last day of Borrower's fiscal year or within five (5) days of filing of the same with the SEC, audited consolidated financial statements covering the consolidated operations of Borrower and its consolidated Subsidiaries for such fiscal year, prepared under GAAP, consistently applied, together with an unqualified opinion (other than with respect to a going concern limitation based solely on the amount of cash and Cash Equivalents held by Borrower) on the financial statements from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion;

(iv) no later than sixty (60) days after the last day of Borrower's fiscal year, but no later than ten (10) days' after approval thereof by the Borrower's board of directors, Borrower's annual financial projections for the entire current fiscal year as approved by Borrower's board of directors; provided that, any revisions to such projections approved by Borrower's board of directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval);

(v) together with the delivery of the Compliance Certificate, copies of all non-ministerial statements, reports and notices made available to Borrower's security holders or holders of Subordinated Debt (except as otherwise required to be delivered hereunder, other than materials provided to members of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or provided to members of Borrower's solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members or management of Borrower's board of directors solely in their capacities as board members of Borrower's board of directors solely i

(vi) with each Compliance Certificate, copies of the month-end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s);

(vii) prompt delivery of (and in any event within five (5) days after the same are sent or received) copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or that otherwise could reasonably be expected to have a Material Adverse Change;

(viii) prompt notice of any event that (A) could reasonably be expected to materially and adversely affect the value of the Intellectual Property or (B) could reasonably be expected to result in a Material Adverse Change;

(ix) written notice delivered at least five (5) days' prior to Borrower's creation of a New Subsidiary in accordance with the terms of Section 6.10;

(x) written notice delivered at least twenty (20) days' prior to Borrower's (A) adding any new offices or business locations, including warehouses (unless such new offices or business locations contain less than Five Hundred Thousand Dollars (\$500,000) in assets or property of Borrower or any of its Subsidiaries), (B) changing its respective jurisdiction of organization, (C) changing its organizational structure or type, (D) changing its respective legal name, or (E) changing any organizational number(s) (if any) assigned by its respective jurisdiction of organization;

(xi) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, prompt (and in any event within three (3) Business Days) written notice of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, and Borrower's proposal regarding how to cure such Event of Default or event;

(xii) immediate notice if Borrower or such Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering;

(xiii) together with the delivery of the Compliance Certificate, notice of any commercial tort claim (as defined in the Code) or letter of credit rights (as defined in the Code) held by Borrower or any Guarantor, in each case in an amount greater than One Hundred Thousand Dollars (\$100,000) and of the general details thereof;

(xiv) if Borrower has any Subsidiaries any of which is not a Registered Organization upon formation thereof but later becomes one, written notice of such occurrence and information regarding such Person's organizational identification number within seven (7) Business Days of receiving such organizational identification number;

(xv) no later than 45 days after the end of each fiscal quarter an updated Perfection Certificate to reflect any amendments, modifications and updates, if any, to certain information in the Perfection Certificate after the Effective Date; and

(xvi) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the terms herein, documents and notices required to be delivered pursuant to the terms hereof (to the extent any such documents and notices are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than thirty (30) days after the last day of each month, deliver to Collateral Agent:

(i) a duly completed Compliance Certificate signed by a Responsible Officer;

(ii) copies of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries;

Section 5.8 hereof;

(iii) written notice of the commencement of, and any material development in, the proceedings contemplated by

(iv) written notice of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Two Hundred Fifty Thousand Dollars (\$250,000); and

(v) written notice of all returns, recoveries, disputes and claims regarding Inventory that involve more than Five Hundred Thousand Dollars (\$500,000) individually or in the aggregate in any calendar year.

(c) Keep proper, complete and true books of record and account in accordance with GAAP in all material respects. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than twice every year unless (and more frequently if) an Event of Default has occurred and is continuing.

**6.3 Inventory; Returns.** Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, as applicable, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, as applicable, customary practices.

**6.4 Taxes; Pensions.** Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, as applicable, except as otherwise permitted pursuant to the terms of Section 5.8 hereof, and shall deliver to Collateral Agent, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

**6.5 Insurance.** Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are standard for companies in Borrower's industry and location. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and shall waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent (for the ratable benefit of the Secured Parties), as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days prior written notice before any such policy or policies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall have the option of applying the proceeds of any casualty policy within one hundred eighty (180) days of receipt thereof up to Seven Hundred Fifty Thousand Dollars (\$750,000) with respect to any loss, but not exceeding One Million Five Hundred Thousand Dollars (\$1,500,000), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be deemed Collateral Agent, for the ratable benefit of the secured or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first pri

Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent may make (but has no obligation to do so), at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent deems prudent.

# 6.6 Operating Accounts.

(a) Maintain Borrower's and Guarantors Collateral Accounts with depositary institutions that have agreed to execute Control Agreements in favor of Collateral Agent with respect to such Collateral Accounts. The provisions of the previous sentence shall not apply to Deposit Accounts exclusively used for cash collateral for Permitted Liens under clause (j) of the definition thereof, payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any Guarantor's, employees in an aggregate amount not to exceed the amount reasonably expected to be due and payable for the next two (2) succeeding pay periods and identified to Collateral Agent by Borrower as such in the Disclosure Schedules and any deposit accounts at Western Alliance Bank (provided the accounts at Western Alliance Bank do not have an aggregate balance in excess of One Hundred Thousand Dollars (\$100,000) from and after the date that is three (3) Business Days after the Effective Date and such accounts are closed as required by Section 6.12(b)).

(b) Borrower shall provide Collateral Agent ten (10) days' prior written notice before Borrower or any Guarantor establishes any Collateral Account. In addition, for each Collateral Account that Borrower or any Guarantor, at any time maintains, Borrower or such Guarantor shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account (held for the ratable benefit of the Secured Parties) in accordance with the terms hereunder prior to the establishment of such Collateral Account. The provisions of the previous sentence shall not apply to Deposit Accounts exclusively used for cash collateral for Permitted Liens under clause (j) of the definition thereof, payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any Guarantor's, employees in an aggregate amount not to exceed the amount reasonably expected to be due and payable for the next two (2) succeeding pay periods and identified to Collateral Agent by Borrower as such in the Disclosure Schedules or otherwise in writing to the Collateral Agent and any deposit accounts at Western Alliance Bank (provided the accounts at Western Alliance Bank do not have an aggregate balance in excess of One Hundred Thousand Dollars (\$100,000) from and after the date that is three (3) Business Days after the Effective Date and such accounts are closed as required by Section 6.12(b)).

(c) Neither Borrower nor any Guarantor shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with this Section 6.6.

**6.7 Protection of Intellectual Property Rights.** Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its respective Intellectual Property that is material to its business; (b) promptly advise Collateral Agent in writing of material infringement by a third party of its respective Intellectual Property; and (c) not allow any of its respective Intellectual Property material to its respective business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

**6.8** Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent with respect to any Collateral or relating to Borrower.

**6.9** Landlord Waivers; Bailee Waivers. In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then, in the event that the Collateral at any new location is valued (based on book value) in excess of Five Hundred Thousand Dollars (\$500,000) in the aggregate,

at Collateral Agent's election, Borrower or such Subsidiary shall use commercially reasonable efforts to cause such bailee or landlord, as applicable, to execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

**6.10 Creation/Acquisition of Subsidiaries.** In the event any Borrower or any Subsidiary of any Borrower creates or acquires any Subsidiary after the Effective Date, Borrower or such Subsidiary shall promptly notify the Collateral Agent of such creation or acquisition, and Borrower or such Subsidiary shall take all actions reasonably requested by the Collateral Agent to achieve any of the following with respect to such "New Subsidiary" (defined as a Subsidiary formed after the date hereof during the term of this Agreement): (i) if such New Subsidiary is a Domestic Subsidiary (except for a Domestic Subsidiary (1) substantially all of the assets of which consist of the equity interests of one or more Foreign Subsidiaries or (2) that is a subsidiary of a Foreign Subsidiary (each, an "Excluded Domestic Subsidiary")), to cause such New Subsidiaries owned directly by Borrower or a Guarantor, to grant and pledge to Collateral Agent a perfected security interest in (A) 100% of the stock, units or other evidence of ownership held by Borrower or its Subsidiary), or (B) 65% of the stock, units or other evidence of ownership held by Borrower or a Guarantor of any such New Subsidiary or an Excluded Domestic Subsidiary or a Guarantor of any such New Subsidiary or an Excluded Domestic Subsidiary.

**6.11 Further Assurances.** Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

**6.12 Post-Effective Date Obligations.** Notwithstanding any provision herein or in any other Loan Document to the contrary, to the extent not actually delivered on or prior to the Effective Date, Borrower shall, and shall cause each Subsidiary to:

(a) within thirty (30) days after the Effective Date (as such date may be extended by Collateral Agent in its sole discretion), deliver to Collateral Agent the insurance endorsements, in each case satisfying the requirements of Section 6.5;

(b) within sixty (60) days after the Effective Date (as such date may be extended by Collateral Agent in its sole discretion), deliver to Collateral Agent evidence in form and substance reasonably acceptable to Collateral Agent, that the Collateral Accounts of Borrower at Western Alliance Bank have been closed;

(c) use commercially reasonable efforts to deliver to Collateral Agent a landlord's consent executed in favor of Collateral Agent in respect Borrower's leased locations at 400 Fifth Avenue, Suites 210 & 300, Waltham, MA 02451 and 34175 Ardenwood Blvd, Fremont, CA 94555 no later than sixty (60) days after the Effective Date (as such date may be extended by Collateral Agent in its sole discretion);

(d) use commercially reasonable efforts to deliver to Collateral Agent a bailee waiver executed in favor of Collateral Agent in respect of each third party bailee where Borrower or any Subsidiary maintains Collateral having a book value in excess of Five Hundred Thousand Dollars (\$500,000) in the aggregate no later than sixty (60) days after the Effective Date (as such date may be extended by Collateral Agent in its sole discretion);

(e) within two (2) Business Days after the Effective Date (as such date may be extended by Collateral Agent in its sole discretion) deliver to Collateral Agent evidence in form and substance reasonably acceptable to Collateral Agent that Borrower has transferred all of its cash and Cash Equivalents from its Collateral Accounts at Western Alliance Bank to one or more Collateral Accounts at Silicon Valley Bank that are subject to Control Agreements in favor of Collateral Agent;

(f) within ten (10) Business Days after the Effective Date (as such date may be extended by Collateral Agent in its sole discretion) deliver to Collateral Agent good standing certificates for each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business; and

(g) within ten (10) Business Days after the Effective Date (as such date may be extended by Collateral Agent in its sole discretion) deliver to Collateral Agent an executed Control Agreement in favor of Collateral Agent with respect to the Collateral Account at Capital Advisors Group; provided, however, until such time that the Collateral Account is subject to a Control Agreement, Borrower shall not Transfer any assets into such Collateral Account.

