
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2015

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER: 001-36485

ARDELYX, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

**DELAWARE
(STATE OR OTHER JURISDICTION OF
INCORPORATION OR ORGANIZATION)**

**26-1303944
(I.R.S. EMPLOYER
IDENTIFICATION NUMBER)**

**34175 Ardenwood Boulevard, Suite 200
Fremont, California 94555
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES, INCLUDING ZIP CODE)**

**(510) 745-1700
(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)**

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (do not check if a smaller reporting company)

Smaller reporting company

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 August 10, 2015 was 25,924,232.

[Table of Contents](#)

ARDELYX, INC.

	<u>PAGE</u>
PART I. FINANCIAL INFORMATION	
Item 1. Condensed Financial Statements:	2
Condensed Balance Sheets as of June 30, 2015 (unaudited) and December 31, 2014	2
Condensed Statements of Operations and Comprehensive Income for the three and six months ended June 30, 2015 and 2014 (unaudited)	3
Condensed Statements of Cash Flows for the six months ended June 30, 2015 and 2014 (unaudited)	4
Notes to Condensed Financial Statements (unaudited)	5
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	10
Item 3. Quantitative and Qualitative Disclosures About Market Risk	17
Item 4. Controls and Procedures	17
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	17
Item 1A. Risk Factors	17
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	47
Item 3. Defaults Upon Senior Securities	47
Item 4. Mine Safety Disclosures	47
Item 5. Other Information	47
Item 6. Exhibits	48
Signatures	49

[Table of Contents](#)

PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS

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

	<u>June 30,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
	<u>(Unaudited)</u>	<u>(1)</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 141,534	\$ 107,286
Accounts receivable	27	2,584
Prepaid expenses and other current assets	2,362	1,209
Total current assets	143,923	111,079
Property and equipment, net	4,061	2,131
Other assets	104	104
Restricted cash	100	100
Total assets	<u>\$ 148,188</u>	<u>\$ 113,414</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,684	\$ 3,129
Accrued compensation and benefits	1,457	1,648
Accrued and other liabilities	1,405	780
Deferred revenue, current portion	—	15,979
Total current liabilities	5,546	21,536
Other long-term liabilities	382	122
Deferred revenue, non-current	—	31,074
Total liabilities	<u>5,928</u>	<u>52,732</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized as of June 30, 2015 and December 31, 2014, respectively; no shares issued and outstanding as of June 30, 2015 and December 31, 2014, respectively	—	—
Common stock, \$0.0001 par value; 300,000,000 shares authorized as of June 30, 2015 and December 31, 2014, respectively; 25,911,537 and 18,589,245 shares issued and outstanding as of June 30, 2015 and December 31, 2014, respectively.	3	2
Additional paid-in capital	208,619	132,547
Accumulated deficit	<u>(66,362)</u>	<u>(71,867)</u>
Total stockholders' equity	<u>142,260</u>	<u>60,682</u>
Total liabilities and stockholders' equity	<u>\$ 148,188</u>	<u>\$ 113,414</u>

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

See accompanying notes to Condensed Financial Statements.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
	<u>(Unaudited)</u>	<u>(Unaudited)</u>	<u>(Unaudited)</u>	<u>(Unaudited)</u>
Revenue:				
Licensing revenue	\$ 17,727	\$ 6,507	\$ 21,611	\$ 9,743
Collaborative development revenue	416	2,630	2,415	7,944
Total revenue	18,143	9,137	24,026	17,687
Operating expenses:				
Research and development	6,198	5,183	12,396	12,820
General and administrative	2,889	1,203	6,064	2,580
Total operating expenses	9,087	6,386	18,460	15,400
Income from operations	9,056	2,751	5,566	2,287
Other expense, net	(49)	(8)	(61)	(12)
Change in fair value of preferred stock warrant liability	—	1,010	—	(1,593)
Income before provision for income taxes	9,007	3,753	5,505	682
Provision for income taxes	—	—	—	—
Net income and comprehensive income	<u>\$ 9,007</u>	<u>\$ 3,753</u>	<u>\$ 5,505</u>	<u>\$ 682</u>
Basic net income per share	<u>\$ 0.43</u>	<u>\$ 0.20</u>	<u>\$ 0.28</u>	<u>\$ —</u>
Diluted net income per share	<u>\$ 0.42</u>	<u>\$ 0.18</u>	<u>\$ 0.27</u>	<u>\$ —</u>
Shares used in computing basic net income per share	<u>20,880,235</u>	<u>2,611,259</u>	<u>19,749,778</u>	<u>1,937,509</u>
Shares used in computing diluted net income per share	<u>21,636,487</u>	<u>3,904,136</u>	<u>20,506,916</u>	<u>1,937,509</u>

See accompanying notes to Condensed Financial Statements.

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

	Six Months Ended June 30,	
	2015 (Unaudited)	2014 (Unaudited)
Operating activities		
Net income	\$ 5,505	\$ 682
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	278	128
Stock-based compensation	1,165	163
Change in fair value of preferred stock warrant liability	—	1,593
Loss from disposal of fixed assets	11	—
Changes in operating assets and liabilities:		
Accounts receivable	2,557	3,411
Prepaid expenses and other assets	(959)	2
Accounts payable	(631)	24
Accrued compensation and benefits	(192)	(125)
Accrued and other liabilities	886	903
Deferred revenue	(47,053)	16,093
Net cash (used in) provided by operating activities	<u>(38,433)</u>	<u>22,874</u>
Investing activities		
Purchases of property and equipment	(2,320)	(736)
Net cash used in investing activities	<u>(2,320)</u>	<u>(736)</u>
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	74,654	61,241
Proceeds from exercise of stock options	317	—
Other	30	—
Net cash provided by financing activities	<u>75,001</u>	<u>61,241</u>
Net decrease in cash and cash equivalents	34,248	83,379
Cash and cash equivalents at beginning of period	<u>107,286</u>	<u>34,435</u>
Cash and cash equivalents at end of period	<u>\$ 141,534</u>	<u>\$ 117,814</u>
Supplemental cash flow disclosure:		
Cash paid during the period for income taxes	\$ 310	\$ —
Supplemental noncash financing activities:		
Acquisition of property and equipment included in accounts payable and accrued liabilities	\$ 134	\$ 499
Common stock issuance costs included in accounts payable and accrued liabilities	\$ 287	\$ —

See accompanying notes to Condensed Financial Statements.

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

NOTE 1. ORGANIZATION AND BASIS OF PRESENTATION

Ardelyx, Inc. (the “Company”) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative, minimally-systemic therapeutic drugs that work exclusively in the gastrointestinal, or GI, tract to treat cardio-renal and GI diseases. The Company has developed a proprietary drug discovery and design platform enabling it, in a rapid and cost-efficient manner, to discover and design novel drug candidates. Utilizing its platform, the Company discovered and designed its lead product candidate, tenapanor, which in a Phase 2b clinical study has demonstrated the ability to improve the symptoms of constipation-predominant irritable bowel syndrome, or IBS-C. In a separate Phase 2b clinical trial, tenapanor demonstrated the ability to treat hyperphosphatemia, or elevated serum phosphorus, in chronic kidney disease, or CKD, patients on dialysis. The Company is developing another drug candidate, RDX022, for the treatment of hyperkalemia, or elevated serum potassium, in patients with CKD, and in patients with heart failure, or HF. The Company has several other drug candidates in earlier stages of research and development focused in cardio-renal and GI diseases including RDX002, which it has licensed to Sanofi S.A., or Sanofi, for the treatment of hyperphosphatemia, RDX009, a secretagogue of glucagon-like peptide-1, or GLP-1, and glucagon-like peptide-2, or GLP-2, and RDX013, a potassium secretagogue.

Basis of Presentation

These unaudited condensed financial statements and the related footnote information of the Company have been prepared pursuant to the requirements of the Securities and Exchange Commission (the “SEC”) for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of the Company’s management, the accompanying interim unaudited condensed financial statements include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information for the periods presented. The results for the three and six months ended June 30, 2015 are not necessarily indicative of results to be expected for the entire year ending December 31, 2015 or future operating periods.

The accompanying condensed financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2014, included in the Company’s Annual Report on Form 10-K filed with the SEC (the 2014 Form 10-K). The balance sheet at December 31, 2014 has been derived from the audited financial statements at that date, as filed with the 2014 Form 10-K.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Although management believes these estimates are based upon reasonable assumptions within the bounds of its knowledge of the Company’s business and operations, actual results could differ materially from those estimates.

Revenue Recognition

Revenue from research activities made under collaboration partnership agreements are recognized as the services are provided and when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured. Revenue generated from research and licensing agreements typically includes up-front signing or license fees, cost reimbursements, research services, minimum sublicense fees, milestone payments, and royalties on future licensees’ product sales.

For revenue agreements with multiple-element arrangements, such as license and development agreements, the Company allocates revenue to each deliverable based on the relative selling price of each deliverable. When applying the relative selling price method, the Company determines the selling price for each deliverable using vendor-specific objective evidence or third-party evidence. If neither exists, the Company uses its best estimate of selling price for that deliverable. Revenue allocated is then recognized when the four basic revenue recognition criteria are met for each deliverable.

[Table of Contents](#)

The Company recognizes revenue from upfront payments ratably over the term of its estimated period of performance under the agreement which is recorded as licensing revenue. Reimbursements for development costs incurred under the Company's license agreement with AstraZeneca were classified as collaborative development revenue. The Company recognizes cost reimbursement revenue under collaboration partnership agreements as the related research and development costs for services are rendered. Deferred revenue represents the portion of research or license payments received which has not been earned.

Revenues from milestones, if they are nonrefundable and deemed substantive, are recognized upon successful accomplishment of the milestones. To the extent that non-substantive milestones are achieved and the Company has remaining performance obligations, milestones are deferred and recognized as revenue over the estimated remaining period of performance. The Company will recognize revenue associated with the non-substantive milestones upon achievement of the milestone if there are no undelivered elements and it has no remaining performance obligations. The Company will account for sales-based milestones as royalties that will be recognized as revenue upon achievement of the milestone.

Recent Accounting Pronouncements

In May, 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In July 2015, the FASB voted to approve a deferral of the effective date of this ASU by one year, and to permit entities to adopt up to one year earlier if they choose. Therefore, the new standard will become effective for the Company on January 1, 2018 and early application is permitted for periods beginning on or after January 1, 2017. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its condensed financial statements and related disclosures. The Company has not yet selected an implementation date or a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

The Company has reviewed all other significant newly-issued accounting pronouncements and concluded that they either are not applicable to the Company's operations or that no material effect is expected on its condensed financial statements as a result of future adoption.

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. Examples of assets and liabilities utilizing Level 1 inputs are certain money market funds, U.S. Treasuries and trading securities with quoted prices on active markets.
- 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. Examples of assets and liabilities utilizing Level 2 inputs are U.S. government agency bonds, corporate bonds, commercial paper, certificates of deposit and over-the-counter derivatives.
- Level 3 – Valuations based on unobservable inputs in which there is little or no market data, which require us to develop our own assumptions.

Table of Contents

The following table sets forth the fair value of the Company's financial assets measured on a recurring basis by level within the fair value hierarchy (in thousands):

	June 30, 2015			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	\$139,202	\$139,202	\$ —	\$ —
Certificates of deposit	100	—	100	—
Total	<u>\$139,302</u>	<u>\$139,202</u>	<u>\$ 100</u>	<u>\$ —</u>

	December 31, 2014			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	\$105,410	\$105,410	\$ —	\$ —
Certificates of deposit	100	—	100	—
Total	<u>\$105,510</u>	<u>\$105,410</u>	<u>\$ 100</u>	<u>\$ —</u>

Where quoted prices are available in an active market, securities are classified as Level 1. The Company classifies money market funds as Level 1. When quoted market prices are not available for the specific security, then the Company estimates fair value by using benchmark yields, reported trades, broker/dealer quotes, and issuer spreads. The Company classifies certificates of deposit as Level 2. In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3. There were no transfers between Level 1 and Level 2 during the periods presented.

The carrying amounts reflected in the condensed balance sheets for cash, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values at June 30, 2015 and December 31, 2014, due to their short-term nature.

NOTE 4. COLLABORATION AND LICENSING AGREEMENTS

AstraZeneca AB ("AstraZeneca")

In October 2012, the Company entered into a collaboration partnership with AstraZeneca for the worldwide development and commercialization of tenapanor. Under the terms of the AstraZeneca collaboration partnership agreement (the "AstraZeneca Agreement"), the Company received an up-front license fee of \$35.0 million in October 2012 and a \$15.0 million payment in December 2013, which were both being recognized as revenue on a straight-line basis over the estimated period of performance. AstraZeneca reimbursed the Company for its internal and external development-related costs. These reimbursements were recognized as collaborative development revenue when the development-related costs were incurred.

In May 2014, the Company received from AstraZeneca a \$25.0 million payment as a result of the dosing of the first patient in the Phase 2b clinical trial in hyperphosphatemia. As the \$25.0 million did not meet the criteria to be considered the achievement of a substantive milestone for accounting purposes, the amount was recorded as deferred revenue when received and was recognized as revenue on a straight-line basis over the remaining estimated period of performance.

In June 2015, the Company entered into a termination agreement with AstraZeneca (the "Termination Agreement") pursuant to which all licenses granted to AstraZeneca to the Company's portfolio of NHE3 inhibitors, including the Company's lead product candidate, tenapanor, were terminated, except for the limited purpose of allowing AstraZeneca to satisfy its obligations under the Termination Agreement. Under the terms of the Termination Agreement, the Company agreed to pay AstraZeneca certain amounts for the return of the licenses granted to it, including (a) an upfront fee of \$15.0 million, (b) future royalties at a royalty rate of 10% of net sales of tenapanor or other NHE3 products by the Company or its licensees, and (c) 20% of non-royalty revenue received from a new collaboration partner should the Company elect to license, or otherwise provide rights to develop and commercialize tenapanor, or another NHE3 inhibitor. The amounts payable by the Company as described in (a)-(c) are capped at the aggregate amount of \$90.0 million. The Company also paid AstraZeneca \$10.0 million as reimbursement for certain research and development expenses incurred by AstraZeneca under the collaboration agreement during 2015 and in consideration of the acceleration of the transfer of information and materials to the Company. In addition, AstraZeneca is obligated to supply the Company with clinical trial materials, drug substance and drug product using transfer pricing for the aggregate amount of up to \$10 million.

[Table of Contents](#)

As the AstraZeneca Agreement was terminated in June 2015, the Company recognized the remaining deferred revenue balance of \$43.1 million during the three months ended June 30, 2015. Also in the three months ended June 30, 2015, the Company recorded the \$15.0 million upfront payment for the return of the licenses as well as the \$10.0 million payment for reimbursement of research and development expenses and the acceleration of the transfer of information and materials as a reduction in licensing revenue in the condensed statements of operations and comprehensive income.

Sanofi SA (“Sanofi”)

In February 2014, the Company entered into a license option and license agreement with Sanofi (the “Sanofi Agreement”) for its phosphate transport NaP2b inhibitor program. Under the terms of the Sanofi Agreement, the Company granted Sanofi an exclusive worldwide license to conduct research utilizing the Company’s small molecule NaP2b inhibitors. In addition, Sanofi has the option to obtain an exclusive license to develop, manufacture and commercialize potential products under the agreement. Under the License Option and License Agreement, Sanofi is responsible for all of the costs and expenses for research and preclinical activities and, should it exercise its option, for the development and commercialization efforts under the program.

Under the Sanofi Agreement, the Company received a payment of \$1.25 million in March 2014, which was fully recognized as licensing revenue in May 2014 after the Company completed its obligation to provide to Sanofi the background know-how, listed patents, and materials described in the Sanofi Agreement.

NOTE 5. STOCK-BASED COMPENSATION

The following table presents stock-based compensation expense recognized for stock options and the Company’s employee stock purchase program (the “ESPP”) in the Company’s statements of operations (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Research and development	\$ 346	\$ 38	\$ 632	\$ 75
General and administrative	295	61	533	88
Total	<u>\$ 641</u>	<u>\$ 99</u>	<u>\$ 1,165</u>	<u>\$ 163</u>

At June 30, 2015, the Company had \$6.2 million and \$0.1 million of total unrecognized compensation expense, net of estimated forfeitures, related to stock option grants and purchase rights, respectively, that will be recognized over an average vesting period of 2.7 years and 0.2 years, respectively.

[Table of Contents](#)

NOTE 6. NET INCOME PER COMMON SHARE

Basic net income per share is calculated by dividing the net income by the weighted-average number of shares of common stock outstanding during the period. Diluted net income per share is calculated by dividing the net income by the weighted-average number of shares of common stock outstanding during the period, plus potentially dilutive common shares, consisting of stock options. The Company uses the treasury-stock method to compute diluted earnings per share with respect to its stock options and equivalents. For purposes of this calculation, options to purchase stock are considered to be potential common shares and are only included in the calculation of diluted net income per share when their effect is dilutive. Basic and diluted earnings per common share are calculated as follows (in thousands, except share and per share data):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Numerator:				
Net income	\$ 9,007	\$ 3,753	\$ 5,505	\$ 682
Noncumulative dividends on convertible preferred stock	—	(1,099)	—	(682)
Undistributed earnings allocated to participating securities	—	(2,139)	—	—
Net income attributable to common stockholders, basic	\$ 9,007	\$ 515	\$ 5,505	\$ —
Adjustment to undistributed earnings allocated to participating securities	—	\$ 188	—	—
Net income attributable to common stockholders, diluted	<u>\$ 9,007</u>	<u>\$ 703</u>	<u>\$ 5,505</u>	<u>\$ —</u>
Denominator:				
Basic shares:				
Weighted average common shares outstanding	20,880,235	2,611,259	19,749,778	1,937,509
Dilutive shares:				
Weighted average effect of dilutive stock options	692,110	765,672	724,890	—
Weighted average convertible preferred stock warrants outstanding	—	527,205	—	—
Weighted average private placement warrants outstanding	64,142	—	32,248	—
	<u>21,636,487</u>	<u>3,904,136</u>	<u>20,506,916</u>	<u>1,937,509</u>
Net income per share:				
Basic	<u>\$ 0.43</u>	<u>\$ 0.20</u>	<u>\$ 0.28</u>	<u>\$ —</u>
Diluted	<u>\$ 0.42</u>	<u>\$ 0.18</u>	<u>\$ 0.27</u>	<u>\$ —</u>

For the three and six months ended June 30, 2015, the total number of anti-dilutive outstanding common stock options excluded from the diluted net income per common share computation was 0.5 million and 0.4 million, respectively. For the three and six months ended June 30, 2014, the total number of anti-dilutive outstanding common stock options excluded from the diluted net income per common share computation was insignificant and 1.1 million, respectively.

NOTE 7. STOCKHOLDERS EQUITY

Option Exercises

For the three and six months ended June 30, 2015 employees and consultants exercised options to purchase 20,189 and 46,401 shares of the Company's common stock, respectively, with net proceeds to the Company of insignificant and \$0.1 million, respectively. For the three and six months ended June 30, 2014 employees exercised options to purchase 46,797 and 92,781 shares of the Company's common stock, respectively, with insignificant and approximately \$0.1 million net proceeds to the Company, respectively.

Employee Stock Purchase Plan

In February 2015, the Company sold 19,614 shares under the ESPP. The shares were purchased at a purchase price of \$12.43 per share with proceeds to the Company of approximately \$0.2 million.

Offering of Common Stock and Warrants

In June 2015, the Company sold and issued an aggregate of 7,242,992 shares of its common stock and warrants to purchase 2,172,899 shares of common stock for aggregate gross proceeds of approximately \$77.8 million or net proceeds, after deducting issuance costs, of approximately \$74.4 million. The purchase price for the common stock was \$10.70 per share and the purchase price for the warrants was \$0.125 per warrant. The warrants are exercisable for an exercise price of \$13.91 per share at any time prior to the earlier of (i) 5 years from the date of issuance or (ii) certain changes in control of the Company. The Company has determined that the warrants should be classified as equity. In July 2015, the Company filed a registration statement with the SEC with respect to the common stock and warrants.

Other than with respect to warrants issued to holders affiliated with New Enterprise Associates, the warrants contain limitations that prevent each holder of warrants from acquiring shares upon exercise of the warrants that would cause the number of shares beneficially owned by it and its affiliates to exceed 9.99% of the total number of shares of the Company's common stock then issued and outstanding. In addition, upon certain changes in control of the Company, each holder of a warrant can elect to receive, subject to certain limitations and assumptions, securities in a successor entity. None of the warrants issued in June 2015 have been exercised during the three months ended June 30, 2015.

NOTE 8. SUBSEQUENT EVENTS

On July 13, 2015, the Company filed a registration statement on Form S-3 (File No. 333-205631) with the SEC, under which it may sell an aggregate of up to \$200.0 million of common stock, preferred stock, debt securities, warrants, purchase contract and/or units. The S-3 shelf registration statement included a prospectus covering the offering, issuance and sale of up to \$50.0 million of shares of common stock from time to time in “at the market offerings” pursuant to an At the Market Issuance Sales Agreement entered into with Cantor Fitzgerald on July 13, 2015.

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 consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2014. This discussion and analysis and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk Factors." These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason. Unless the context requires otherwise, the terms "Ardelyx," "Company," "we," "us," and "our" refer to Ardelyx, Inc.

ABOUT ARDELYX

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative, minimally-systemic therapeutic drugs that work exclusively in the gastrointestinal, or GI, tract to treat cardio-renal and GI diseases. We have developed a proprietary drug discovery and design platform enabling us, in a rapid and cost-efficient manner, to discover and design novel drug candidates. Utilizing our platform, we discovered and designed our lead product candidate, tenapanor, which in a Phase 2b clinical study has demonstrated the ability to improve the symptoms of constipation-predominant irritable bowel syndrome, or IBS-C. We expect to initiate a Phase 3 clinical program to evaluate tenapanor in the treatment of IBS-C in the fourth quarter 2015. In a separate Phase 2b clinical trial, tenapanor demonstrated the ability to treat hyperphosphatemia, or elevated serum phosphorus, chronic kidney disease, or CKD, patients on dialysis. We expect to initiate a Phase 2b clinical trial to evaluate dosing regimens of tenapanor for the treatment of hyperphosphatemia in these patients in the fourth quarter 2015. We are developing another drug candidate, RDX022, for the treatment of hyperkalemia, or elevated serum potassium, in patients with CKD, and in patients with heart failure, or HF. In the fourth quarter 2015, we expect to begin a Phase 1 clinical trial in healthy adults evaluating the safety and pharmacodynamic, or biological activity, of RDX022. We intend to pursue a 505(b)(2) regulatory pathway for RDX022, and we expect to advance RDX022 into a Phase 3 clinical program as early as the second half of 2016. We have several other drug candidates in earlier stages of research and development focused in cardio-renal and GI diseases including RDX002, which we have licensed to Sanofi S.A., or Sanofi, for the treatment of hyperphosphatemia, RDX009, a secretagogue of glucagon-like peptide-1, or GLP-1, and glucagon-like peptide-2, or GLP-2, and RDX013, a potassium secretagogue.

AstraZeneca AB ("AstraZeneca")

In October 2012, we entered into a collaboration partnership with AstraZeneca for the worldwide development and commercialization of tenapanor. Under the terms of the AstraZeneca collaboration partnership agreement (the "AstraZeneca Agreement"), we received an up-front license fee of \$35.0 million in October 2012, a \$15.0 million payment in December 2013 and a \$25 million payment in May 2014. The amounts were recorded as deferred revenue when received and were recognized as revenue on a straight-line basis over the remaining estimated period of performance under the AstraZeneca Agreement, which during the three months ended March 31, 2015, we estimated to be December 2017.