### 7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

**7.1 Dispositions.** Convey, sell, lease, transfer, assign, dispose of, license (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn-out, surplus, uneconomic or obsolete Equipment; (c) in connection with the Permitted Royalty Transaction, Permitted Licens, Permitted Investments and Permitted Licenses; (d) cash or Cash Equivalents pursuant to transactions not prohibited by this Agreement; (e) sales or discounting of delinquent accounts in the ordinary course of business; or (f) other Transfers not to exceed Two Hundred Fifty Thousand Dollars (\$250,000) in any fiscal year.

**7.2 Changes in Business, Management, Ownership, or Business Locations.** (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower or such Subsidiary, as applicable, as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) permit any Key Person to cease being actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent within ten (10) Business Days of such cessation, or (ii) enter into any transaction or series of related transactions in which (A) the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than 49% of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions and (B) except as permitted by Section 7.3, Borrower ceases to own, directly or indirectly, 100% of the ownership interests in each Subsidiary of Borrower. Borrower shall not, and shall not permit any of its Subsidiaries to, without at least twenty (20) days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than Five Hundred Thousand Dollars (\$500,000) in assets or property of Borrower or any of its Subsidiaries, as applicable); (B) change its respective jurisdiction of organization, (C) except as permitted by Section 7.3, change its respective organizational structure or type, (D) change its respective legal name, or (E) change any organizational number(s) (if any) assigned by its respective jurisdiction of organization.

**7.3 Mergers or Acquisitions.** Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person, other than Permitted Acquisitions. A Subsidiary may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder in accordance with Section 6.10) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom.

**7.4** Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

**7.5** Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable

benefit of the Secured Parties) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens".

**7.6** Maintenance of Collateral Accounts. With respect to Borrower and any Guarantors, maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

**7.7 Restricted Payments.** (a) Declare or pay any dividends (other than dividends payable solely in capital stock) or make any other distribution or payment on account of or redeem, retire or purchase any capital stock (other than (i) the declaration or payment of dividends or other distributions to Borrower or any of its Subsidiaries, (ii) so long as no Event of Default or Default exists or would result therefrom, the declaration or payment of any dividends solely in the form of equity securities, and (iii) repurchases pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, similar plans to any of the foregoing, or payments in connection with tax withholding obligations in connection with the foregoing, provided such repurchases do not exceed Three Hundred Fifty Thousand Dollars (\$350,000) in the aggregate per fiscal year and One Million Dollars (\$1,000,000) over the term of this Agreement), (b) other than the Obligations in accordance with the terms hereof, purchase, redeem, defease or prepay any principal of, premium, if any, interest or other amount payable in respect of any Indebtedness prior to its scheduled maturity unless being replaced with Indebtedness of at least the same principal amount and such new Indebtedness is Permitted Indebtedness, or (c) be a party to or bound by an agreement that restricts a Subsidiary from paying dividends or otherwise distributing property to Borrower other than this Agreement.

**7.8 Investments.** Directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so other than Permitted Investments.

**7.9 Transactions with Affiliates.** Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries, and (c) compensation arrangements for Borrower's and its Subsidiaries' officers, directors and employees that are customary in Borrower's industry.

**7.10 Subordinated Debt.** (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

**7.11 Compliance.** (a) Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Term Loan for that purpose; (b) fail to meet the minimum funding requirements of ERISA; (c) permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; (d) fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; or (e) withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

**7.12 Compliance with Anti-Terrorism Laws.** Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the

OFAC Lists. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (a) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (b) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (c) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

**7.13 Minimum Liquidity.** Borrower shall not allow, at any time, the consolidated aggregate balance of its unrestricted cash and Cash Equivalents in Collateral Accounts that are subject to Control Agreements to be less than an amount equal to eighty percent (80%) of the outstanding principal balance of the Term Loans for any measurement period in which the Net Product Revenue of Borrower, calculated on a trailing six (6) month basis as of the last day of each month, is less than an amount equal to sixty percent (60%) of the outstanding principal balance of the Term Loans as of such date.

#### 8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "Event of Default") under this Agreement:

**8.1 Payment Default.** Borrower fails to (a) make any payment of principal or interest on any Term Loan on its due date, or (b) pay any other Obligation within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date or acceleration pursuant to Section 9.1(a) hereof).

### 8.2 Covenant Default.

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Landlord Waivers; Bailee Waivers), 6.10 (Creation/Acquisition of Subsidiaries), 6.12 (Post-Effective Date Obligations) or Borrower violates any provision in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any other Loan Document to which such person is a party, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within fifteen (15) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the fifteen (15) day period or cannot after diligent attempts by Borrower or such Subsidiary, as applicable, be cured within such fifteen (15) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Term Loans shall be made during such cure period).

**8.3** Material Adverse Change. Required Lenders determine that a Material Adverse Change has occurred.

## 8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) of this clause

(a) are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business.

**8.5 Insolvency.** (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Term Loans shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed).

**8.6 Other Agreements.** There is a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Three Hundred Fifty Thousand Dollars (\$350,000) or that could reasonably be expected to have a Material Adverse Change.

**8.7 Judgments.** One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Three Hundred Fifty Thousand Dollars (\$350,000) (not covered by independent third-party insurance as to which (a) Borrower reasonably believes such insurance carrier will accept liability, (b) Borrower or the applicable Subsidiary has submitted such claim to such insurance carrier and (c) liability has not been rejected by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof.

**8.8 Misrepresentations.** Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or the Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement, when taken as a whole, is incorrect in any material respect when made.

**8.9 Subordinated Debt.** A default or breach occurs under any subordination agreement, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement.

**8.10** Guaranty. (a) Any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; or (c) any circumstance described in Section 8 occurs with respect to any Guarantor.

**8.11 Governmental Approvals; FDA Action.** (a) Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or (b) (i) the FDA or other Governmental Authority initiates a Regulatory Action or any other enforcement action against Borrower or any of its Subsidiaries or any supplier of Borrower or any of its Subsidiaries that causes Borrower or any of its Subsidiaries to recall, withdraw, remove or discontinue marketing any of its products; (ii) the FDA or any other comparable Governmental Authority issues a warning letter to Borrower or any of its Subsidiaries or products which could reasonably be expected to result in a Material Adverse Change; (iii) Borrower or any of its Subsidiaries of the Applicable FDA Threshold or more; (iv) Borrower or any of its Subsidiaries enters into a settlement agreement with the FDA that results in aggregate liability as to any single or related series of transactions, incidents or conditions, of the Applicable FDA Threshold or more, or that could reasonably be expected to result in a Material Adverse Change; or (v) the FDA or any other comparable Governmental Authority is of transactions, incidents or conditions, of the Applicable FDA Threshold or more, or that could reasonably be expected to result in a Material Adverse Change; or (v) the FDA or any other comparable Governmental Authority revokes any authorization or permission granted under any

Registration, or Borrower or any of its Subsidiaries withdraws any Registration, that could reasonably be expected to result in a Material Adverse Change.

**8.12** Lien Priority. Except as the result of the action or inaction of the Collateral Agent or the Lenders, any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien (to the extent required to be perfected) on any material Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens arising as a matter of applicable law.

# 9. RIGHTS AND REMEDIES

### 9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall at the written direction of Required Lenders, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall at the written direction of the Required Lenders, without notice or demand, to do any or all of the following:

- (i) foreclose upon and/or sell or otherwise liquidate, the Collateral;
- (ii) make a demand for payment upon any Guarantor pursuant to the Guaranty delivered by such Guarantor;

(iii) apply to the Obligations any (A) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, (B) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower, or (C) amounts received from any Guarantors in accordance with the respective Guaranty delivered by such Guarantor; and/or

Proceeding.

(iv) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall at the written direction of the Required Lenders, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its Liens in the Collateral (held for the ratable benefit of the Secured Parties). Borrower shall assemble the Collateral if Collateral Agent requests and make it available at such location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the

Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, any of the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any Collateral Account maintained with Collateral Agent or any Lender or otherwise in respect of which a Control Agreement has been delivered in favor of Collateral Agent (for the ratable benefit of the Secured Parties) and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

# (v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence and during the continuance of an Exigent Circumstance.

**9.2 Power of Attorney.** Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts of Borrower directly with the applicable Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than (a) inchoate indemnity obligations, and (b) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to extend Term Loans rights and powers, coupled with an interest, are irrevocable until all Obligations (other than (a) inchoate indemnity obligations, and (b) other obligation of this Agreement, in each case, for which no claim has been made) have been fully repaid and performed and Collateral Agent's and the Lenders' obligations (other than (b) other obligations, and (b) other obligation

**9.3 Protective Payments.** If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fail to pay any premium thereon or fail to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the 9.4 occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other Obligations owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," proportionally" or in similar terms shall refer to the Lenders' Pro Rata Shares unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's Pro Rata Share of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its Pro Rata Share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other the Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its Pro Rata Share, then the portion of such payment or distribution in excess of such Lender's Pro Rata Share shall be received and held by such Lender in trust for and shall be promptly paid over to the other Lenders (in accordance with their respective Pro Rata Shares) for application to the payments of amounts due on such other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for the Secured Parties for purposes of perfecting Collateral Agent's security interest therein (held for the ratable benefit of the Secured Parties).

**9.5** Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

**9.6 No Waiver; Remedies Cumulative.** Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or by

Borrower or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

**9.7 Demand Waiver.** Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

## **10. NOTICES**

Other than as specifically provided herein, all notices, consents, requests, approvals, demands, or other communication (collectively, "**Communications**") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:	
	ARDELYX, INC. 400 Fifth Avenue, Suite 210 Waltham, MA 02451 Attn: Justin Renz Email:
with a copy (which shall not	
constitute notice) to:	LATHAM & WATKINS LLP 140 Scott Drive Menlo Park, CA 94025 Attn: Mark Roeder Email:
If to Collateral Agent:	SLR INVESTMENT CORP. 500 Park Avenue, 3rd Floor New York, NY 10022 Attn: Anthony Storino Fax: (212) 993-1698 Email:
with a copy (which shall not constitute notice) to:	DLA Piper LLP (US) 500 8 <sup>th</sup> Street, NW Washington, DC 20004 Attn: Eric Eisenberg Fax: (202) 799-5211 Email:

### 11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

**11.1 Waiver of Jury Trial.** EACH OF BORROWER, COLLATERAL AGENT AND LENDERS UNCONDITIONALLY WAIVES ANY AND ALL RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, ANY OF THE OTHER LOAN DOCUMENTS, ANY OF THE INDEBTEDNESS SECURED HEREBY, ANY DEALINGS AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT. THIS WAIVER IS IRREVOCABLE. THIS WAIVER MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING. THE WAIVER ALSO SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT, ANY OTHER LOAN DOCUMENTS, OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THIS TRANSACTION OR ANY RELATED TRANSACTION. THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

**11.2 Governing Law and Jurisdiction.** THIS AGREEMENT, THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND THEREUNDER 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 (OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW)), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE,

REGARDLESS OF THE LOCATION OF THE COLLATERAL, <u>PROVIDED</u>, <u>HOWEVER</u>, 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.

**11.3 Submission to Jurisdiction.** Any legal action or proceeding with respect to the Loan Documents shall be brought exclusively in the courts of the State of New York located in the City of New York, Borough of Manhattan, or of the United States of America for the Southern District of New York and, by execution and delivery of this Agreement, Borrower hereby accepts for itself and in respect of its Property, generally and unconditionally, the jurisdiction of the aforesaid courts. Notwithstanding the foregoing, Collateral Agent and Lenders shall have the right to bring any action or proceeding against Borrower (or any property of Borrower) in the court of any other jurisdiction Collateral Agent or Lenders deem necessary or appropriate in order to realize on the Collateral or other security for the Obligations. The parties hereto hereby irrevocably waive any objection, including any objection to the laying of venue or based on the grounds of *forum non conveniens*, that any of them may now or hereafter have to the bringing of any such action or proceeding in such jurisdictions.

**11.4 Service of Process.** Borrower irrevocably waives personal service of any and all legal process, summons, notices and other documents and other service of process of any kind and consents to such service in any suit, action or proceeding brought in the United States of America with respect to or otherwise arising out of or in connection with any Loan Document by any means permitted by applicable requirements of law, including by the mailing thereof (by registered or certified mail, postage prepaid) to the address of Borrower specified herein (and shall be effective when such mailing shall be effective, as provided therein). Borrower agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

**11.5 Non-exclusive Jurisdiction.** Nothing contained in this Article 11 shall affect the right of Collateral Agent or Lenders to serve process in any other manner permitted by applicable requirements of law or commence legal proceedings or otherwise proceed against Borrower in any other jurisdiction.

### 12. GENERAL PROVISIONS

12.1 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's prior written consent (which may be granted or withheld in Collateral Agent's discretion, subject to Section 12.5). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "Lender Transfer") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; provided, however, that any such Lender Transfer (other than (i) any Transfer at any time that an Event of Default has occurred and is continuing, or (ii) a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Collateral Agent (such approved assignee, an "Approved Lender"); and provided, further, that on the date it becomes a party to this Agreement, an Approved Lender must be capable, through its applicable lending office, of receiving payments of interest from Borrower without the imposition of any withholding taxes that would be required to be borne by Borrower or requiring the payment of any additional amounts by Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender Transfer promptly following such Lender Transfer promptly following such Lender Transfer. Notwithstanding anything to the contrary contained herein, so long as no E

(other than a Lender Transfer in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower, a vulture hedge fund or a distressed debt fund, each as reasonably determined by Collateral Agent at the time of such assignment. Collateral Agent, acting solely for this purpose as an agent of Borrower, shall maintain at one of its offices in the United States a register for the recordation of the names and addresses of the Lenders, and the Term Loan Commitments of, and principal amounts (and stated interest) of the Term Loans owing to each Lender pursuant to the terms hereof from time to time (the "**Register**"). The entries in the Register shall be conclusive absent manifest error, and Borrower, Collateral Agent and Lenders shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as Lender hereunder for all purposes of this Agreement. The Register shall be available for inspection by Borrower and any Lender at any reasonable time and from time to time upon reasonable prior notice. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of Borrower, maintain a register on which it enters the name and address of each participant and the principal amounts (and stated interest) of each participant's interest in the Term Loans or other obligations under the Loan Documents (the "**Participant Register**"); provided that no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans or its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan or other obligation is in registered form under Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. For the avoidance of doubt, Collateral Agent (in its capacity as Collateral Agent) shall have no responsibility for maintaining a Participant Register. Borrower agrees that each participant shall be entitled to the benefits of the provisions in Exhibit C attached hereto (subject to the requirements and limitations therein, including the requirements under Section 7 of Exhibit C attached hereto (it being understood that the documentation required under Section 7 of Exhibit C attached hereto shall be delivered to the participating Lender)) to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to this Section 12.1; provided that such participant shall not be entitled to receive any greater payment under Exhibit C attached hereto, with respect to any participation, than its participating Lender would have been entitled to receive, except to the extent such entitlement to receive a greater payment results from a change in law that occurs after the participant acquired the applicable participation.

**12.2** Indemnification. Subject to Section 2.5, Borrower agrees to indemnify, defend and hold each Secured Party and their respective directors, officers, employees, consultants, agents, attorneys, or any other Person affiliated with or representing such Secured Party (each, an "Indemnified Person") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "Claims") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses and Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents (including reasonable attorneys' fees and expenses), except, in each case, for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further agrees to indemnify, defend and hold each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claim

conflict of interest is apparent in connection with the defense of any Claim, Collateral Agent and the Lenders shall first take commercially reasonable efforts to use the same counsel as Borrower, or, if a conflict does exist, use only one counsel among all Indemnified Persons with respect to the defense of any Claim. This Section 12.2 shall not apply with respect to any Indemnified Taxes subject to indemnification under Section 2.5 or Excluded Taxes.

**12.3 Severability of Provisions.** Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

**12.4 Correction of Loan Documents.** Collateral Agent may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties.

#### 12.5 Amendments in Writing; Integration.

(a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature; and

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (cother than default interest) or any fees provided for hereunder (other than late charges) or for any termination of any commitment); (C) change the definition of the term "Required Lenders" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its Guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.5 or the definitions of the terms used in this Section 12.5 insofar as the definitions affect the substance of this Section 12.5; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of C

(b) Other than as expressly provided for in Section 12.5(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about

the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

**12.6 Counterparts.** This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

**12.7 Survival.** All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than (a) inchoate indemnity obligations, and (b) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.8 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

**12.8 Confidentiality.** In handling any confidential information of Borrower, each of the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Term Loans (provided, however, the Lenders and Collateral Agent shall obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent agent so long as such service providers have executed a confidentiality agreement or have agreed to similar confidentiality terms with the Lenders and/or Collateral Agent, as applicable, with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent agent, or (ii) is disclosed to the Lenders and/or Collateral Agent agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent agent agent, are puppose, including, without limitation, for the development of client databases, reporting pupposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.8.

**12.9 Right of Set Off.** Borrower hereby grants to Collateral Agent and to each Lender, a Lien, security interest and right of set off as security for all Obligations to Secured Parties hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of any Secured Party or any entity under the control of such Secured Party (including a Collateral Agent Affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, any Secured Party may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED BY BORROWER.

**12.10 Cooperation of Borrower.** If necessary, Borrower agrees to (i) execute any documents reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment (or portion thereof) or Term Loan (or portion thereof) to an assignee in accordance with Section 12.1, (ii) make Borrower's management personnel available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments, the Term Loans or portions thereof (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent and the Lenders in the preparation of information relating to the financial affairs of Borrower for any prospective participant or assignee of a Term Loan Commitment (or portions thereof) or Term Loan (or portions thereof) as Collateral Agent or such Lender may reasonably may request. Subject to the provisions of Section 12.8, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment (or portions thereof), any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement, in each case subject to Section 12.8.

**12.11 Public Announcement.** Collateral Agent and each Lender may, with the prior written consent of Borrower (which consent may not be unreasonably conditioned, withheld or delayed), make a public announcement of the transactions contemplated by this Agreement, and may publicize the same in marketing materials, newspapers and other publications, and otherwise, and in connection therewith may use Borrower's name, tradenames and logos. Notwithstanding the foregoing, such prior written consent from Borrower shall not be required for any disclosures by Collateral Agent or the Lenders required by the Securities and Exchange Commission or other governmental agency and any other public disclosure with investors, other governmental agencies or other related persons, in each case, subject to applicable law and regulations.

**12.12 Collateral Agent and Lender Agreement.** Collateral Agent and each Lender hereby agree to the terms and conditions set forth on Exhibit B attached hereto. Borrower acknowledges and agrees to the terms and conditions set forth on Exhibit B attached hereto.

**12.13 Time of Essence.** Time is of the essence for the performance of Obligations under this Agreement.

**12.14 Termination Prior to Maturity Date; Survival.** All covenants, representations and warranties made in this Agreement continue in full force until this Agreement has terminated pursuant to its terms and all Obligations have been satisfied (other than (a) inchoate indemnity obligations, and (b) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made). So long as Borrower has satisfied the Obligations (other than (a) inchoate indemnity obligations, and (b) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made). So long as Borrower has satisfied the Obligations (other than (a) inchoate indemnity obligations, and (b) other obligations that, by their terms, survive termination of this Agreement, in each case, for which no claim has been made) in accordance with the terms of this Agreement, this Agreement may be terminated prior to the Maturity Date by Borrower, effective three (3) Business Days after written notice of termination is given to the Collateral Agent and the Lenders.

**12.15** Electronic Execution of Certain Other Documents. 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 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.

#### [Balance of Page Intentionally Left Blank]

**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be executed as of the Effective Date.

## **BORROWER:**

ARDELYX, INC.

By /s/ Justin A. Renz Name: Justin A. Renz Title: CFO

### **COLLATERAL AGENT AND LENDER:**

SLR INVESTMENT CORP.

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

[Signature Page to Loan and Security Agreement]

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#### LENDERS:

#### SLR SENIOR INVESTMENT CORP.

By <u>/s/ Anthony Storino</u> Name: Anthony Storino Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND SPV, LLC

By <u>/s/ Anthony Storino</u> Name: Anthony Storino Title: Authorized Signatory

### SCP PRIVATE CREDIT INCOME BDC SPV LLC

By <u>/s/ Anthony Storino</u> Name: Anthony Storino Title: Authorized Signatory

### SCP PRIVATE CORPORATE LENDING FUND SPV LLC

By <u>/s/ Anthony Storino</u> Name: Anthony Storino Title: Authorized Signatory

### SCP SF DEBT FUND L.P.

By <u>/s/ Anthony Storino</u> Name: Anthony Storino Title: Authorized Signatory

## SLR HC FUND SPV, LLC

By <u>/s/ Anthony Storino</u> Name: Anthony Storino Title: Authorized Signatory

# SLR HC BDC LLC

By <u>/s/ Anthony Storino</u> Name: Anthony Storino Title: Authorized Signatory

[Signature Page to Loan and Security Agreement]

# **SCHEDULE 1.1**

# Lenders and Commitments

	Term A Loans	
Lender	Term A Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	\$7,846,125.90	28.53%
SLR SENIOR INVESTMENT CORP.	\$1,629,125.26	5.92%
SCP PRIVATE CREDIT INCOME FUND SPV, LLC	\$4,449,548.38	16.18%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	\$3,319,342.73	12.07%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	\$4,321,998.05	15.72%
SCP SF DEBT FUND L.P.	\$1,038,567.36	3.78%
SLR HC FUND SPV, LLC	\$4,044,074.37	14.71%
SLR HC BDC LLC	\$851,217.95	3.10%
TOTAL	\$27,500,000	100.00%