In June 2015, we entered into a termination agreement with AstraZeneca (the "Termination Agreement") pursuant to which all licenses granted to AstraZeneca to our portfolio of NHE3 inhibitors, including our lead product candidate, tenapanor, were terminated, except for the limited purpose of allowing AstraZeneca to satisfy its obligations under the Termination Agreement. Under the terms of the Termination Agreement, we agreed to pay AstraZeneca certain amounts for the return of the licenses granted to it, including (a) an upfront fee of \$15.0 million, (b) future royalties at a royalty rate of 10% of net sales of tenapanor or other NHE3 products by us or our licensees, and (c) 20% of non-royalty revenue received from a new collaboration partner should we elect to license, or otherwise provide rights to develop and commercialize tenapanor or another NHE3 inhibitor. The amounts described in (a)-(c) are capped at the aggregate amount of \$90.0 million. We also paid AstraZeneca \$10.0 million as reimbursement for certain research and development expenses incurred by AstraZeneca under the collaboration agreement during 2015, and the acceleration of the transfer of the information materials to us. In addition, AstraZeneca is obligated to supply us with clinical trial material, drug substance and drug product using transfer pricing for the aggregate amount of up to \$10.0 million.

As the AstraZeneca Agreement was terminated in June 2015, we recognized the remaining deferred revenue balance of \$43.1 million during the three months ended June 30, 2015. Also in the three months ended June 30, 2015, we recorded the \$15.0 million upfront payment for the return of the licenses as well as the \$10.0 million payment for reimbursement of research and development expenses the acceleration of the transfer of information and materials as a reduction in licensing revenue in the condensed statements of operations and comprehensive income.

[Table of Contents](#)

Sanofi SA (“Sanofi”)

In February 2014, we entered into an option and license agreement with Sanofi, or the Sanofi Agreement, under which we granted Sanofi an exclusive worldwide license to conduct research utilizing our program evaluating small molecule NaP2b inhibitors for the treatment of hyperphosphatemia in CKD patients on dialysis. In addition, Sanofi has the option to obtain an exclusive license to develop, manufacture and commercialize our NaP2b inhibitors. Under our Sanofi Agreement, Sanofi is responsible for all of the costs and expenses for research and preclinical activities and, should it exercise its option, for the development and commercialization efforts under the program. Under the Sanofi Agreement, we received an upfront payment of \$1.25 million in March 2014, which was fully recognized as licensing revenue in May 2014 after we completed our obligation to provide Sanofi the background know-how, listed patents, and materials described in the Sanofi Agreement. We have the potential to earn future development, regulatory and commercial milestone payments of up to \$196.75 million if Sanofi continues to advance the program into development and through commercialization. If a NaP2b inhibitor is commercialized by Sanofi as a result of this program, we will receive tiered royalties ranging from the mid-single digits into the low double digits. As part of our agreement with Sanofi, we retain an option to co-promote licensed products in the United States.

Financial Operations Overview

Revenue

We have not generated any revenue from product sales. Our revenue to date has been generated from non-refundable license payments and reimbursements for research and development expenses under our license agreements. We recognize revenue from upfront payments ratably over the term of our estimated period of performance under the agreement which we consider to be licensing revenue. In addition to receiving upfront payments, we may also be entitled to milestone and other contingent payments upon achieving predefined objectives. Such payments are recorded as revenue when we achieve the underlying milestone if it is deemed to be a substantive milestone at the date the arrangement is entered into. To the extent that non-substantive milestones are achieved and we have remaining performance obligations, milestones are deferred and recognized as revenue over the estimated remaining period of performance. Reimbursements from AstraZeneca for development costs incurred under our license and collaboration agreement with them are classified as collaborative development revenue.

We expect that any revenue we generate will fluctuate from year to year as a result of the timing and amount of milestones and other payments from our collaboration partnership with Sanofi and or any future collaboration partners.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our unpartnered product candidates, and prior to the termination of the AstraZeneca Agreement, research and development expenses also included costs we incurred in connection with the development of tenapanor pursuant to our license agreement with AstraZeneca. We recognize all research and development expenses as they are incurred.

Research and development expenses consist of the following:

- external research and development expenses incurred under agreements with consultants, third-party contract research organizations, or CROs, and investigative sites where a substantial portion of our clinical studies are conducted, and with contract manufacturing organizations, or CMOs, where our clinical supplies are produced;
- employee-related expenses, which include salaries, benefits 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 and other supplies.

Prior to the execution of our license agreement with AstraZeneca in October 2012, we incurred \$18.0 million in research and development expenses related to tenapanor. Following the execution of the license agreement and through June 30, 2015, we incurred \$38.8 million in research and development expenses related to tenapanor, all of which were reimbursed by AstraZeneca under the license agreement. The reimbursements are recognized in collaborative development revenue in the statement of operations and comprehensive income.

We expect our unpartnered research and development expenses will increase substantially in the future as we progress the development of tenapanor and our other our internal product candidates, advance our discovery research projects into the preclinical stage and continue our early stage research including further development of our APECCS cell-culture system. The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time consuming. We or our collaboration partner(s) may never succeed in achieving marketing approval for any of our product candidates. The probability of success of each of the product candidates may be affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability and commercial viability.

[Table of Contents](#)

Many of our product development programs are at an early stage; therefore, the successful development of our product candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. Given the uncertainty associated with clinical trial enrollment and the risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical trials of our product candidates or if and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. We anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment as to each product candidate's commercial potential. We will need to raise additional capital or may seek additional collaboration partnerships in the future in order to complete the development and commercialization of our product candidates, including tenapanor.

General and Administrative

General and administrative expenses include personnel costs, travel expenses and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs includes salaries, bonus, benefits and stock-based compensation. We have incurred, and expect to continue to incur, additional expenses as a result of being a public company following the completion of our initial public offering, or IPO, in June 2014, including expenses to comply with the rules and regulations applicable to companies listed on a national securities exchange and costs related to compliance and reporting obligations pursuant to the rules and regulations of the SEC, as well as increases in expenses for additional insurance, investor relations activities and other administration and professional services.

Provision for Income Taxes

We did not record a provision for income taxes for the three and six months ended June 30, 2015 because we expect to generate a net operating loss for the year ending December 31, 2015. Our deferred tax assets continue to be fully offset by a valuation allowance.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based upon our unaudited condensed financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We consider certain accounting policies related to revenue recognition, research and development expense and accruals and stock-based compensation to be critical policies. There have been no changes to our critical accounting policies since we filed our 2014 Annual Report on Form 10-K, or 2014 Form 10-K, with the SEC on March 5, 2015. For a description of our critical accounting policies, please refer to our 2014 Form 10-K.

[Table of Contents](#)**Results of Operations**

Three and Six Months Ended June 30, 2015 and 2014

Revenue

Licensing revenues for the three and six months ended June 30, 2015 as compared to the prior year was as follows (in thousands):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Licensing revenue	\$ 17,727	\$ 6,507	\$ 21,611	\$ 9,743
Dollar change from prior year	11,220		11,868	
Percent change from prior year	172%		122%	

Licensing revenue for the three months ended June 30, 2015 was \$17.7 million, an increase of \$11.2 million, or 172%, compared to licensing revenue of \$6.5 million for the three months ended June 30, 2014. Licensing revenue for the six months ended June 30, 2015 was \$21.6 million, an increase of \$11.9 million, or 122%, compared to licensing revenue of \$9.7 million for the six months ended June 30, 2014. The increase was primarily due to recognition of the remaining deferred revenue balance of \$43.1 million during the three months ended June 30, 2015 as a result of the Termination Agreement with AstraZeneca. This recognition of deferred revenue was offset by two payments to AstraZeneca (1) a \$15.0 million upfront payment for the return of the license granted to AstraZeneca (2) \$10.0 million reimbursement for research and development expenses and payment for the acceleration of the transfer of information and materials.

Collaborative development revenues for the three and six months ended June 30, 2015 as compared to the prior year was as follows (in thousands):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Collaborative development revenue	\$ 416	\$ 2,630	\$ 2,415	\$ 7,944
Dollar change from prior year	(2,214)		(5,529)	
Percent change from prior year	-84%		-70%	

Collaborative development revenue consists of our development expenses that were reimbursable to us by AstraZeneca as part of our license agreement. Collaborative development revenue for the three months ended June 30, 2015 was \$0.4 million, a decrease of \$2.2 million, or 84%, compared to \$2.6 million for the three months ended June 30, 2014. Collaborative development revenue for the six months ended June 30, 2015 was \$2.4 million, a decrease of \$5.5 million, or 70%, compared to \$7.9 million for the six months ended June 30, 2014. The decrease was due to the Termination Agreement with AstraZeneca.

Research and Development

Research and development expenses for the three and six months ended June 30, 2015 as compared to the prior year was as follows (in thousands):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Research and development	\$ 6,198	\$ 5,183	\$ 12,396	\$ 12,820
Dollar change from prior year	1,015		(424)	
Percent change from prior year	20%		-3%	

Research and development expenses were \$6.2 million for the three months ended June 30, 2015, an increase of \$1.0 million, or 20%, compared to \$5.2 million for the three months ended June 30, 2014. The change was due to a \$3.2 million increase in discovery research expenses primarily due to an increase in our personnel costs, consultant service fees, process development costs and lab supply expenses from increased research activities for unpartnered programs. The increase was offset by a \$2.2 million decrease in AstraZeneca collaboration development expense due to the decrease in development activities related to tenapanor conducted by us under the license agreement with AstraZeneca.

Table of Contents

Research and development expenses were \$12.4 million for the six months ended June 30, 2015, a decrease of \$0.4 million, or 3%, compared to \$12.8 million for the six months ended June 30, 2014. The change was due to a decrease in AstraZeneca collaboration development expense of \$5.5 million due to the decrease in development activities related to tenapanor conducted by us under the license agreement with AstraZeneca. The decrease was offset by a \$5.1 million increase in discovery research expenses primarily due to an increase in our personnel costs, consultant service fees, process development costs and lab supply expenses from increased research activities for unpartnered programs.

General and Administrative

General and administrative expenses for the three and six months ended June 30, 2015 as compared to the prior year was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
General and administrative	\$ 2,889	\$ 1,203	\$ 6,064	\$ 2,580
Dollar change from prior year	1,686		3,484	
Percent change from prior year	140%		135%	

General and administrative expenses were \$2.9 million for the three months ended June 30, 2015, an increase of \$1.7 million, or 140%, compared to \$1.2 million for the three months ended June 30, 2014. General and administrative expenses were \$6.1 million for the six months ended June 30, 2015, an increase of \$3.5 million, or 135%, compared to \$2.6 million for the six months ended June 30, 2014. The increase was primarily due to an increase in professional services fees, personnel and operational costs as a result of our being a public company.

Change in Fair Value of Preferred Stock Warrant Liability

Change in fair value of preferred stock warrant liability for the three and six months ended June 30, 2015 as compared to the prior year was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Change in fair value of preferred stock warranty	\$ —	\$ 1,010	\$ —	\$ (1,593)
Dollar change from prior year	(1,010)		1,593	
Percent change from prior year	-100%		100%	

Change in fair value of preferred stock warrant liability was zero for the three and six months ended June 30, 2015, respectively, compared to \$1.0 million and (\$1.6) million for the three and six months ended June 30, 2014, respectively. The preferred stock warrants were net exercised upon the completion of our initial public offering (IPO) in June 2014.

Liquidity and Capital Resources

The following table displays a summary of our cash and cash equivalents as of June 30, 2015 and December 31, 2014:

	June 30, 2015	December 31, 2014
Cash and cash equivalents	\$141,534	\$ 107,286

In connection with our IPO in June of 2014, we received cash proceeds of \$61.2 million, net of underwriters' discounts and commissions and expenses paid by us. Additionally, in June 2015, we closed a financing in which we raised approximately \$77.8 million in gross proceeds or \$74.4 million in net proceeds, after deducting issuance costs. On July 13, 2015, the Company filed a registration statement on Form S-3 (File No. 333-205631) with the SEC, under which it may sell an aggregate of up to \$200.0 million of common stock, preferred stock, debt securities, warrants, purchase contract and/or units.

[Table of Contents](#)

Prior to the IPO, we funded our operations primarily with cash flows from the sales of our convertible preferred stock in private placements and from the upfront payments and other collaboration related payments received from our collaboration partners AstraZeneca and Sanofi.

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

We believe that our existing capital resources as of June 30, 2015 will be sufficient to meet our projected operating requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures. We currently have no credit facility or committed sources of capital other than potential milestones receivable under our current collaboration partnerships. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, the potential for one or more of our existing collaboration partners to terminate the agreement with us and return the program to us, and the extent to which we may enter into additional collaboration partnerships with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies. Our future funding requirements will depend on many factors, including the following:

- the progress, timing, scope, results and costs of our clinical trial programs evaluating tenapanor in IBS-C and for the treatment of hyperphosphatemia in chronic kidney disease patients on dialysis;
- the progress, timing, scope, results and costs of our clinical program for RDX022;
- the time and cost necessary to obtain regulatory approvals for our product candidates and the costs of post-marketing studies that could be required by regulatory authorities;
- our ability to successfully commercialize our product candidates, either alone or with one or more collaboration partners;
- the manufacturing costs of our product candidates, and the availability of one or more suppliers for our product candidates at reasonable costs, both for clinical and commercial supply;
- the selling and marketing costs associated with product candidates, including the cost and timing of building our sales and marketing capabilities;
- our ability to establish and maintain collaboration partnerships, in-license/out-license or other similar arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the sales price and the availability of adequate third-party reimbursement for our product candidates;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the number and scope of preclinical and discovery programs that we decide to pursue or initiate, and any clinical trials we decide to pursue for other product candidates;
- the time and cost necessary to respond to technological and market developments; and
- 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 our product candidates.

[Table of Contents](#)

The following table summarizes our cash flows for the periods indicated (in thousands):

	Six Months Ended June 30,	
	2015	2014
Cash (used in) provided by operating activities	\$ (38,433)	\$ 22,874
Cash used in investing activities	(2,320)	(736)
Cash provided by financing activities	75,001	61,241
Net decrease in cash and cash equivalents	<u>\$ 34,248</u>	<u>\$ 83,379</u>

Cash Flows from Operating Activities

Net cash used in operating activities during the six months ended June 30, 2015 was approximately \$38.4 million. Net cash provided by operating activities during the six months ended June 30, 2014 was approximately \$22.9 million. The change was primarily due to net income for each respective period adjusted for stock-based compensation, depreciation expense and changes in working capital.

Cash Flows from Investing Activities

Cash used in investing activities for the six months ended June 30, 2015 and 2014 was approximately \$2.3 million, and \$0.7 million, respectively, and was primarily due to the acquisition of property and equipment related to the expansion of our laboratory and related equipment.

Cash Flows from Financing Activities

Cash provided by financing activities for the six months ended June 30, 2015 and 2014 was approximately \$75.0 million, and \$61.2 million, respectively, and was primarily due to proceeds from issuance of common stock and exercise of stock options and purchase rights.

[Table of Contents](#)**Contractual Obligations and Other Commitments**

The following table summarizes our contractual obligations as of June 30, 2015 (in thousands):

Contractual Obligation:	Payments Due by Period				Total
	Less than 1 year	1 to 3 Years	4 to 5 Years	More Than 5 Years	
Purchase commitments	\$10,567	—	—	—	\$10,567
Operating leases (1)	855	1,789	1,118	—	3,762
Capital expenditures	262	—	—	—	262
Total contractual obligations	<u>\$11,683</u>	<u>\$1,789</u>	<u>\$1,118</u>	<u>—</u>	<u>\$14,591</u>

(1) Operating leases include total future minimum rent payments under non-cancelable operating lease agreements.

Off-Balance Sheet Arrangements

None.

Recent Accounting Pronouncements

Refer to Note 2 in the accompanying notes to our unaudited interim condensed financial statements for a discussion of recent accounting pronouncements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in the sources and effects of our market risk compared to the disclosures in Item 7A of our 2014 Form 10-K.

ITEM 4. CONTROLS AND PROCEDURES***Evaluation of Disclosure Controls and Procedures***

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2015. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Controls

During the second quarter of 2015, we began using a new Enterprise Resource Planning, or ERP, system for financial reporting and logistics. As a result, our financial and operating transactions utilize the functionality provided by the new ERP system. This new system is not in response to any identified deficiency or weakness in our internal control over financial reporting. The system implementation was designed, in part, to enhance the overall system of internal controls over financial reporting through further automation of various business processes.

There were no changes in our internal controls over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended June 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION**ITEM 1. LEGAL PROCEEDINGS**

We are not currently a party to any material litigation or other material legal proceedings.

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 related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or

[Table of Contents](#)

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 Limited Operating History, 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.

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 our lead product candidate, tenapanor, and developing our proprietary drug discovery and design platform. To date, we have not commercialized any products or generated any revenue from the sale of products. 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 have only a limited operating history upon which to evaluate our business and prospects. We continue to incur significant research, development and other expenses related to our ongoing operations. As of June 30, 2015, we had an accumulated deficit of \$66.4 million.

We expect that our operating losses will substantially increase for the foreseeable future as we as we continue the development of our lead compound, tenapanor, in a Phase 3 clinical program in IBS-C and in a Phase 2b clinical trial for the treatment of hyperphosphatemia in patients with chronic kidney disease on dialysis, each of which are expected to be initiated in the fourth quarter of 2015. In addition, we expect our operating losses to substantially increase as we incur manufacturing costs and advance RDX022 into a Phase 3 clinical program which we expect to initiate in the second half of 2016, and as we continue our discovery, research, development, manufacturing and commercialization activities.

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 never generated any revenue from product sales and may never be profitable.

We have no products approved for sale and have never generated any revenue from product sales. Our ability to generate revenue from product sales and achieve profitability depends on our ability to successfully complete the development of and obtain the regulatory and marketing approvals necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales or pursuant to milestone payments depends heavily on many factors, including but not limited to:

- the completion of research and preclinical and clinical development of our product candidates;
- obtaining regulatory approvals for our product candidates, either on our own, or with one or more collaboration partners;
- our ability to successfully commercialize our product candidates, either on our own, or with a collaboration partner;
- developing a sustainable and scalable manufacturing process for any approved product candidates and establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates, if approved, as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring, in-licensing and/or developing new product candidates;
- negotiating favorable terms in any collaboration partnership, licensing or other arrangements into which we may enter;
- 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

[Table of Contents](#)

- attracting, hiring, and retaining qualified personnel.

In cases where we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which regulatory approval is granted, the accepted price for the product, the ability to get reimbursement at any price and whether we are commercializing the product or the product is being commercialized by a collaboration partner, and in such case, whether we have royalty and/or co-promotion rights for that territory. If the number of patients suitable for our product candidates is not as significant as we estimate, the indication approved by regulatory authorities is narrower than 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 such products, even if approved. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to generate 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.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our planned clinical programs for tenapanor and RDX022, or our other product development and platform development activities.

Since our inception, most of our resources have been dedicated to our research and development activities, including developing our lead product candidate, tenapanor, and developing our proprietary drug discovery and design platform. We believe that we will continue to expend substantial resources for the foreseeable future, including costs associated with conducting the Phase 3 clinical programs for tenapanor and RDX022, research and development, conducting preclinical studies and clinical trials for our other programs, obtaining regulatory approvals, and sales and marketing. Because the outcome of any clinical trial and/or regulatory approval process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization or co-promotion of any of our product candidates. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, timing, scope, results and costs of our clinical trial programs evaluating tenapanor in IBS-C and for the treatment of hyperphosphatemia in chronic kidney disease patients on dialysis;
- the progress, timing, scope, results and costs of our clinical program for RDX022;
- the time and cost necessary to obtain regulatory approvals for our product candidates and the costs of post-marketing studies that could be required by regulatory authorities;
- our ability to successfully commercialize our product candidates, either alone or with one or more collaboration partners;
- the manufacturing costs of our product candidates, and the availability of one or more suppliers for our product candidates at reasonable costs, both for clinical and commercial supply;
- the selling and marketing costs associated with product candidates, including the cost and timing of building our sales and marketing capabilities;
- our ability to establish and maintain collaboration partnerships, in-license/out-license or other similar arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the sales price and the availability of adequate third-party reimbursement for our product candidates;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the number and scope of preclinical and discovery programs that we decide to pursue or initiate, and any clinical trials we decide to pursue for other product candidates;
- the time and cost necessary to respond to technological and market developments; and
- 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 our product candidates.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay the clinical development of tenapanor and/or RDX022, delay, limit,

[Table of Contents](#)

reduce or terminate our research activities, preclinical and clinical trials for our other product candidates and our establishment and maintenance of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, either alone or with a collaboration partner.

Risks Related to Our Business

We are substantially dependent on the success of our lead product candidate, tenapanor, which may not be successful in nonclinical studies or clinical trials, receive regulatory approval or be successfully commercialized.

To date, we have invested a significant amount of our efforts and financial resources in the research and development of tenapanor, which is currently our lead product candidate and one of only two product candidates in clinical trials. With the termination of the license agreement with AstraZeneca AB in June 2015, all rights to develop and commercialize tenapanor were returned to us. The clinical and commercial success of tenapanor will depend on a number of factors, including the following:

- our timely receipt from AstraZeneca of clinical trial material in sufficient quantities to enable us to initiate the Phase 3 clinical program and the Phase 2b clinical trial for tenapanor in the fourth quarter of 2015, and to complete these clinical programs without delay;
- whether we can successfully and in a timely manner complete the transfer from AstraZeneca to us of all research, pre-clinical, clinical, regulatory and manufacturing operations for tenapanor;
- our ability to, and AstraZeneca's cooperation to enable us to, complete, in a timely manner, the transfer of the manufacturing process for tenapanor drug product to a third party manufacturer;
- our ability, in a timely manner and at costs that are acceptable to us, to establish contractual relationships with third-party manufacturers utilized by AstraZeneca to manufacture tenapanor drug substance;
- whether the clinical trial material delivered by AstraZeneca meets our quality specifications and those of the FDA in order to be utilized in the Phase 3 clinical program for tenapanor as designed;
- our ability to, in a timely manner and under terms that are acceptable to us, to establish a collaborative relationship for the commercialization of tenapanor for IBS-C;
- the ability of the third-party manufacturers we contract with, to successfully execute and scale up the manufacturing processes for tenapanor, which has not yet been demonstrated, and to manufacture supplies of tenapanor and to develop, validate and maintain a commercially viable manufacturing processes that are compliant with current good manufacturing practice, or cGMP, requirements;
- whether the specifications for tenapanor drug product and drug substance will be acceptable to the FDA for use in the clinical development of tenapanor as planned, or whether we will be required to produce such material to different specifications, which if required, could delay the development of tenapanor, and result in substantial additional costs;
- whether the long-term rat carcinogenicity study required for regulatory approval of tenapanor, which is currently ongoing, will provide data acceptable to the FDA, or whether we will be required to start a new long-term rat carcinogenicity study, which if required, could delay the development of tenapanor;
- whether, as a result of the observation of the absorption of inactive metabolites of tenapanor seen in our radiolabeled human ADME study, the FDA or foreign regulatory authorities require additional nonclinical and/or clinical studies, which could delay the commercialization of tenapanor;
- whether FDA or foreign regulatory authorities require additional clinical trials than those anticipated prior to approval to market tenapanor;
- the prevalence and severity of adverse side effects of tenapanor;
- whether tenapanor's safety and efficacy profile is satisfactory to the FDA and foreign regulatory authorities to gain marketing approval;
- the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities;
- our ability, either alone, or with a collaboration partner, to successfully commercialize tenapanor, if approved for marketing and sale by the FDA or foreign regulatory authorities, including educating physicians and patients about the benefits, administration and use of tenapanor;
- achieving and maintaining compliance with all regulatory requirements applicable to tenapanor;

[Table of Contents](#)

- acceptance of tenapanor as safe, effective and well-tolerated by patients and the medical community;
- our ability to manage the complex pricing and reimbursement negotiations associated with marketing the same product at different doses for separate indications, if tenapanor is approved for marketing and sale by the FDA or foreign regulatory authorities for both IBS-C and hyperphosphatemia in dialysis patients;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- obtaining and sustaining an adequate level of coverage and reimbursement for tenapanor by third-party payors;
- enforcing intellectual property rights in and to tenapanor;
- avoiding 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 tenapanor following approval.