## Term B Loans

Lender	Term B Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	\$6,419,557.56	28.53%
SLR SENIOR INVESTMENT CORP.	\$1,332,920.67	5.92%
SCP PRIVATE CREDIT INCOME FUND SPV, LLC	\$3,640,539.58	16.18%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	\$2,715,825.87	12.07%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	\$3,536,180.22	15.72%
SCP SF DEBT FUND L.P.	\$849,736.93	3.78%
SLR HC FUND SPV, LLC	\$3,308,788.12	14.71%
SLR HC BDC LLC	\$696,451.05	3.10%
TOTAL	\$22,500,000	100.00%

# Aggregate (all Term Loans)

Lender	Term Loan Commitment	Commitment Percentage
SLR INVESTMENT CORP.	\$14,265,683.46	28.53%
SLR SENIOR INVESTMENT CORP.	\$2,962,045.93	5.92%
SCP PRIVATE CREDIT INCOME FUND SPV, LLC	\$8,090,087.96	16.18%
SCP PRIVATE CREDIT INCOME BDC SPV LLC	\$6,035,168.60	12.07%
SCP PRIVATE CORPORATE LENDING FUND SPV LLC	\$7,858,178.27	15.72%
SCP SF DEBT FUND L.P.	\$1,888,304.29	3.78%
SLR HC FUND SPV, LLC	\$7,352,862.49	14.71%
SLR HC BDC LLC	\$1,547,669.00	3.10%
TOTAL	\$50,000,000	100.00%

#### EXHIBIT A

#### **Description of Collateral**

The Collateral consists of all of Borrower's and Guarantors' right, title and interest in and to the following personal property:

All goods, Accounts (including health care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (a) (1) more than 65% of the presently existing and hereafter arising issued and outstanding shares of capital stock owned by Borrower or any Guarantor of any Foreign Subsidiary or any Excluded Domestic Subsidiary which shares entitle the holder thereof to vote for directors or any other matter or (2) any of the stock or other equity interests in any Foreign Subsidiary that is not owned by Borrower or a Guarantor, (b) any interest of Borrower as a lessee or sublessee under a real property lease; (c) rights held under a license or other agreement that are not assignable by their terms without the consent of the counterparty thereof (but only to the extent such restriction on assignment is effective under Section 9-406, 9-407, 9408 or 9-409 of the Code (or any successor provision or provisions) of any relevant jurisdiction or any other applicable law (including the Bankruptcy Code) or principles of equity); (d) any interest of Borrower or any Guarantor as a lessee or borrower under an Equipment lease or Equipment financing if Borrower or such Guarantor, as applicable, is prohibited by the terms of such agreement from granting a security interest in such lease or agreement or under which such an assignment or Lien would cause a default to occur under such lease; provided, however, that upon termination of such prohibition, such interest shall immediately become Collateral without any action by Borrower (or such Guarantor, as applicable), Collateral Agent or any Lender, or (e) any Intellectual Property and any sale of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property. If a judicial authority interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collater

## EXHIBIT B Collateral Agent and Lender Terms

#### 1. Appointment of Collateral Agent.

(a) Each Lender hereby appoints SLR (together with any successor Collateral Agent pursuant to Section 7 of this Exhibit B) as Collateral Agent under the Loan Documents and authorizes Collateral Agent to (i) execute and deliver the Loan Documents and accept delivery thereof on its behalf from Borrower, (ii) take such action on its behalf and to exercise all rights, powers and remedies and perform the duties as are expressly delegated to Collateral Agent under such Loan Documents and (iii) exercise such powers as are reasonably incidental thereto.

(b) Without limiting the generality of clause (a) above, Collateral Agent shall have the sole and exclusive right and authority (to the exclusion of the Lenders), and is hereby authorized, to (i) act as the disbursing and collecting agent for the Lenders with respect to all payments and collections arising in connection with the Loan Documents (including in any other bankruptcy, insolvency or similar proceeding), and each Person making any payment in connection with any Loan Document to any Lender is hereby authorized to make such payment to Collateral Agent, (ii) file and prove claims and file other documents necessary or desirable to allow the claims of Collateral Agent and Lenders with respect to any Obligation in any bankruptcy, insolvency or similar proceeding (but not to vote, consent or otherwise act on behalf of such Lender), (iii) act as collateral agent for the Secured Parties for purposes of the perfection of all Liens created by the Loan Documents and all other purposes stated therein, (iv) manage, supervise and otherwise deal with the Collateral as permitted pursuant to the Loan Agreement, (v) take such other action as is necessary or desirable to maintain the perfection and priority of the Liena Documents, applicable Requirements of Law or otherwise and (vii) execute any amendment, consent or waiver under the Loan Documents on behalf of any Lender that has consented in writing to such amendment, consent or waiver; <u>provided, however</u>, that Collateral Agent hereby appoints, authorizes and directs each Lender to act as collateral sub-agent for Collateral Agent and the Lenders for purposes of the perfections to the Collateral, mand may purposes of enforcing such Lender, and may further authorize and direct the Lenders to take further actions as collateral Agent and secture and agent for Collateral agent and the Lenders for purposes of the perfection of all Liens with respect to the Collateral, including any Deposit Account maintained by Borrower or any Guarantor with, and cash for purposes of enforci

(c) Under the Loan Documents, and except as expressly set forth in this Exhibit B, Collateral Agent (i) is acting solely on behalf of the Lenders, with duties that are entirely administrative in nature, notwithstanding the use of the defined term "Collateral Agent", the terms "agent", "Collateral Agent" and "collateral agent" and similar terms in any Loan Document to refer to Collateral Agent, which terms are used for title purposes only, (ii) is not assuming any obligation under any Loan Document other than as expressly set forth therein or any role as agent, fiduciary or trustee of or for any Lender or any other Person and (iii) shall have no implied functions, responsibilities, duties, obligations or other liabilities under any Loan Document, and each Lender, by accepting the benefits of the Loan Documents, hereby waives and agrees not to assert any claim against Collateral Agent based on the roles, duties and legal relationships expressly disclaimed in clauses (i) through (iii) above. Except as expressly set forth in the Loan Documents, Collateral Agent shall not have any duty to disclose, and shall not be liable for failure to disclose, any information relating to Borrower or any of its Subsidiaries that is communicated to or obtained by SLR or any of its Affiliates in any capacity.

#### 2. Binding Effect; Use of Discretion; E-Systems.

(a) Each Lender, by accepting the benefits of the Loan Documents, agrees that (i) any action taken by Collateral Agent or the Required Lenders (or, if expressly required in any Loan Document, a

greater proportion of the Lenders) in accordance with the provisions of the Loan Documents, (ii) any action taken by Collateral Agent in reliance upon the instructions of the Required Lenders (or, where so required, such greater proportion) and (iii) the exercise by Collateral Agent or the Required Lenders (or, where so required, such greater proportion) of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of Lenders.

(b) If Collateral Agent shall request instructions from the Required Lenders or all affected Lenders with respect to any act or action (including failure to act) in connection with any Loan Document, then Collateral Agent shall be entitled to refrain from such act or taking such action unless and until Collateral Agent shall have received instructions from the Required Lenders or all affected Lenders, as the case may be, and Collateral Agent shall not incur liability to any Person by reason of so refraining. Collateral Agent shall be fully justified in failing or refusing to take any action under any Loan Document (i) if such action would, in the opinion of Collateral Agent, be contrary to any Requirement of Law or any Loan Document, (ii) if Collateral Agent shall not first be indemnified to its satisfaction against any and all liability and expense which may be incurred by it by reason of taking or continuing to take any such action. Without limiting the foregoing, no Lender shall have any right of action whatsoever against Collateral Agent as a result of Collateral Agent acting or refraining from acting under any Loan Document in accordance with the instructions of the Required Lenders or all affected Lenders, as applicable.

(c) Collateral Agent is hereby authorized by Borrower and each Lender to establish procedures (and to amend such procedures from time to time) to facilitate administration and servicing of the Term Loans and other matters incidental thereto. Without limiting the generality of the foregoing, Collateral Agent is hereby authorized to establish procedures to make available or deliver, or to accept, notices, documents (including, without limitation, borrowing base certificates) and similar items on, by posting to or submitting and/or completion, on E-Systems. Borrower and each Lender acknowledges and agrees that the use of transmissions via an E-System or electronic mail is not necessarily secure and that there are risks associated with such use, including risks of interception, disclosure and abuse, and Borrower and each Lender assumes and accepts such risks by hereby authorizing the transmission via E-Systems or electronic mail. Each "e-signature" on any such posting shall be deemed sufficient to satisfy any requirement for a "signature", and each such posting shall be deemed sufficient to satisfy any requirement for a "writing", in each case including pursuant to any Loan Document, any applicable provision of any Code, the federal Uniform Electronic Transactions Act, the Electronic Signatures in Global and National Commerce Act and any substantive or procedural Requirement of Law governing such subject matter. All uses of an E-System shall be governed by and subject to, in addition to this Section, the separate terms, conditions and privacy policy posted or referenced in such E-System (or such terms, conditions and privacy policy as may be updated from time to time, including on such E-System. ALL E-SYSTEMS AND ELECTRONIC TRANSMISSIONS SHALL BE PROVIDED "AS IS" AND "AS AVAILABLE". NO REPRESENTATION OR WARRANTY OF ANY KIND IS MADE BY AGENT, ANY LENDER OR ANY OF THEIR RELATED PERSONS IN CONNECTION WITH ANY E-SYSTEMS.

#### 3. Collateral Agent's Reliance, Etc

. Collateral Agent may, without incurring any liability hereunder, (a) consult with any of its Related Persons and, whether or not selected by it, any other advisors, accountants and other experts (including advisors to, and accountants and experts engaged by, Borrower) and (b) rely and act upon any document and information (including those transmitted by electronic transmission) and any telephone message or conversation, in each case believed by it in good faith to be genuine and transmitted, signed or otherwise authenticated by the appropriate parties. None of Collateral Agent and its Related Persons shall be liable for any action taken or omitted to be taken by any of them under or in connection with any Loan Document, and each Lender and Borrower hereby waives and shall not assert (and Borrower shall cause its Subsidiaries to waive and agree not to assert) any right, claim or cause of action based thereon, except to the extent of liabilities resulting from the gross negligence or willful misconduct of Collateral Agent or, as the case may be, such Related Person (each as determined in a final, non-appealable judgment of a court of competent jurisdiction) in connection with the duties of Collateral Agent expressly set forth herein. Without limiting the foregoing, Collateral Agent: (i) shall not be responsible or otherwise incur liability for any action or omission taken in reliance upon the instructions of the Required Lenders or for the actions or omissions of

any of its Related Persons, except to the extent that a court of competent jurisdiction determines in a final non-appealable judgment that Collateral Agent acted with gross negligence or willful misconduct in the selection of such Related Person; (ii) shall not be responsible to any Lender or other Person for the due execution, legality, validity, enforceability, effectiveness, genuineness, sufficiency or value of, or the attachment, perfection or priority of any Lien created or purported to be created under or in connection with, any Loan Document; (iii) makes no warranty or representation, and shall not be responsible, to any Lender or other Person for any statement, document, information, representation or warranty made or furnished by or on behalf of Borrower or any Related Person of Borrower in connection with any Loan Document or any transaction contemplated therein or any other document or information with respect to Borrower, whether or not transmitted or (except for documents expressly required under any Loan Document to be transmitted to the Lenders) omitted to be transmitted by Collateral Agent, including as to completeness, accuracy, scope or adequacy thereof, or for the scope, nature or results of any due diligence performed by Collateral Agent in connection with the Loan Documents; and (iv) shall not have any duty to ascertain or to inquire as to the performance or observance of any provision of any Loan Document, whether any condition set forth in any Loan Document is satisfied or waived, as to the financial condition of Borrower or as to the existence or continuation or possible occurrence or continuation of any Event of Default, and shall not be deemed to have notice or knowledge of such occurrence or continuation unless it has received a notice from Borrower or any Lender describing such Event of Default that is clearly labelled "notice of default" (in which case Collateral Agent shall promptly give notice of such receipt to all Lenders, <u>provided</u> that Collateral Agent shall not be liable to

4. **Collateral Agent Individually.** Collateral Agent and its Affiliates may make loans and other extensions of credit to, acquire stock and stock equivalents of, engage in any kind of business with, Borrower or any Affiliate of Borrower as though it were not acting as Collateral Agent and may receive separate fees and other payments therefor. To the extent Collateral Agent or any of its Affiliates makes any Term Loans or otherwise becomes a Lender hereunder, it shall have and may exercise the same rights and powers hereunder and shall be subject to the same obligations and liabilities as any other Lender and the terms "Lender", "Required Lender" and any similar terms shall, except where otherwise expressly provided in any Loan Document, include, without limitation, Collateral Agent or such Affiliate, as the case may be, in its individual capacity as Lender, or as one of the Required Lenders.

5. Lender Credit Decision; Collateral Agent Report. Each Lender acknowledges that it shall, independently and without reliance upon Collateral Agent, any Lender or any of their Related Persons or upon any document solely or in part because such document was transmitted by Collateral Agent or any of its Related Persons, conduct its own independent investigation of the financial condition and affairs of Borrower and make and continue to make its own credit decisions in connection with entering into, and taking or not taking any action under, any Loan Document or with respect to any transaction contemplated in any Loan Document, in each case based on such documents and information as it shall deem appropriate. Except for documents expressly required by any Loan Document to be transmitted by Collateral Agent to the Lenders, Collateral Agent shall not have any duty or responsibility to provide any Lender with any credit or other information concerning the business, prospects, operations, Property, financial and other condition or creditworthiness of Borrower or any Affiliate of Borrower that may come in to the possession of Collateral Agent or any of its Related Persons. Each Lender agrees that is shall not rely on any field examination, audit or other report provided by Collateral Agent or its Related Persons (an "Collateral Agent Report"). Each Lender further acknowledges that any Collateral Agent Report (a) is provided to the Lenders solely as a courtesy, without consideration, and based upon the understanding that such Lender will not rely on such Collateral Agent or its Related Persons end (c) may not be complete and may not reflect all information provided by Borrower solely for Collateral Agent's own internal use, and (c) may not be complete and may not reflect all information and findings obtained by Collateral Agent or its Related Persons or warranties of any kind with respect to (i) any existing or proposed financing, (ii) the accuracy or completeness of the information contained in any Collateral Agent Re

connection with or using any Collateral Agent Report or any related documentation. Neither Collateral Agent nor any of its Related Persons shall have any duties or obligations in connection with or as a result of any Lender receiving a copy of any Collateral Agent Report. Without limiting the generality of the forgoing, neither Collateral Agent nor any of its Related Persons shall have any responsibility for the accuracy or completeness of any Collateral Agent Report, or the appropriateness of any Collateral Agent Report for any Lender's purposes, and shall have no duty or responsibility to correct or update any Collateral Agent Report or disclose to any Lender any other information not embodied in any Collateral Agent Report, including any supplemental information obtained after the date of any Collateral Agent Report. Each Lender releases, and agrees that it will not assert, any claim against Collateral Agent or its Related Persons that in any way relates to any Collateral Agent Report or arises out of any Lender having access to any Collateral Agent Report or any discussion of its contents, and agrees to indemnify and hold harmless Collateral Agent and its Related Persons from all claims, liabilities and expenses relating to a breach by any Lender arising out of such Lender's access to any Collateral Agent Report or any discussion of its contents.

6. Indemnification. Each Lender agrees to reimburse Collateral Agent and each of its Related Persons (to the extent not reimbursed by Borrower as required under the Loan Documents (including pursuant to Section 12.2 of the Agreement)) promptly upon demand for its Pro Rata Share of any out-of-pocket costs and expenses (including, without limitation, fees, charges and disbursements of financial, legal and other advisors and any Taxes or insurance paid in the name of, or on behalf of, Borrower) incurred by Collateral Agent or any of its Related Persons in connection with the preparation, syndication, execution, delivery, administration, modification, amendment, consent, waiver or enforcement of, or the taking of any other action (whether through negotiations, through any work-out, bankruptcy, restructuring or other legal or other proceeding (including, without limitation, preparation for and/or response to any subpoena or request for document production relating thereto) or otherwise) in respect of, or legal advice with respect to, its rights or responsibilities under, any Loan Document. Each Lender further agrees to indemnify Collateral Agent and each of its Related Persons (to the extent not reimbursed by Borrower as required under the Loan Documents (including pursuant to Section 12.2 of the Agreement)), ratably according to its Pro Rata Share, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind or nature whatsoever (including, to the extent not indemnified by the applicable Lender, Taxes, interests and penalties imposed for not properly withholding or backup withholding on payments made to or for the account of any Lender) that may be imposed on, incurred by, or asserted against Collateral Agent or any of its Related Persons in any matter relating to or arising out of, in connection with or as a result of any Loan Document or any other act, event or transaction related, contemplated in or attendant to any such document, or, in each case, any action taken or omitted to be taken by Collateral Agent or any of its Related Persons under or with respect to the foregoing; provided that no Lender shall be liable to Collateral Agent or any of its Related Persons under this Section 6 of this Exhibit B to the extent such liability has resulted from the gross negligence or willful misconduct of Collateral Agent or, as the case may be, such Related Person, as determined by a final non-appealable judgment of a court of competent jurisdiction. To the extent required by any applicable Requirement of Law, Collateral Agent may withhold from any payment to any Lender under a Loan Document an amount equal to any applicable withholding Tax. If the IRS or any other Governmental Authority asserts a claim that Collateral Agent did not properly withhold Tax from amounts paid to or for the account of any Lender for any reason, or if Collateral Agent reasonably determines that it was required to withhold Taxes from a prior payment to or for the account of any Lender but failed to do so, such Lender shall promptly indemnify Collateral Agent fully for all amounts paid, directly or indirectly, by Collateral Agent as Tax or otherwise, including penalties and interest, and together with all expenses incurred by Collateral Agent. Collateral Agent may offset against any payment to any Lender under a Loan Document, any applicable withholding Tax that was required to be withheld from any prior payment to such Lender but which was not so withheld, as well as any other amounts for which Collateral Agent is entitled to indemnification from such Lender under the immediately preceding sentence of this Section 6 of this Exhibit B.

7. **Successor Collateral Agent.** Collateral Agent may resign at any time by delivering notice of such resignation to the Lenders and Borrower, effective on the date set forth in such notice or, if no such date is set forth therein, upon the date such notice shall be effective, in accordance with the terms of this Section 7 of this Exhibit B. If Collateral Agent delivers any such notice, the Required Lenders shall have the right to appoint a successor Collateral Agent. If, after thirty (30) days after the date of the retiring Collateral Agent's notice of resignation, no successor Collateral Agent has been appointed by the Required Lenders and has accepted such appointment, then the retiring Collateral Agent may, on behalf of the Lenders, appoint a successor Collateral Agent from among the Lenders. Effective immediately upon its resignation, (a) the

retiring Collateral Agent shall be discharged from its duties and obligations under the Loan Documents, (b) the Lenders shall assume and perform all of the duties of Collateral Agent until a successor Collateral Agent shall have accepted a valid appointment hereunder, (c) the retiring Collateral Agent and its Related Persons shall no longer have the benefit of any provision of any Loan Document other than with respect to any actions taken or omitted to be taken while such retiring Collateral Agent was, or because such Collateral Agent had been, validly acting as Collateral Agent under the Loan Documents, and (iv) subject to its rights under Section 2(b) of this Exhibit B, the retiring Collateral Agent shall take such action as may be reasonably necessary to assign to the successor Collateral Agent its rights as Collateral Agent under the Loan Documents. Effective immediately upon its acceptance of a valid appointment as Collateral Agent, a successor Collateral Agent shall succeed to, and become vested with, all the rights, powers, privileges and duties of the retiring Collateral Agent under the Loan Documents.

8. **Release of Collateral.** Each Lender hereby consents to the release and hereby directs Collateral Agent to release (or in the case of clause (b)(ii) below, release or subordinate) the following:

(a) any Guarantor if all of the stock of such Subsidiary owned by Borrower is sold or transferred in a transaction permitted under the Loan Documents (including pursuant to a valid waiver or consent), to the extent that, after giving effect to such transaction, such Subsidiary would not be required to guaranty any Obligations pursuant to any Loan Document; and

(b) any Lien held by Collateral Agent for the benefit of the Secured Parties against (i) any Collateral that is sold or otherwise disposed of by Borrower in a transaction permitted by the Loan Documents (including pursuant to a valid waiver or consent), (ii) any Collateral subject to a Lien that is expressly permitted under clause (c) of the definition of the term "Permitted Lien" and (iii) all of the Collateral and Borrower, upon (A) termination of all of the Commitments, (B) the payment in full in cash of all of the Obligations (other than (a) inchoate indemnity obligations, and (ii) other obligations that, by their terms, survive termination of this Agreement, in each case for which no claim has been made), and (C) to the extent requested by Collateral Agent, receipt by Collateral Agent and Lenders of liability releases from Borrower in form and substance acceptable to Collateral Agent (the satisfaction of the conditions in this clause (iii), the "**Termination Date**").