As tenapanor is a first-in-class drug, there is a higher likelihood that approval may not be attained as compared to a class of drugs with approved products. We cannot be certain that tenapanor will be successful in non-clinical safety studies or clinical trials, or that it will receive regulatory approval. Further, it may not be possible or practicable to demonstrate, or if approved, to market on the basis of, certain of the benefits we believe tenapanor possesses. For example, the reduction of serum phosphorus is currently an approvable endpoint in CKD patients on dialysis, but not for the broader CKD patient population in the United States. If the number of patients in the market for tenapanor or the price that the market can bear is not as significant as we estimate, we may not generate sufficient revenue from sales of tenapanor, if approved. Accordingly, there can be no assurance that tenapanor will ever be successfully commercialized or that we will ever generate income from sales of tenapanor. If we are not successful in completing the development of, obtaining approval for, and commercializing tenapanor, or are significantly delayed in doing so, our business will be materially harmed.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays in our clinical studies. Furthermore, results of earlier studies and trials may not be predictive of future trial results.

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. Failure can occur at any time during the clinical trial process. The results of preclinical and clinical studies of our product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in preclinical and clinical studies for tenapanor do not ensure that the ongoing clinical trial, or future clinical trials, will demonstrate similar results. An unexpected adverse event profile may present challenges for the future development and commercialization of a product candidate for a particular condition despite receipt of positive efficacy data in a clinical study. For example, in a Phase 2b study evaluating tenapanor for the treatment of hyperphosphatemia in CKD patients on dialysis, we observed that the study met its primary endpoint by demonstrating a statistically significant dose-related decrease in serum phosphate levels for tenapanor-treated patients compared to patients receiving placebo, while also observing that the rate of diarrhea and the discontinuation rate due to diarrhea at the highest doses were higher than expected based upon previous clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials for similar indications that we are pursuing due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We do not know whether future clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delay or failure to:

- manufacture sufficient quantities of product candidate for use in clinical trials;
- obtain regulatory approval to commence a trial, if applicable;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain institutional review board, or IRB, approval at each site;

Table of Contents

- recruit suitable patients in a timely manner to participate in our trials;
- have patients complete a trial or return for post-treatment follow-up;
- ensure that clinical sites observe trial protocol, comply with good clinical practices, or GCPs, or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations; or
- initiate or add a sufficient number of clinical trial sites,

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by an independent data safety monitoring board, or DSMB, for such trial 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.

Further, conducting clinical trials in foreign countries presents additional risks that may delay completion of clinical trials. These risks include the failure of physicians or enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes and political and economic risks relevant to such foreign countries. In addition, the FDA may determine that the clinical trial results obtained in foreign subjects do not represent the safety and efficacy of a product candidate when administered in U.S. patients and are thus not supportive of an NDA approval in the United States. If there are delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenue from product sales from any of these product candidates will be delayed. In addition, any delays in completing the clinical trials will increase costs, slow down our product candidate development and approval process and jeopardize the ability to commence product sales and generate revenue from product sales. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We intend to devote significant resources to the development of RDX022 which may not be successful in nonclinical studies or clinical trials, receive regulatory approval or be successfully commercialized.

With the advancement of RDX022 into human studies in June 2015, and the expected initiation of a Phase 3 clinical program for RDX022 in the second half of 2016, we expect to invest a significant amount of our efforts and financial resources in the development of RDX022. We are pursuing a 505(b)(2) regulatory path for approval of RDX022, which, among other things allows us to rely on the FDA's previous findings of safety and efficacy and may eliminate the need to conduct certain nonclinical and clinical studies of our product candidate. This accelerated pathway is only available to the first applicant to file for and receive 505(b)(2) regulatory approval for a particular active pharmaceutical ingredient. There can be no assurances that we will be the first to file and receive regulatory approval for the drug substance comprising RDX022. If we are able to rely upon a 505(b)(2) regulatory pathway for the approval of RDX022, the development of RDX022 may be substantially delayed or we may be required to abandon such development.

The clinical and commercial success of RDX022 will depend on a number of factors, including the following:

- the ability of the third-party manufacturers we contract with, to successfully develop and scale up the manufacturing processes for RDX022, which has not yet been demonstrated, to manufacture supplies of RDX022 and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practice, or cGMP, requirements;
- the significant expansion of the market for the treatment of hyperkalemia beyond its currently limited size, including the success of commercial launches of new hyperkalemia products and the use of any such products by nephrologists and cardiologists in the chronic setting;

[Table of Contents](#)

- the availability, perceived advantages regarding relative palatability, relative cost, relative safety, relative tolerance and relative efficacy of alternative and competing treatments;
- whether we are able to obtain intellectual property protection for RDX022, and the strength of such protection if granted
- the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities;
- our the ability to successfully commercialize RDX022, if approved for marketing and sale by the FDA or foreign regulatory authorities, including educating physicians and patients about the benefits, administration and use of RDX022;
- obtaining and sustaining an adequate level of coverage and reimbursement for RDX022 by third-party payors; and
- the effectiveness of our marketing, sales and distribution strategy and operations.

We are pursuing a 505(b)(2) regulatory path for approval of RDX022, which, among other things allows us to rely on the FDA's previous findings of safety and efficacy and may eliminate the need to conduct certain nonclinical and clinical studies of our product candidate. As a result, we may not evaluate the efficacy of RDX022 in patients with hyperkalemia prior to the initiation of the Phase 3 clinical program. We cannot be certain that clinical trials evaluating RDX022 will establish a safety and efficacy profile sufficient to enable RDX022 to gain approval by the FDA, or if approved, compete effectively with alternative and competing treatments. Further, it may not be possible or practicable to demonstrate, or if approved, to market on the basis of, certain of the benefits we believe RDX022 may possess. Accordingly, there can be no assurance that RDX022 will ever be successfully commercialized or that we will ever generate revenue from sales of RDX022. If we are not successful in completing the development of, obtaining approval for, and commercializing RDX022, or are significantly delayed in doing so, our business will be materially harmed.

If Sanofi does not exercise its option to obtain an exclusive license to develop, manufacture and commercialize our NaP2b inhibitors or if it exercises the option and subsequently terminates any development program under its collaboration partnership with us, any potential milestone payments or revenue from product sales under this collaboration partnership will be significantly reduced or non-existent, and our results of operations and financial condition will be materially and adversely affected.

In February 2014, we entered into a license option and license agreement with Sanofi under which we granted Sanofi an exclusive worldwide license to conduct research utilizing our small molecule NaP2b inhibitors, which we refer to as our RDX002 program, solely for the purpose of completing activities under a preclinical development plan. We believe the inhibition of NaP2b, an intestinal phosphate transporter, would provide utility for the treatment of hyperphosphatemia in CKD-5D patients, which is also one of the lead indications for which we are developing tenapanor.

Under the terms of this agreement, Sanofi has the option to obtain an exclusive license to develop, manufacture and commercialize our NaP2b inhibitors. Sanofi may exercise this option at any time following the effective date of the agreement and ending 45 days after the filing of an investigational new drug application, or IND, subject to certain exceptions, and if Sanofi does not file an IND on or before the 40th month anniversary of the completion of the technology transfer phase, the agreement will terminate.

If Sanofi does not exercise its option under its agreement with us, or terminates its rights and obligations with respect to the development program or the entire agreement, then depending on the timing of such event:

- the development of our NaP2b inhibitor program may be terminated or significantly delayed;
- we would bear all of the risks and costs related to the further development and commercialization of product candidates that were previously the subject of the agreement if we decided to continue work under the NaP2b inhibitor program independently;
- we would not be eligible to receive any of the remaining development or regulatory milestone payments or royalties on product sales;
- in order to fund further development and commercialization of the NaP2b program, we may need to raise additional capital if we choose to internally pursue the development of the program, or we may need to seek out and establish alternative collaboration partnerships with third-party collaboration partners for the program, which may not be possible, or we may not be able to do so on terms which are acceptable to us, in which case it may be necessary for us to limit the size or scope of the programs or increase our expenditures and seek additional funding by other means; and

[Table of Contents](#)

- our cash expenditures could increase significantly if it is necessary for us to hire additional employees and allocate scarce resources to the development and commercialization of the NaP2b program.

Any of these events would have a material adverse effect on our results of operations and financial condition.

We may not be successful in our efforts to develop our products candidates that are at an early stage of development or expand our pipeline of product candidates.

A key element of our strategy is to expand our pipeline of products candidates utilizing our proprietary drug discovery and design platform and to advance such product candidates through clinical development. Those product candidates that are in the discovery and lead identification stages of preclinical development and will require substantial preclinical and clinical development, testing and regulatory approval prior to commercialization. In particular, tenapanor and RDX022 are our only product candidates in clinical trials and all of our other product candidates are in the preclinical stage with significant research and development required before we could begin clinical studies. Of the large number of drugs in development, only a small percentage of such drugs successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to continue to fund our research programs, there can be no assurance that any product candidates will reach the clinic or be successfully developed or commercialized.

Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Although our research and development efforts to date have resulted in several development programs, we may not be able to develop product candidates that are safe, effective and well-tolerated. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- the research methodology used and our drug discovery and design platform may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective, well-tolerated or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe, effective and well-tolerated by patients, the medical community or third-party payors, if applicable.

Even if we are successful in continuing to expand our pipeline, through our own research and development efforts or by pursuing in-licensing or acquisition of product candidates, the potential product candidates for which we identify or acquire rights may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize a product pipeline, we may not be able to generate revenue from product sales in future periods or ever achieve profitability.

Our proprietary drug discovery and design platform, and, in particular, APECCS, is a new approach to the discovery, design and development of new product candidates and may not result in any products of commercial value.

We have developed a proprietary drug discovery and design platform to enable the identification, screening, testing, design and development of new product candidates, and we recently enhanced this platform with the addition of APECCS. We plan to utilize APECCS to identify new and potentially novel targets in the GI tract. However, there can be no assurance that APECCS will be able to identify new targets in the GI tract or that any of these potential targets or other aspects of our proprietary drug discovery and design platform will yield product candidates that could enter clinical development and, ultimately, be commercially valuable.

Although we expect to continue to enhance the capabilities of our APECCS system by advancing the cell culture and screening process and/or acquiring new technologies to broaden the scope of APECCS, we may not be successful in any of our enhancement and

[Table of Contents](#)

development efforts. In addition, we may not be able to enter into agreements on suitable terms to utilize technologies required to exploit certain capabilities of APECCS, and in such case, we may be forced to limit our use or further development of APECCS, or to modify APECCS for continued use. It may not be possible to modify APECCS in manner that avoids the utilization of certain technologies, without materially and adversely affecting the performance of APECCS or without incurring substantial cost and delay in advancement of the system. In addition, we may not be successful in developing the conditions necessary to grow multiple segments of intestine or from multiple species, or otherwise develop assays or cell cultures necessary to expand these capabilities. If our enhancement or development efforts are unsuccessful, we may not be able to advance our drug discovery capabilities as quickly as we expect or identify as many potential drugable targets as we desire.

We rely on third parties to conduct some of our preclinical and nonclinical studies and all of our 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 or commercialize our product candidates.

We do not have the ability to independently conduct clinical trials and, in some cases, preclinical or nonclinical studies. 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 some of our preclinical and nonclinical studies and all of 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 good laboratory practices, or GLPs, for preclinical and nonclinical studies, and good clinical practices, or 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, or EEA, and comparable foreign regulatory authorities for all of our products in preclinical and clinical development, respectively. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third party contractors fail to comply with applicable regulatory requirements, including GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the European Medicines Agency, or 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 current good manufacturing practices or cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Even if our product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success, which will depend, in part, upon the degree of acceptance among physicians, patients, patient advocacy groups, health care payors and the medical community.

Even if our product candidates obtain FDA or other regulatory approvals, and are ultimately commercialized, our product candidates may not achieve market acceptance among physicians, patients, third-party payors, patient advocacy groups, health care payors and the medical community. Market acceptance of our product candidates for which marketing approval is obtained depends on a number of factors, including:

- the efficacy of the products as demonstrated in clinical trials;
- the prevalence and severity of any side effects and overall safety and tolerability profile of the product;
- the clinical indications for which the product is approved;
- advantages over existing therapies;
- acceptance by physicians, major operators of clinics and patients of the product as a safe, effective and well-tolerated treatment;
- relative convenience and ease of administration of our products;
- the potential and perceived advantages of our product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the cost of treatment in relation to alternative treatments and willingness to pay for our products, if approved, on the part of physicians and patients;
- the availability of alternative products and their ability to meet market demand;

[Table of Contents](#)

- the strength of our or our collaboration partners' marketing and distribution organizations;
- the quality of our relationships with patient advocacy groups; and
- sufficient third-party coverage or reimbursement.

Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations.

Our product candidates may cause undesirable side effects or have other properties that could delay our clinical trials, or delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any. If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product candidate, the ability to market the product candidates could be compromised.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, result in the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities or limit the commercial profile of an approved label. To date, patients treated with tenapanor have experienced drug-related side effects including diarrhea, nausea, flatulence, abdominal discomfort, abdominal pain, abdominal distention and changes in electrolytes, and in the Phase 2b evaluating tenapanor for the treatment of hyperphosphatemia in CKD-5D patients, we observed that the rate of diarrhea and the discontinuation rate due to diarrhea at the highest doses was higher than expected based upon the results of previous clinical trials. In the event that trials conducted by us with tenapanor or trials we conduct with our other product candidates, reveal an unacceptable severity and prevalence of these or other side effects, such trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of tenapanor, or any such other product candidate, for any or all targeted indications. Additionally, despite a positive efficacy profile, the prevalence and/or severity of these or other side effects could cause us to cease further development of a product candidate for a particular indication, or entirely. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, in the event that any of our product candidates receives regulatory approval and we or others later identify undesirable side effects caused by one of our products, a number of potentially significant negative consequences could occur, including:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we 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 Strategies, or REMS, plan that may require creation of a Medication Guide outlining the risks of such side effects for distribution to patients, as well as elements to assure safe use of the product, such as a patient registry and training and certification of prescribers;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of 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 from achieving or maintaining market acceptance of a particular product candidate, if approved, and could result in the loss of significant revenue to us, which would materially and adversely affect our results of operations and business.

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 and RDX022, as well as our product candidates, would compete against existing treatments. For example, tenapanor will, if approved,

[Table of Contents](#)

compete directly with phosphate binders for the treatment of hyperphosphatemia in patients with CKD-5D, including sevelamer hydrochloride (Renagel) and sevelamer carbonate (Renvela), which were launched by Genzyme. Synthon announced the successful completion of a Phase 3 multicenter, randomized, double-blind, multiple-dose, crossover trial in Europe to compare safety and demonstrate equivalence of serum phosphate control of Synthon sevelamer carbonate tablets to Renvela tablets in chronic kidney disease patients on hemodialysis in April 2014. Currently, several pharmaceutical companies are distributing Synthon manufactured sevelamer carbonate tablets in multiple European countries including, but not limited to, the United Kingdom, Spain, Sweden and Denmark. In addition to the currently marketed phosphate binders, Keryx has received FDA approval for ferric citrate (Auryxia), an iron-based binder, that is also approved in Japan and we are aware of ferrogate (Alpharen), an iron-based binder in Phase 2 being developed by Opko Health. Additionally, RDX022, if approved, will compete directly with Kayexalate and its generic equivalents, known as sodium polystyrene sulfonate, on the market in the United States. We are also aware of two products for which regulatory approval in the United States has been sought for treatment of hyperkalemia, patiromer from Relypsa and ZS-9 from ZS Pharma.

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 Dulcolax), 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 relieve temporary constipation. We are also aware of two prescription drugs currently on the U.S. market that are approved to treat IBS-C, Linzess (linaclotide), which was developed by Ironwood Pharmaceuticals and is approved for IBS-C and chronic constipation in both the United States and in Europe, and Amitiza (lubiprostone), which was first approved in the United States in 2006 and is currently marketed by Sucampo and Takeda for treatment of chronic idiopathic constipation, or CIC, IBS-C and opioid induced constipation, or OIC. Additionally, Synergy is currently conducting Phase 3 clinical trials of Plecanatide for the treatment of CIC and IBS-C.

It is possible that our competitors will develop and market drugs or other treatments that are 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 currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to commercialize tenapanor and RDX022, or any of our other product candidates.

We currently do not have a sales organization. In order to promote tenapanor and RDX022, either alone, or with a collaboration partner, and in order to commercialize or co-promote any of our other product candidates, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In order to commercialize tenapanor or RDX022 outside of the United States, we expect to enter into collaborative relationships with one or more third parties. Additionally, in order to commercialize tenapanor for IBS-C, we expect to enter into a collaborative relationship with one or more third parties in the United States to address the primary care market. There can be no assurances that we will be successful in establishing such relationships in a timely manner or on terms that are acceptable to us. If one or more of our product candidates receives regulatory approval, we expect to establish a specialty sales organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming. As a company, we have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, comply with regulatory requirements applicable to the marketing and sale of drug products and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products.

We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates.

[Table of Contents](#)

We rely completely on third parties to manufacture our preclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidate. Our business would be harmed if those third parties fail to obtain approval of the FDA, Competent Authorities of the Member States of the EEA or comparable regulatory authorities, fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in the conduct of our preclinical and clinical studies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers to manufacture any drug products must be approved by the FDA pursuant to inspections that will be conducted after an NDA is submitted to the FDA. We do not control the manufacturing process of our product candidates, and we are completely dependent on our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of both active drug substances and finished drug products. We are completely dependent upon AstraZeneca's cooperation to achieve a smooth transition of the manufacturing process to our contract manufacturers and should AstraZeneca fail to provide such cooperation, our development plans for tenapanor could be significantly delayed, and the costs we incur in connection with the transfer could be substantially increased.

If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a limited number of suppliers for raw materials that we use to manufacture our drugs, and there may be a need to identify alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical studies, and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Although we generally do not begin a clinical study unless we believe we have on hand, or will be able to manufacture, a sufficient supply of a product candidate to complete such study, any significant delay or discontinuity in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing, and potential regulatory approval of our product candidates, which could harm our business and results of operations.

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

The pricing, coverage and reimbursement of our product candidates, if approved, 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 such as ours, assuming approval. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates 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 may not be able to successfully commercialize our product candidates. 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, or CMS, an agency within the U.S. 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.

In July 2010, CMS released its final rule to implement a bundled prospective payment system for the treatment of ESRD patients as required by the Medicare Improvements for Patients and Providers Act, or MIPPA. The bundled payment covers a bundle of items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at

[Table of Contents](#)

their home, including the cost of certain routine drugs. The final rule delayed the inclusion of oral medications without intravenous equivalents in the bundled payment until January 1, 2014 and in April 2014, President Obama signed the Protecting Access to Medicare Act of 2014, which further extends this implementation date to January 1, 2024. As a result of the recent legislation, beginning in 2024, ESRD-related drugs will be included in the bundle and separate Medicare reimbursement will no longer be available for such drugs, as it is today under Medicare Part D. While it is too early to project the full impact bundling may have on the industry, the impact could potentially cause dramatic price reductions for tenapanor and RDX022, if approved. We may be unable to sell tenapanor and/or RDX022, 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 increase faster than increases in reimbursement levels.

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 our product candidates. 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 new products approved 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 any of our product candidates 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.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. 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 our product candidates;
- 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 product candidates.

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. We currently carry product liability insurance covering use in our clinical trials in the amount of \$10.0 million in the aggregate. Although we maintain such 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.

[Table of Contents](#)

We are highly dependent on the services of our President and Chief Executive Officer, Michael Raab, our Executive Vice President and Chief Scientific Officer, Jeremy Caldwell, Ph.D., and our Senior Vice President of Drug Development, David Rosenbaum, Ph.D. If we are not able to retain these members of our management team, or recruit additional management, clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified personnel. In particular, we are highly dependent upon Michael Raab, our President and Chief Executive Officer, Jeremy Caldwell, Ph.D., our Chief Scientific Officer and David Rosenbaum, Ph.D., our Senior Vice President of Drug Development. The loss of services of any of these individuals could delay or impair the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates. Although we have entered into employment agreements with our senior management team, including Mr. Raab and Drs. Caldwell and Rosenbaum, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. In addition to the competition for personnel, the San Francisco Bay area in particular is characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

We will need to continue to increase the size of our organization, and we may experience difficulties in managing growth.

We will need to continue to expand our clinical, managerial, operational, finance and other resources in order to manage our operations, preclinical and clinical trials, research and development activities, regulatory filings, manufacturing and supply activities, and any marketing and commercialization activities. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- expand our general and administrative functions;
- establish and build a marketing and commercial organization;
- identify, recruit, retain, incentivize and integrate additional employees;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, legal, financial and management controls, reporting systems and procedures.

If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

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, or 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.

[Table of Contents](#)

In addition, we are in the process of implementing enterprise resource planning, or ERP, system for our company. An ERP system is intended to combine and streamline the management of our financial, accounting, human resources, sales and marketing and other functions, enabling us to manage operations and track performance more effectively. However, an ERP system will require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Additionally, during the conversion process, we may be limited in our ability to convert any business that we acquire to the ERP. Any disruptions or difficulties in implementing or using an ERP system could adversely affect our controls and harm our business, including our ability to forecast or make sales and collect our receivables. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

We are subject to Section 404 of The Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the Securities and Exchange Commission, or SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our IPO (December 31, 2019), (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.0 billion, or (3) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (4) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

To date, we have not conducted any other review of our internal control for the purpose of providing the reports required by Section 404 and the related SEC rules. During the course of our review and testing, 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 form additional collaboration partnerships in the future, and we may not realize the benefits of such collaborations.

We may form collaboration partnerships, create joint ventures or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. In particular, we expect to form one or more collaboration partnerships in connection with the commercialization of tenapanor outside of the United States, and in the United States for IBS-C to address the primary care market, if approved. We have historically engaged, and intend to continue to engage, in partnering discussions with a range of pharmaceutical and biotechnology companies and could enter into new collaboration partnerships at any time. We face significant competition in seeking appropriate collaboration partners, and the negotiation process to secure appropriate terms is time-consuming and complex. Any delays in identifying suitable 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. Moreover, we may not be successful in our efforts to establish such a collaboration partnership for any future product candidates and programs on terms that are acceptable to us, or at all. This may be because our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, and/or third parties may not view our product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile. Even if we are successful in entering into a collaboration partnership or license arrangement, there is no guarantee that the collaboration partnership will be successful, or that any future 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.

[Table of Contents](#)

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

We intend to consider strategic transactions, such as acquisitions of companies, asset purchases, and or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, 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 to pay for acquisitions;
- 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, 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 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 expect that we will be subject to additional risks related to entering into these international business markets and relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing 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

[Table of Contents](#)

- 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 research and 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, research 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.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such 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 programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

We may be adversely affected by the current 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 and inflationary pressures. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. We cannot anticipate all the ways in which the current global economic climate and global financial market conditions could adversely impact our business.

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, the volatility in the financial markets could cause significant fluctuations in the interest rate and currency markets. We currently do not hedge for these risks. The foregoing events, in turn, could adversely affect our financial condition and liquidity. In addition, if economic challenges in the United States result in widespread and prolonged unemployment, either regionally or on a national basis, prior to the effectiveness of certain provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively known as the Affordable Care Act, 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.

[Table of Contents](#)

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.