Setoff and Sharing of Payments. In addition to any rights now or hereafter granted under any applicable Requirement of 9 Law and not by way of limitation of any such rights, upon the occurrence and during the continuance of any Event of Default and subject to Section 10(d) of this Exhibit B, each Lender is hereby authorized at any time or from time to time upon the direction of Collateral Agent, without notice to Borrower or any other Person, any such notice being hereby expressly waived, to setoff and to appropriate and to apply any and all balances held by it at any of its offices for the account of Borrower (regardless of whether such balances are then due to Borrower) and any other properties or assets at any time held or owing by that Lender or that holder to or for the credit or for the account of Borrower against and on account of any of the Obligations that are not paid when due. Any Lender exercising a right of setoff or otherwise receiving any payment on account of the Obligations in excess of its Pro Rata Share thereof shall purchase for cash (and the other Lenders or holders shall sell) such participations in each such other Lender's or holder's Pro Rata Share of the Obligations as would be necessary to cause such Lender to share the amount so offset or otherwise received with each other Lender or holder in accordance with their respective Pro Rata Shares of the Obligations. Borrower agrees, to the fullest extent permitted by law, that (a) any Lender may exercise its right to offset with respect to amounts in excess of its Pro Rata Share of the Obligations and may purchase participations in accordance with the preceding sentence and (b) any Lender so purchasing a participation in the Term Loans made or other Obligations held by other Lenders or holders may exercise all rights of offset, bankers' liens, counterclaims or similar rights with respect to such participation as fully as if such Lender or holder were a direct holder of the Term Loans and the other Obligations in the amount of such participation. Notwithstanding the foregoing, if all or any portion of the offset amount or payment otherwise received is thereafter recovered from the Lender that has exercised the right of offset, the purchase of participations by that Lender shall be rescinded and the purchase price restored without interest.

#### 10. Advances; Payments; Non-Funding Lenders; Actions in Concert.

(a) <u>Advances; Payments</u>. If Collateral Agent receives any payment with respect to a Term Loan for the account of the Lenders on or prior to 2:00 p.m. (New York time) on any Business Day, Collateral Agent shall pay to each applicable Lender such Lender's Pro Rata Share of such payment on such

Business Day. If Collateral Agent receives any payment with respect to a Term Loan for the account of Lenders after 2:00 p.m. (New York time) on any Business Day, Collateral Agent shall pay to each applicable Lender such Lender's Pro Rata Share of such payment on the next Business Day.

### (b) <u>Return of Payments</u>.

(i) If Collateral Agent pays an amount to a Lender under this Agreement in the belief or expectation that a related payment has been or will be received by Collateral Agent or on behalf of from Borrower and such related payment is not received by Collateral Agent, then Collateral Agent will be entitled to recover such amount (including interest accruing on such amount at the rate otherwise applicable to such Obligation) from such Lender on demand without setoff, counterclaim or deduction of any kind.

(ii) If Collateral Agent determines at any time that any amount received by Collateral Agent under any Loan Document must be returned to Borrower or paid to any other Person pursuant to any insolvency law or otherwise, then, notwithstanding any other term or condition of any Loan Document, Collateral Agent will not be required to distribute any portion thereof to any Lender. In addition, each Lender will repay to Collateral Agent on demand any portion of such amount that Collateral Agent has distributed to such Lender, together with interest at such rate, if any, as Collateral Agent is required to pay to Borrower or such other Person, without setoff, counterclaim or deduction of any kind and Collateral Agent will be entitled to set off against future distributions to such Lender any such amounts (with interest) that are not repaid on demand.

#### (c) Non-Funding Lenders.

(i) Unless Collateral Agent shall have received notice from a Lender prior to the date of any Term Loan that such Lender will not make available to Collateral Agent such Lender's Pro Rata Share of such Term Loan, Collateral Agent may assume that such Lender will make such amount available to it on the date of such Term Loan in accordance with Section 2(b) of this Exhibit B, and Collateral Agent may (but shall not be obligated to), in reliance upon such assumption, make available a corresponding amount for the account of Borrower on such date. If and to the extent that such Lender shall not have made such amount available to Collateral Agent, such Lender and Borrower severally agree to repay to Collateral Agent forthwith on demand such corresponding amount together with interest thereon, for each day from the day such amount is made available to Borrower until the day such amount is repaid to Collateral Agent, at a rate per annum equal to the interest rate applicable to the Obligation that would have been created when Collateral Agent made available such amount to Borrower had such Lender made a corresponding payment available. If such Lender shall repay such corresponding amount to Collateral Agent, the amount so repaid shall constitute such Lender's portion of such Term Loan for purposes of this Agreement.

(ii) To the extent that any Lender has failed to fund any Term Loan or any other payments required to be made by it under the Loan Documents after any such Term Loan is required to be made or such payment is due (a "**Non-Funding Lender**"), Collateral Agent shall be entitled to set off the funding short-fall against that Non-Funding Lender's Pro Rata Share of all payments received from or on behalf of Borrower thereunder. The failure of any Non-Funding Lender to make any Term Loan or any payment required by it hereunder shall not relieve any other Lender (each such other Lender, an "**Other Lender**") of its obligations to make such Term Loan or make any other payment required hereunder. Notwithstanding anything set forth herein to the contrary, a Non-Funding Lender shall not have any voting or consent rights under or with respect to any Loan Document or constitute a "Lender" (or be included in the calculation of "Required Lenders" hereunder) for any voting or consent rights under or with respect to any Loan Document or bulgation) to purchase from any Non-Funding Lender, and each Lender agrees that if it becomes a Non-Funding Lender it shall, at Collateral Agent's request, sell and assign to Collateral Agent or such Person, all of the outstanding Term Loan of that Non-Funding Lender for an amount equal to the aggregate outstanding principal balance of the Term Loan held by such Non-Funding Lender and all accrued interest with respect thereto through the date of sale, such purchase and sale to be consummated pursuant to an executed assignment agreement in form and substance reasonably satisfactory to, and acknowledged by, Collateral Agent.

(d) <u>Actions in Concert</u>. Anything in this Agreement to the contrary notwithstanding, each Lender hereby agrees with each other Lender that no Lender shall take any action to protect or enforce its rights arising out of any Loan Document (including exercising any rights of setoff) without first obtaining the prior written consent of Collateral Agent or Required Lenders, it being the intent of Lenders that any such action to protect or enforce rights under any Loan Document shall be taken in concert and at the direction or with the consent of Collateral Agent or Required Lenders.

# EXHIBIT C

#### Taxes; Increased Costs.

#### 1. Defined Terms

. For purposes of this Exhibit C:

(a) **"Connection Income Taxes**" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

(b) "Excluded Taxes" means any of the following Taxes imposed on or with respect to a Recipient or required to be withheld or deducted from a payment to a Recipient, (i) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (Å) imposed as a result of such Recipient being organized under the laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (B) that are Other Connection Taxes, (ii) in the case of a Lender, U.S. federal withholding Taxes imposed on amounts payable to or for the account of such Lender with respect to an applicable interest in a Term Loan or Term Loan Commitment pursuant to a law in effect on the date on which (A) such Lender acquires such interest in the Term Loan or Term Commitment or (B) such Lender changes its lending office, except in each case to the extent that, pursuant to Section 2 or Section 4 of this Exhibit C, amounts with respect to such Taxes were payable either to such Lender's assignor immediately before such Lender became a party hereto or to such Lender immediately before it changed its lending office, (iii) Taxes attributable to such Recipient's failure to comply with Section 7 of this Exhibit C and (iv) any withholding Taxes imposed under FATCA.

(c) **"FATCA**" means Sections 1471 through 1474 of the Internal Revenue Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Internal Revenue Code, and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Internal Revenue Code.

(d) **"Foreign Lender**" means a Lender that is not a U.S. Person.

(e) **"Indemnified Taxes**" means (i) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of Borrower under any Loan Document and (ii) to the extent not otherwise described in clause (i), Other Taxes.

(f) "**Other Connection Taxes**" means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Term Loan or Loan Document).

(g) "**Other Taxes**" means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

- (h) "**Recipient**" means Collateral Agent or any Lender, as applicable.
- (i) "U.S. Person" means any Person that is a "United States person" as defined in Section 7701(a)(30) of the Internal Revenue

Code.

- (j) "Withholding Agent" means Borrower and Collateral Agent.
- 2. **Payments Free of Taxes**

. Any and all payments by or on account of any obligation of Borrower under any Loan Document shall be made without deduction or withholding for any Taxes, except as required by applicable law. If any applicable law (as determined in the good faith discretion of an applicable Withholding Agent) requires the deduction or withholding of any Tax from any such payment by a Withholding Agent, then the applicable Withholding Agent shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with applicable law and, if such Tax is an Indemnified Tax, then the sum payable by Borrower shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 2 or Section 4 of this Exhibit C) the applicable Recipient receives an amount equal to the sum it would have received had no such deduction or withholding been made.

3. **Payment of Other Taxes by Borrower.** Borrower shall timely pay to the relevant Governmental Authority in accordance with applicable law, or at the option of Collateral Agent timely reimburse it for the payment of, any Other Taxes.

4. **Indemnification by Borrower.** Borrower shall indemnify each Recipient, within 10 days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under Section 2 of this Exhibit C or this Section 4) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to Borrower by a Lender (with a copy to Collateral Agent), or by Collateral Agent on its own behalf or on behalf of a Lender, shall be conclusive absent manifest error.

5. **Indemnification by the Lenders.** Each Lender shall severally indemnify Collateral Agent, within 10 days after demand therefor, for (a) any Indemnified Taxes attributable to such Lender (but only to the extent that Borrower has not already indemnified Collateral Agent for such Indemnified Taxes and without limiting the obligation of Borrower to do so), (b) any Taxes attributable to such Lender's failure to comply with the provisions of Section 12.1 of the Agreement relating to the maintenance of a Participant Register and (c) any Excluded Taxes attributable to such Lender, in each case, that are payable or paid by Collateral Agent in connection with any Loan Document, and any reasonable expenses arising therefrom or with respect thereto, whether or not such Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to any Lender by Collateral Agent shall be conclusive absent manifest error. Each Lender hereby authorizes Collateral Agent to set off and apply any and all amounts at any time owing to such Lender under any Loan Document or otherwise payable by Collateral Agent to the Lender from any other source against any amount due to Collateral Agent under this Section 5.

6. **Evidence of Payments.** As soon as practicable after any payment of Taxes by Borrower to a Governmental Authority pursuant to the provisions of this Exhibit C, Borrower shall deliver to Collateral Agent the original or a certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to Collateral Agent.