Our corporate headquarters and other facilities are 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 headquarters, 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

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor any of our collaboration partners is permitted to market any drug product in the United States until we receive marketing approval from the FDA. We have not submitted an application or obtained marketing approval for any of our product candidates anywhere in the world. Obtaining regulatory approval of a new drug application, or NDA, can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable United States and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

- warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of regulatory approval of products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending NDAs or supplements to approved NDAs.

Prior to obtaining approval to commercialize a drug candidate in the United States or abroad, we or our collaboration partners must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such drug candidates are safe and effective for their intended uses. The number of nonclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our drug candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering drug candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a drug candidate for any or all targeted indications.

[Table of Contents](#)

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical studies, and depends upon numerous factors. The FDA and comparable foreign authorities have substantial discretion in the approval process and we may encounter matters with the FDA or such comparable authorities that requires us to expend additional time and resources and delay or prevent the approval of our product candidates. For example, the FDA may require us to conduct additional studies or trials for drug product either prior to or post-approval, such as additional drug-drug interaction studies or safety or efficacy studies or trials, or it may object to elements of our clinical development program such as the number of subjects in our current clinical trials from the United States. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or result in a decision not to approve an application for regulatory approval. Despite the time and expense exerted, failure can occur at any stage. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our, or our collaboration partners', clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which approval is sought;
- the FDA or comparable foreign regulatory authorities may disagree with the interpretation of data from preclinical studies or clinical studies;
- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- we or our collaboration partners may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers responsible for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical studies, may result in our failure and/or that of our collaboration partners to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. Additionally, if the FDA requires that we conduct additional clinical studies, places limitations in our label, delays approval to market our product candidates or limits the use of our products, our business and results of operations may be harmed.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, any product candidates, if approved, could be subject to labeling and 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, adverse event reporting, 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 GCPs 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 letters, fines or holds on clinical trials;

[Table of Contents](#)

- 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 our product candidates. 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 that could prevent, limit or delay regulatory approval of our product candidates. 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 and our contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. 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 candidates for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates 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. 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. Some of our contract manufacturers have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent suspension of production or closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be materially harmed.

[Table of Contents](#)

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. If tenapanor, RDX022 or our other product candidates receive marketing approval, we and our collaborating partners, if any, will be restricted from marketing the product outside of its approved labeling, also referred to as off-label promotion. However, physicians may nevertheless prescribe an approved product to their patients in a manner that is inconsistent with the approved label, which is an off-label use. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations regarding off-label promotion. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our product candidates for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Over the past several years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Food, Drug and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "qui tam" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim, or caused a false claim to be submitted, to the government for payment. The person bringing a qui tam suit is entitled to a share of any recovery or settlement. Qui tam suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a qui tam suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the 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.

If approved, tenapanor, RDX022 and our other product candidates 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, nausea, flatulence, abdominal discomfort, abdominal pain, abdominal distention and changes in electrolytes and in the Phase 2b evaluating tenapanor for the treatment of hyperphosphatemia in CKD-5D patients, we observed that the rate of diarrhea and the discontinuation rate due to diarrhea at the highest doses was higher than expected based upon the results of previous clinical trials. 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.

[Table of Contents](#)

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: (1) FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the reporting of true and accurate financial information and data. 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 be in compliance with such laws or regulations. 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, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, 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 28 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, or MA. Before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not be able to file for regulatory approvals or to do so on a timely basis, and even if we do file we may not receive necessary approvals to commercialize our products in any market.

We and our collaboration partners, if any, 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.

Although we do not currently have any products on the market, once we begin commercializing our products, we and our collaboration partners, if any, 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;
- 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;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

[Table of Contents](#)

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal physician sunshine requirements under the Affordable Care Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers 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 marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts; 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. Further, the Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that 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. 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.

[Table of Contents](#)

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 Affordable Care Act 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 Affordable Care Act, 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 agree to offer 50% 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.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, the ATRA was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals.

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. 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.

Risks Related to Intellectual Property

We may become subject to claims alleging infringement of third parties' patents or proprietary rights and/or claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, delay or prevent the development and commercialization of tenapanor, RDX022 or our other product candidates, or prevent or delay the continued use of our drug discovery and development platform, including APECCS.

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. There can be no assurances that we will not be subject to claims alleging that the manufacture, use or sale of tenapanor, RDX022 or any other product candidates, or that the use of our drug discovery and development platform, including APECCS 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 tenapanor, RDX022 or other product candidates or by the use of APECCS. 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 tenapanor, RDX022 or our other product candidates, or by the use of APECCS.

We may be subject to third-party patent infringement claims in the future against us or our that would cause us to incur substantial expenses and, if successful against us, 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 research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. In addition, if a patent infringement suit were brought against us regarding the use of APECCS, we could be forced to stop our use of APECCS or modify our processes to avoid infringement, which may not be possible at a reasonable cost, if at all, and which could result in substantial delay in our use of APECCS for the discovery of new product candidates or potential targets. 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, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease our use of APECCS or some other aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. 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.

[Table of Contents](#)

In addition to infringement claims against us, 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 United States Patent and Trademark Office, or 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.

If our intellectual property related to our product candidates is not adequate or if we are not able to protect our trade secrets or our confidential information, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates, our drug discovery and development platform and our development programs. Any disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position 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 our product candidates is successfully challenged, then our ability to commercialize such product candidates could be negatively affected, and we may face unexpected competition that could have a material adverse impact on our business. Further, if we encounter delays in our clinical trials, the period of time during which we or our collaboration partners could market tenapanor or other product candidates 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 the 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 candidate, we would lose at least part, and perhaps all, of the patent protection on such 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 are actively involved in the

[Table of Contents](#)

discovery and design of our 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 our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, if any, one of the U.S. patents covering each of such approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. 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. Nevertheless, 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.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation, including the Leahy-Smith America Invents Act signed into law on September 16, 2011. That Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and new venues and opportunities for competitors to challenge patent portfolios. Because of that Act, the U.S. patent system is now a “first to file” system, which may make it more difficult to obtain patent protection for inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners’ patent applications and the enforcement or defense of our or our collaboration partners’ issued patents, all of which could materially adversely affect our business, results of operations and financial condition.

The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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.

[Table of Contents](#)

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:

- results from, or any delays in, clinical trial programs relating to our product candidates, including the ongoing and planned clinical trials for tenapanor and RDX022;
- announcements relating to our collaboration partnership with Sanofi regarding its option to develop and commercialize NaP2b inhibitors;
- ability to commercialize or obtain regulatory approval for our product candidates, or delays in commercializing or obtaining regulatory approval;
- announcements of regulatory approval or a complete response letter to tenapanor or RDX022, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements relating to future collaboration partnerships;

Table of Contents

- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our product candidates;
- the success of our testing and clinical trials;
- 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;
- 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;
- 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.

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

As of June 30, 2015, entities affiliated with New Enterprise Associates, a venture capital fund associated with one of our directors, collectively beneficially hold approximately 41.6% of our capital stock, including warrants exercisable for shares of our common stock, and together our executive officers, directors, and affiliated stockholders beneficially owned approximately 45.8% of our capital stock, including warrants exercisable for shares of our common stock. Therefore, these stockholders may be able to determine all matters requiring stockholder approval, and the entities affiliated with New Enterprise Associates alone, will have significant ability to influence decisions through their ownership position. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that certain stockholders may feel are in their best interest as one of our stockholders.

We are an “emerging growth company” and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. If some investors find our common stock less attractive as a result of our reliance on the JOBS Act exemption, there may be

[Table of Contents](#)

a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our IPO (December 31, 2019), (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.0 billion, or (3) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (4) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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.

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 June 30, 2015, we had 25,911,537 shares of common stock outstanding. Of those shares, 11,461,794 were held by current directors, executive officers and other affiliates, or may otherwise be subject to Rule 144 under the Securities Act of 1933, or the Securities Act.

In addition, as of June 30, 2015, 1,271,296 shares of common stock that are subject to outstanding options, were eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, and Rule 144 and Rule 701 under the Securities Act. In addition, approximately 7.2 million of our shares outstanding, and approximately 2.2 million shares underlying outstanding warrants will be eligible for sale in the public market after the Registration Statement on Form S-3 filed on July 13, 2015 becomes effective, and subject in certain circumstances to additional restrictions. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of approximately 9.7 million shares of our outstanding common stock as of June 30, 2015, are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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 66 2/3% 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;

[Table of Contents](#)

- the required approval of at least 66 2/3% 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 acquiror from conducting a solicitation of proxies to elect the acquiror'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 indemnitees, 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.

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

Unregistered Sale of Equity Securities

On June 2, 2015, we entered into a Securities Purchase Agreement, or the Purchase Agreement, with the purchasers named therein, or the Purchasers. Pursuant to the Purchase Agreement, on June 5, 2015 we sold an aggregate of 7,242,992 shares of common stock, or the Shares, and warrants, or the Warrants, to purchase 2,172,898 shares of common stock, or Warrant Shares, for aggregate gross proceeds of approximately \$77.8 million, or net proceeds, after deducting issuance costs, of approximately \$74.4 million. The purchase price for each Share was \$10.70, which was equal to the consolidated closing bid price on the NASDAQ Global Market on the day of pricing, June 2, 2015. The purchase price for each Warrant was equal to \$0.125 for each Warrant Share, consistent with NASDAQ Global Market requirements for an “at the market” offering, and the Warrants are exercisable at an exercise price of \$13.91 per share. Investors participating in the offering include entities associated with New Enterprise Associates, a venture capital firm that is one of our significant shareholders, and a combination of new and existing investors, including RA Capital Management, Broadfin Capital LLC, Cormorant Asset Management LLC, Foresite Capital Management, LLC, Rock Springs Capital Management LP, and a fund managed by Sabby Capital, LLC. Leerink Partners LLC acted as the sole placement agent of the offering and Wedbush PacGrow acted as a financial advisor in connection with the offering. We expect to use the net proceeds from the offering to develop our drug candidates, tenapanor and RDX022.

In connection with the Purchase Agreement, we entered into a Registration Rights Agreement, or the Registration Rights Agreement, with the Purchasers. Pursuant to the Registration Rights Agreement, we agreed to prepare and file a registration statement with the Securities and Exchange Commission, or SEC, by July 20, 2015 for purposes of registering the resale of the Shares, the Warrant Shares, and any shares of common stock issued as a dividend or other distribution with respect to the Shares or Warrant Shares. We filed the registration statement on July 13, 2015 and it was declared effective by the SEC on July 20, 2015. We also agreed, among other things, to indemnify the selling holders under the registration statements from certain liabilities and to pay all fees and expenses (excluding underwriting discounts and selling commissions and all legal fees of any selling holder) incident to our obligations under the Registration Rights Agreement.

The financing is exempt from registration pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) of the Securities Act of 1933, as amended, and Regulation D under the Securities Act of 1933, as amended.

Use of Proceeds

On June 18, 2014, the U.S. Securities and Exchange Commission declared effective our registration statement on Form S-1 (File No. 333-196090), as amended in connection with our IPO.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

[Table of Contents](#)**ITEM 6. Exhibits**

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Incorporated by Reference</u>			
		<u>Form</u>	<u>Date</u>	<u>Number</u>	<u>Filed Herewith</u>
3.1	Amended and Restated Certificate of Incorporation.	8-K	6/24/2014	3.1	
3.2	Amended and Restated Bylaws.	8-K	6/24/2014	3.2	
4.1	Reference is made to exhibits 3.1 and 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	6/18/2014		
10.1	Termination Agreement by and between Ardelyx, Inc. and AstraZeneca AZ, dated June 2, 2015.				X
10.2	Securities Purchase Agreement by and among Ardelyx, Inc. and the purchasers signatory thereto, dated June 2, 2015.				X
10.3	Registration Rights Agreement by and among Ardelyx, Inc. and the investors signatory thereto, dated June 2, 2015.	S-3	7/13/2015	99.1	
10.4	Form of Warrant issued pursuant to the Securities Purchase Agreement by and among Ardelyx, Inc. and the purchasers signatory thereto, dated June 2, 2015.	S-3	7/13/2015	4.3	
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C §1350.				X
101	The following financial statements, formatted in XBRL: (i) Condensed Balance Sheets as of June 30, 2015 and December 31, 2014, (ii) Condensed Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2015 and 2014; (iii) Condensed Statements of Cash Flows for the six months ended June 30, 2015 and 2014; and (v) Notes to Unaudited Condensed Financial Statements.				X

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: August 12, 2015

Ardelyx, Inc.