#### 7. Status of Lenders.

(a) Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to Borrower and Collateral Agent, at the time or times reasonably requested by Borrower or Collateral Agent, such properly completed and executed documentation reasonably requested by Borrower or Collateral Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender, if reasonably requested by Borrower or Collateral Agent, shall deliver such other documentation prescribed by applicable law or reasonably requested by Borrower or Collateral Agent as will enable Borrower or Collateral Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Sections 7(b)(i), 7(b)(ii) and 7(b)(iv) of this Exhibit C) shall not be required if in the Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender. (b) Without limiting the generality of the foregoing, in the event that Borrower is a U.S. Person,

(i) any Lender that is a U.S. Person shall deliver to Borrower and Collateral Agent on or prior to the date on which such Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Collateral Agent), executed copies of IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax;

(ii) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower and Collateral Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Collateral Agent), whichever of the following is applicable:

- (A) in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document, executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;
- (B) executed copies of IRS Form W-8ECI;
- (C) in the case of a Foreign Lender claiming the benefits of the exemption for portfolio interest under Section 881(c) of the Internal Revenue Code, (x) a certificate, in form and substance reasonably acceptable to Borrower and Collateral Agent, to the effect that such Foreign Lender (or other applicable Person) is not a "bank" within the meaning of Section 881(c)(3)(A) of the Internal Revenue Code, a "10 percent shareholder" of Borrower within the meaning of Section 871(h)(3)(B) of the Internal Revenue Code, or a "controlled foreign corporation" related to Borrower as described in Section 881(c)(3)(C) of the Internal Revenue Code (a "U.S. Tax Compliance Certificate") and (y) executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E; or
- (D) to the extent a Foreign Lender is not the beneficial owner, executed copies of IRS Form W-8IMY, accompanied by IRS Form W-8ECI, IRS Form W-8BEN, IRS Form W-8BEN-E, a U.S. Tax Compliance Certificate, IRS Form W-9, and/or other certification documents from each beneficial owner, as applicable; provided that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a U.S. Tax Compliance Certificate on behalf of each such direct and indirect partner;

(iii) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower and Collateral Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower or Collateral Agent), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit Borrower or Collateral Agent to determine the withholding or deduction required to be made; and

(iv) if a payment made to a Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Internal

Revenue Code, as applicable), such Lender shall deliver to Borrower and Collateral Agent at the time or times prescribed by law and at such time or times reasonably requested by Borrower or Collateral Agent such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the Internal Revenue Code) and such additional documentation reasonably requested by Borrower or Collateral Agent as may be necessary for Borrower and Collateral Agent to comply with their obligations under FATCA and to determine that such Lender has complied with such Lender's obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this clause (iv), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

(v) Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify Borrower and Collateral Agent in writing of its legal inability to do so.

#### 8. Treatment of Certain Refunds

. If any party determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to the provisions of this Exhibit C (including by the payment of additional amounts pursuant to the provisions of this Exhibit C), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under the provisions of this Exhibit C with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this Section 8 (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this Section 8, in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this Section 8 the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This Section 8 shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

#### 9. Increased Costs

. If any change in applicable law shall subject any Recipient to any Taxes (other than (A) Indemnified Taxes, (B) Taxes described in clauses (ii) through (iv) of the definition of Excluded Taxes and (C) Connection Income Taxes) on its loans, loan principal, commitments, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto, and the result shall be to increase the cost to such Recipient of making, converting to, continuing or maintaining any Term Loan or of maintaining its obligation to make any such Term Loan, or to reduce the amount of any sum received or receivable by such Recipient (whether of principal, interest or any other amount), then, upon the request of such Recipient, Borrower will pay to such Recipient such additional amount or amounts as will compensate such Recipient for such additional costs incurred or reduction suffered.

#### 10. Survival

. Each party's obligations under the provisions of this Exhibit C shall survive the resignation or replacement of Collateral Agent or any assignment of rights by, or the replacement of, a Lender, the termination of the Term Loan Commitments and the repayment, satisfaction or discharge of all obligations under any Loan Document.

# EXHIBIT D Loan Payment Request Form

Fax To: (212) 993-1698 Date:			
Loan Payment:	Ardelyx, Inc	C.	
From Account #(Deposit Account #)	To Account #		
Principal \$	To Account # (Loan Account #) and/or Interest \$		-
Authorized Signature: Phone Number: Print Name/Title:			
Loan Advance:			
Complete Outgoing Wire Request section bel	ow if all or a portion of the funds from this loan ad	dvance are for an outgoing wire.	
From Account #	To Account #		
(Loan Account #)	(Deposit Account #)		
Amount of Advance \$			
the text thereof; and provided, further that the respects as of such date: Authorized Signature: Phone Number: Print Name/Title:	se representations and warranties expressly refe	rring to a specific date shall be true, accu	irate and complete in all material
Outgoing Wire Request: Complete only if all or a portion of funds f	om the loan advance above is to be wired.		
Beneficiary Name:	Amount of Wire: \$		
Beneficiary Name: Beneficiary Bank: City and State:	Account Number:		
Beneficiary Bank Transit (ABA) #: Benef <b>(For International Wire Only)</b> Intermediary Bank: Transit (ABA) #: For Further Credit to:	ciary Bank Code (Swift, Sort, Chip, etc.):		
	ee that my (our) funds transfer request shall be p vice(s), which agreements(s) were previously rec		t to the terms and conditions set forth ir
Authorized Signature:	2 <sup>nd</sup> Signature (if required):		
Print Name/Title: Telephone #: Telephone #:	Print Name/Title:		
	-		

#### EXHIBIT E

#### **Compliance Certificate**

#### TO: SLR INVESTMENT CORP., as Collateral Agent and Lender

FROM: ARDELYX, INC.

The undersigned authorized officer ("**Officer**") of Ardelyx, Inc. ("**Borrower**"), hereby certifies solely in his/her capacity as an officer of Borrower and not in his/her individual capacity, that in accordance with the terms and conditions of the Loan and Security Agreement dated as of February 23, 2022, by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the "**Loan Agreement**;" capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

(a) Borrower is in complete compliance for the period ending \_\_with all required covenants except as noted below;

(b) There are no Defaults or Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

(d) Borrower, and each of Borrower's Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower's Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

	<b>Reporting Covenant</b>	Requirement	Actual		Complies	
1)	Monthly financial statements	Monthly within 30 days (for each month that is not a quarter end)		Yes	No	N/A
2)	Quarterly financial statements	Quarterly within 45 days		Yes	No	N/A
3)	Annual (CPA Audited) statements	Within 90 days after FYE or 5 days after filing with SEC		Yes	No	N/A
4)	Annual Financial Projections/Budget	Annually (within 60 days after FYE) or 10 days of approval and when received (7 days of approval)		Yes	No	N/A
5)	Account statements for each Collateral Account	Monthly within 30 days		Yes	No	N/A
6)	Compliance Certificate	Monthly within 30 days		Yes	No	N/A
7)	IP notice (events reasonably expected to materially and adversely affect value of IP or result in MAC)	When required		Yes	No	N/A

# **Deposit and Securities Accounts**

(Please list all accounts; attach se	parate sheet if additional space needed)	
Lasting Name	A annual Number	NT

Institution Name	Account Number	New Accou	int?	Account Contro Plac	
1)		Yes	No	Yes	No
2)		Yes	No	Yes	No
3)		Yes	No	Yes	No
4)		Yes	No	Yes	No

# **Financial Covenant**

7.13 – Minimum Liquidity (please attach a schedule with the appropriate calculations) Complies? Yes No

# **Other Matters**

1)	Have there been any changes in Key Persons since the last Compliance Certificate?	Yes	No
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3)Have there been any new or pending claims or causes of action against Borrower that involve more than Two Hundred Fifty Thousand Dollars (\$250,000)?Yes4)Has Borrower provided the Collateral Agent with all notices required to be delivered under Sections 6.2(a) and 6.2(b) of the Loan Agreement?Yes5)With respect to each Foreign Subsidiary, do any hold assets worth One Hundred Thousand (\$100,000) or more in book value?Yes6)If the answer to question 5 is Yes, has the Company provided certificates representing a pledge of 65% of the stock, units or other evidence of ownership held by Borrower or Guarantor of such Foreign Subsidiary?Yes7)Have you entered into a Material Agreement since the last Compliance Certificate? If yes, please provide a copy.Yes	2)	Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement?	Yes	No
<ul> <li>4) 6.2(a) and 6.2(b) of the Loan Agreement?</li> <li>5) With respect to each Foreign Subsidiary, do any hold assets worth One Hundred Thousand (\$100,000) or more in book value?</li> <li>6) If the answer to question 5 is Yes, has the Company provided certificates representing a pledge of 65% of the stock, units or other evidence of ownership held by Borrower or Guarantor of such Yes Foreign Subsidiary?</li> <li>7) Have you entered into a Material Agreement since the last Compliance Certificate? If yes, please Yes</li> </ul>	3)	Have there been any new or pending claims or causes of action against Borrower that involve more than Two Hundred Fifty Thousand Dollars (\$250,000)?	Yes	No
<ul> <li>(\$100,000) or more in book value?</li> <li>If the answer to question 5 is Yes, has the Company provided certificates representing a pledge of</li> <li>65% of the stock, units or other evidence of ownership held by Borrower or Guarantor of such Yes Foreign Subsidiary?</li> <li>Have you entered into a Material Agreement since the last Compliance Certificate? If yes, please Yes</li> </ul>	4)		Yes	No
<ul> <li>6) 65% of the stock, units or other evidence of ownership held by Borrower or Guarantor of such Yes Foreign Subsidiary?</li> <li>Have you entered into a Material Agreement since the last Compliance Certificate? If yes, please Yes</li> </ul>	5)		Yes	No
	6)	65% of the stock, units or other evidence of ownership held by Borrower or Guarantor of such	Yes	No
	7)		Yes	No

# **Exceptions**

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

ARDELYX, INC.

By: Name: Title:

Date:

## COLLATERAL AGENT USE ONLY

Received by: Date:

Verified by: Date:

Compliance Status: Yes No

#### EXHIBIT F

# CORPORATE BORROWING CERTIFICATE

**BORROWER:** ARDELYX, INC. **DATE**: February 23, 2022 **LENDER:** SLR INVESTMENT CORP., as Collateral Agent and Lender

I hereby certify, solely in my capacity as an officer of Borrower and not in my individual capacity, as follows, as of the date set forth above:

1. I am the Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.

3. Attached hereto as <u>Exhibit A</u> and <u>Exhibit B</u>, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's board of directors (or a duly authorized committee thereof) at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

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**RESOLVED**, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	<u>Signature</u>	Authorized to Add or Remove <u>Signatories</u>

**RESOLVED FURTHER,** that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

**RESOLVED FURTHER,** that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.

**Execute Loan Documents**. Execute any loan documents any Lender requires.

Grant Security. Grant Collateral Agent a security interest in any of Borrower's assets (excluding intellectual property).

**Negotiate Items**. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

Pay Fees. Pay fees under the Loan Agreement or any other Loan Document.

**Further Acts**. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

**RESOLVED FURTHER,** that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[Balance of Page Intentionally Left Blank]

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

### By: Name: Title:

\*\*\* If the Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.

I, the [\_\_] of Borrower, hereby certify as to paragraphs 1 through 5 above, as [\_\_] on the date set

forth above.

By:

Name: Title:

EXHIBIT A

# Certificate of Incorporation (including amendments)

[see attached]

# EXHIBIT B

# <u>Bylaws</u>

[see attached]

#### EXHIBIT G

#### **ACH LETTER**

SLR INVESTMENT CORP. 500 Park Avenue, 3rd Floor New York, NY 10022 Attention: Anthony Storino Fax: (212) 993-1698 Email:

Re: Loan and Security Agreement dated as of February 23, 2022 (the "Agreement") by and among Ardelyx, Inc. ("Borrower"), SLR Investment Corp. ("<u>SLR</u>"), as collateral agent (in such capacity, "Collateral Agent") and the Lenders listed on <u>Schedule 1.1</u> thereof or otherwise a party thereto from time to time, including SLR in its capacity as a Lender (each a "Lender" and collectively, the "Lenders"). Capitalized terms used but not otherwise defined herein shall have the meanings given them under the Agreement.

In connection with the above referenced Agreement, the Borrower hereby authorizes the Collateral Agent to, at its discretion and with prior notice of at least one (1) Business Day, initiate debit entries to the Borrower's account indicated below (i) on each payment date of all Obligations then due and owing, (ii) at any time any payment due and owing with respect to Lender Expenses, and (iii) upon an Event of Default, any other Obligations outstanding, in each case pursuant to Section 2.3(e) of the Agreement. The Borrower authorizes the depository institution named below to debit to such account.

DEPOSITORY NAME	BRANCH
CITY	STATE AND ZIP CODE
TRANSIT/ABA NUMBER	ACCOUNT NUMBER

This authority will remain in full force and effect so long as any amounts are due under the Agreement.

## ARDELYX, INC.

By: \_\_\_\_

Title:

Date: \_\_\_\_

#### **Exit Fee Agreement**

Reference is made to the Loan and Security Agreement, dated as of February 23, 2022 (as may be amended, amended and restated, supplemented or otherwise modified from time to time, the "Loan Agreement") by and among SLR Investment Corp., a Maryland corporation ("SLR"), as collateral agent (in such capacity, "Agent"), the lenders 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 ("Borrower"). As a condition precedent to the Lenders' entry into the Loan Agreement, the Lenders require that Borrower agree to pay to the Lenders a fee upon the occurrence of certain events as described in this Exit Fee Agreement (as amended, amended and restated, supplemented or otherwise modified from time to time, this "Exit Fee Agreement"), dated as of the date hereof (the "Effective Date"), by and among SLR, as Agent, the Lenders and Borrower. Capitalized terms used herein and not otherwise defined herein have the meanings assigned to them in the Loan Agreement and, in the event that the Loan Agreement terminates prior to the termination of this Exit Fee Agreement, capitalized terms used herein and not otherwise defined herein as in effect immediately prior to the termination of the Loan Agreement.

Therefore, in consideration of the Lenders entering into the Loan Agreement, Borrower hereby agrees as follows:

1. <u>**Trigger Event.**</u> For purposes hereof, "**Trigger Event**" shall mean the first to occur of an Exit Event or a Revenue Milestone Event, as such terms are defined below.

- a. For purposes hereof, "Exit Event" shall mean the first to occur of: (a) any liquidation, dissolution or winding up of Borrower, whether voluntary or involuntary, which results in cash or other non-cash consideration to the stockholders of Borrower; (b) a consolidation, merger or reverse merger of Borrower with or into another corporation or entity or other reorganization or similar transaction or series of related transactions involving Borrower which result in stockholders of Borrower immediately prior to such transaction or series of related transactions owning less than fifty percent (50%) of the outstanding capital stock of the surviving entity (treating all securities convertible or exchangeable into or exercisable for shares of common stock as having been fully converted, exchanged and exercised, and deemed to be outstanding for purposes of this clause, without regard to any exercise, conversion or exchange limitations stock ("Common Stock") (or securities convertible or exchangeable into or exercisable for shares of Common Stock ("Common Stock") (or securities convertible or exchangeable into or exercisable for shares of Common Stock constituting more than fifty percent (50%) of the shares of Common Stock outstanding immediately following such issuance (treating all securities convertible or exchangeable into or exercisable for shares of Common Stock) constituting more than fifty percent (50%) of the shares of Common Stock outstanding immediately following such issuance (treating all securities convertible or exchangeable into or exercisable for shares of Common Stock as having been fully converted, exchanged and exercise, enversion or exchange and exercise, enversion or exchange and exercise, and deemed to be outstanding for purposes of this clause without regard to any exercise, conversion or exchange and exercised, and deemed to be outstanding investors; and (e) any other shares of common stock and fifty percent (50%) of the shares of Common Stock as having been fully converted, exchanged and exerc
- b. For purposes hereof, the "**Revenue Milestone Event**" shall mean the achievement by Borrower of Net Product Revenue equal to or greater than One Hundred Million Dollars (\$100,000,000.00), measured on a trailing six (6) month basis, tested monthly at the end of each month.

2. <u>Reporting</u>. Borrower agrees to provide the Lenders, to the extent reasonably practicable with respect to clause (a) of Section 1 and otherwise with (a) five (5) days' prior written notice of the occurrence of any Exit Event; and (b) written notice of the Trigger Event as soon as practicable following the occurrence of such Trigger Event, but in any event not more than (i) five (5) Business Days after any Exit Event and (ii) thirty (30) days after any Revenue Milestone Event.

3. <u>Exit Fee</u>. Upon the occurrence of the Trigger Event and in accordance with Section 4 below, Borrower agrees to pay to each Lender in accordance with its Pro Rata Share (provided that if such payment is made after the termination of the Loan Agreement, such payment shall be made in accordance with each such Lender's Pro Rata Share as was in effect immediately before the termination of the Loan Agreement), in immediately available funds, a fee (the "**Exit Fee**") in the amount equal to two percent (2.00%) of each Term Loan funded. For the avoidance of doubt, the Exit Fee set forth herein shall be in addition to any fee or amount due and payable pursuant to the Fee Letter or the other Loan Documents. Borrower expressly agrees (to the fullest extent that it may lawfully do so) that: (i) the Exit Fee is reasonable and is the product of an arm's length transaction between sophisticated business people, ably represented by counsel; (ii) the Exit Fee shall be payable notwithstanding the then prevailing market rates at the time payment is made; (iii) there has been a course of conduct between Agent, Lenders and Borrower giving specific consideration in this transaction for such agreement to pay the Exit Fee and (iv) Borrower shall be estopped hereafter from claiming differently than as agreed to in this paragraph. Borrower expressly acknowledges that its agreement to pay the Exit Fee to Lenders as herein described is a material inducement to Lenders to provide the Term Loan Commitments and make the Term Loans.

4. <u>**Payment.**</u> The Exit Fee shall be paid to the Lenders not later than five (5) Business Days after the applicable reporting deadline of the Trigger Event as set forth in Section 2(b) hereof. Failure to so timely pay the full amount of the Exit Fee to the Lenders shall be an Event of Default under the Loan Agreement, so long as the Loan Agreement is then in effect.

5. <u>Termination; Assignment</u>. This Exit Fee Agreement shall be binding on Borrower and its respective successors and assigns and shall terminate upon the earlier to occur of (a) payment in full of the Exit Fee pursuant to the terms herein, or (b) February 23, 2032 (the "**Termination Date**"). For the avoidance of doubt, this Exit Fee Agreement shall survive the termination of the Loan Agreement or any other Loan Document. If the Trigger Event has not occurred on or before the Termination Date, this Exit Fee Agreement shall automatically terminate and be of no further force and effect and neither Borrower nor any successor of Borrower shall have any obligation to pay the Exit Fee. Borrower may not assign this Exit Fee Agreement. Each Lender may assign this Exit Fee Agreement solely in connection with, and subject to the terms of, an assignment or transfer made pursuant to the terms of Section 12.1 of the Loan Agreement, which shall govern such an assignment or transfer even if the Loan Agreement has previously been terminated.

6. <u>GOVERNING LAW</u>. THIS EXIT FEE AGREEMENT SHALL BE CONSTRUED IN ACCORDANCE WITH AND GOVERNED BY THE LAW OF THE STATE OF NEW YORK, WITHOUT REGARD TO CONFLICTS OF LAW PRINCIPLES THAT WOULD REQUIRE THE APPLICATION OF THE LAWS OF ANOTHER JURISDICTION.

7. Indemnification. Borrower agrees to indemnify, defend and hold Agent and the Lenders and their respective directors, officers, employees, consultants, agents, attorneys, or any other Person affiliated with or representing Agent or the Lenders (each, an "Indemnified Person") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "Claims") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by this Exit Fee Agreement; and (b) all losses or Lenders' Expenses incurred, or paid by an Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by this Exit Fee Agreement; and (b) all losses or Lenders' Expenses incurred, or paid by an Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by this Exit Fee Agreement; and (b) all losses or Lenders' Expenses incurred, or paid by an Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by this Exit Fee Agreement between Agent, and/or the Lenders and Borrower (including reasonable and documented attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and any commission, fee or compensation claimed by any broker (other than any broker retained by Agent or Lenders) asserting any right to payment for the transactio

disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct. The provisions of this Section 7 shall survive repayment of the Indebtedness and satisfaction of all Obligations of Borrower to Agent and the Lenders and termination of this Exit Fee Agreement, subject to any applicable statute of limitations.

8. <u>Amendment</u>. No amendment, modification, termination or waiver of any provision of this Exit Fee Agreement shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and each Lender (including any permitted assigns of such parties).

**9.** <u>Severability of Provisions</u>. Each provision of this Exit Fee Agreement is severable from every other provision in determining the enforceability of any provision.

**10.** <u>**Counterparts.**</u> This Exit Fee Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Exit Fee Agreement. Delivery of an executed counterpart of a signature page of this Exit Fee Agreement by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

11. <u>Electronic Execution of Certain Other Documents</u>. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Exit Fee 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 Agent and the Lenders, 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.

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Agreed: SLR INVESTMENT CORP., as Agent and Lender

By: <u>/s/ Anthony Storino</u> Name: Anthony Storino Title: Authorized Signatory

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, as Lenders

By <u>/s/ Anthony Storino</u> Name: Anthony Storino Title: Authorized Signatory

[Signature Page to Exit Fee Agreement]

Agreed:

**ARDELYX, INC.**, as Borrower

By: <u>/s/ Justin A. Renz</u> Name: Justin A. Renz Title: CFO

[Signature Page to Exit Fee Agreement]

I, Michael Raab, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Ardelyx, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2022

By:

/s/ Michael Raab

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

#### CERTIFICATION

I, Justin Renz, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Ardelyx, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2022

By:

/s/ Justin Renz

Justin Renz Chief Financial Officer (Principal Financial Officer)

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

In connection with the Quartlery Report of Ardelyx, Inc. (the "Company") on Form 10-Q for the period ending March 31, 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.

By:

Date: May 5, 2022

By: /s/ Michael Raab

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

Date: May 5, 2022

/s/ Justin Renz

Justin Renz Chief Financial Officer (Principal Financial Officer)