By: /s/ Mark Kaufmann

Mark Kaufmann
Chief Financial Officer
(Principal Financial Officer)

CONFIDENTIAL

EXECUTION COPY

TERMINATION AGREEMENT

This Termination Agreement (the “**Termination Agreement**”) is entered into as of the 2nd day of June, 2015 by and between **AstraZeneca AB (publ)**, a Swedish corporation with corporate identity no. 556011-7482 and a place of business at 431 83 Mölndal, Sweden (“**AstraZeneca**”) and **Ardelyx, Inc.**, a Delaware corporation having its principal place of business at 34175 Ardenwood Boulevard, Fremont, California, United States of America 94555 (“**Ardelyx**”). **Ardelyx** and **AstraZeneca** are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

RECITALS

Whereas, **AstraZeneca** and **Ardelyx** are parties to that certain License Agreement dated as of October 4, 2012, as amended by Amendment Number One to License Agreement dated as December 23, 2013 (together, the “**License Agreement**”).

Whereas, under the License Agreement, **Ardelyx** granted **AstraZeneca** a worldwide, exclusive license to its proprietary compounds known as NHE3 inhibitors, including its lead compound known as either RDX5791, AZD1722 or tenapanor.

Whereas, **AstraZeneca** has determined that it no longer desires to continue its activities under the License Agreement, and the Parties wish to set forth the terms and conditions of the termination of the License Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

**ARTICLE 1.
DEFINITIONS AND CONSTRUCTION**

1.1 Undefined Capitalized Terms. The capitalized terms used, but not defined in this Termination Agreement shall have the meanings assigned in the License Agreement.

1.2 New Definitions. The following terms shall have the following meanings in this Termination Agreement:

“**AZ Non-Clinical Work**” shall have the meaning assigned in Section 3.2.

“**Clinical Trial Material**” or “**CTM**” shall have the meaning assigned in Section 4.1(a).

“**CTM Transfer Price**” shall have the meaning described in Section 4.1(c).

“**Initial Deliverables**” shall have the meaning assigned in Section 4.2.

“**Licensee**” shall mean (i) any Person to which **Ardelyx** grants a license to Exploit the Licensed Compounds or Licensed Products; provided, that, a Licensee shall not include (a) any Person that is an Affiliate of **Ardelyx**, (b) any Person that is a Distributor, or (c) any Person that (x) is granted a license to Exploit the Licensed Compounds or Licensed Products solely to enable such Person to provide contract research or development services or contract manufacturing services for **Ardelyx** or its Affiliates, and (y) does not have the right to

distribute, market or sell the Licensed Product, and (ii) any Person to which Ardelyx completes a sale of assets that includes all rights to Exploit the Licensed Compounds and Licensed Products.

“**MSA**” shall have the meaning described in Section 4.1(b).

“**Partnering Revenue**” shall mean the following forms of consideration received by Ardelyx or any of its Affiliates from a Licensee in respect of Licensed Products:

- (a) any upfront or any license maintenance fee attributable to the Licensed Products;
- (b) any milestone payments (including development, regulatory and sales-based milestone payments) attributable to the Licensed Products;
- (c) amounts paid in the form of a profit share solely to the extent that any such payment represents a sharing of actual profit from sales of a Licensed Product, and not a reimbursement for Ardelyx’s costs and expenses incurred in connection with the Exploitation of the Licensed Product;
- (d) payments for the supply of Licensed Products (excluding the portion of such payments that reimburses Ardelyx for its cost of goods for such Licensed Products or any component thereof);
- (e) payments for performance of research or development activities associated with Licensed Products (excluding the portion of such payments that reimburses Ardelyx for its actual cost of performing such research or development activities); and
- (f) any consideration received by Ardelyx or any of its Affiliates for equity or debt securities issued by Ardelyx or any of its Affiliates to a Licensee (excluding the amount equal to the fair market value of such securities, which shall be determined by the method used to determine the amount paid by such Licensee or if no such method is specified, the average closing price of such securities for the twenty (20) Business Days preceding the date of issuance to such Licensee).

“**Royalties**” shall have the meaning assigned in Section 3.1(ii).

“**Termination Effective Date**” shall have the meaning assigned in Section 2.1.

1.3 Construction. Except where the context requires otherwise, whenever used in this Termination Agreement, the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders and the word “or” has the inclusive meaning represented by the phrase “**and/or**”. Whenever this Termination Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The term “**including**” or “**includes**” as used in this Termination Agreement means including, without limiting the generality of any description preceding such term. The article, section, and subsection headings contained in this Termination Agreement are for the purposes of convenience only and are not intended to define or limit the contents of such articles, sections, and subsections. The wording of this Termination Agreement shall be deemed to be the wording mutually chosen by the Parties and no rule of strict construction shall be applied against any Party.

**ARTICLE 2.
GENERAL PROVISIONS REGARDING TERMINATION**

2.1 Termination Date. Pursuant to Section 5.2(a)(i) of the License Agreement, AstraZeneca hereby terminates the License Agreement effective as of June 2, 2015 (the “**Termination Effective Date**”). Ardelyx waives its right to receive thirty (30) days notice of termination, and accepts AstraZeneca’s notice of termination under Section 5.2(a)(i) and agrees that the effective date of termination shall be June 2, 2015.

2.2 Consequences of Termination. The Parties agree that the termination is an AZ Triggered Termination, and the Parties further agree that the AZ Triggered Termination is not a termination for material safety concerns. The rights and obligations of the Parties following the termination of the License Agreement shall be governed by the surviving provisions of the License Agreement as set forth in Section 14.7 of the License Agreement and Section 14.3, except to the extent that any provisions of the License Agreement are explicitly modified, clarified or deleted as set forth in this Termination Agreement.

2.3 Sole Program Know-How. The Parties acknowledge that certain formulation work conducted by, or on behalf of AstraZeneca under the License Agreement, the results of which is Sole Program Know-How under the License Agreement, may give rise to a patentable invention. AstraZeneca has elected not pursue its right, under Section 11.4(a) of the License Agreement, to file a Patent covering or claiming such Sole Program Know-How, and has given Ardelyx reasonable notice to that effect as required by Section 11.4(e) of the License Agreement. The rights granted to Ardelyx under Section 11.4(e) of the License Agreement shall survive termination of the License Agreement; provided that the timeframe during which Ardelyx may elect to file the relevant Patent shall be extended until December 31, 2015. During such time, AstraZeneca agrees not to take any actions that would impact upon Ardelyx’s ability to obtain patent protection for any invention arising from the formulation work conducted by AstraZeneca.

**ARTICLE 3.
CLARIFICATIONS AND MODIFICATIONS OF SECTION 14.3**

3.1 General. Section 14.3 shall continue in full force and effect except for the following clarifications, modifications and deletions:

(i) **Section 14.3(a).** Section 14.3(a) shall apply, and in addition, the licenses and rights granted to AstraZeneca to the Licensed Technology shall continue to the extent and for so long as is necessary to permit AstraZeneca to satisfy its obligations under this Termination Agreement.

(ii) **Section 14.3(c).** The royalty consideration for the exclusive worldwide license grant to Ardelyx described in Section 14.3(c)(i), and the non-exclusive worldwide license described in Section 14.3(c)(ii), shall be the payments described in Section 14.3(m) subsections (iii) and (iv) (as amended by Section 3.1(vi) below) (the “Royalties”). At such time as the Royalties have been paid in full, the exclusive license granted in Section 14.3(c)(i) and non-exclusive license granted in Section 14.3(c)(ii) shall be fully paid licenses to Ardelyx. The non-exclusive license set forth in Section 14.3(c)(iii) is not a royalty-bearing license and as such is fully paid as of the Termination Effective Date.

(iii) **Section 14.3(h)**. In addition to the obligations set forth in Section 14.3(h), within twenty (20) days of the Termination Effective Date, AstraZeneca shall provide Ardelyx with a list of and a copy of each agreement described in subsections (i) through (iii) of Section 14.3(h), in order to enable Ardelyx to determine the agreements, if any, with respect to which it will request assignment under Section 14.3(h). Notwithstanding the above, in lieu of providing a copy of those agreements described in subsections (i) through (iii) of Section 14.3(h) that AstraZeneca determines are not assignable to Ardelyx and may not be disclosed to Ardelyx due to the confidentiality restrictions contained therein, AstraZeneca shall list them on a schedule to be delivered to Ardelyx within twenty (20) days of the Termination Effective Date.

(iv) **Section 14.3(j)**. In addition to the obligations set forth in Section 14.3(j), within twenty (20) days of the Termination Effective Date, AstraZeneca shall provide Ardelyx with a list and a copy of each Third Party license described in Section 14.3(j) in order to enable Ardelyx to determine the Third Party licenses, if any, with respect to which it will request assignment under Section 14.3(j). If AstraZeneca has not entered into any Third Party licenses described in Section 14.3(j), AstraZeneca shall provide Ardelyx with such written confirmation that no such Third Party licenses have been obtained.

(v) **Section 14.3(1)**. In addition to the obligations set forth in Section 14.3(1) and in order to facilitate Ardelyx's knowledge of AZ Product Data, AstraZeneca shall, on or before September 30, 2015, provide Ardelyx with (a) copies of the electronic databases upon which the AZ Product Data is stored in such format as may be mutually agreed and acceptable to both Parties (which, with respect to raw data may include the deliver of paper documentation instead of electronic transfer if necessary), and (b) a list of all planned or currently in progress reports that will not be included in the electronic databases upon which the AZ Product Data is stored.

(vi) **Section 14.3(m)**. Section 14.3(m) shall be amended and restated to read in full as follows:

(m) In consideration of the licenses granted under Section 14.3(c) and any other rights granted under the above provisions in this Section 14.3, Ardelyx shall pay to AstraZeneca (i) an upfront payment of fifteen million U.S. dollars (U.S. \$15,000,000) within ten (10) days of the Termination Effective Date; (ii) royalty payments, calculated in accordance with Section 9.5 of the License Agreement, but as if all Net Sales by Ardelyx or its Affiliates or licensees in the Territory were Net Sales by AstraZeneca; *provided, however*, that the applicable royalty rate shall be ten percent (10%), and the royalty reduction provisions set forth in Sections 9.5(e), 9.5(f), 9.5(g) and 9.5(j) shall not apply to the calculations of Royalties, and (iii) twenty percent (20%) of all Partnering Revenue; *provided, however*, that the total amount to be paid by Ardelyx under subsections (i) through (iii) of this Section 14.3(m) shall not exceed ninety million U.S. dollars (U.S. \$90,000,000) in the aggregate. The rights and obligations of provisions of Sections 9.8 through 9.15 shall apply to the Net Sales by Ardelyx and its Affiliates and licensee and the royalties and other payments payable to AstraZeneca *mutatis mutandis*.

(vii) **Section 14.3(p)**. Section 14.3(p) shall be deleted.

3.2 Potential Future Joint Research. As of the Termination Effective Date, AstraZeneca has certain ongoing non-clinical experiments regarding the mechanism of action of tenapanor, and AstraZeneca has contemplated conducting certain additional non-clinical experiments with Licensed Compounds (collectively, “**AZ Non-Clinical Work**”). The AZ Non-Clinical Work that is ongoing as of the Termination Effective Date is described on **Exhibit B**. Ardelyx agrees that AstraZeneca shall have the right to finalize the AZ Non-Clinical Work described on **Exhibit B**. AstraZeneca shall not commence any new AZ Non-Clinical Work after the Termination Effective Date without the prior written consent of Ardelyx. Within thirty (30) days following the Termination Effective Date, AstraZeneca shall provide Ardelyx with a summary description of all AZ Non-Clinical Work that AstraZeneca proposes to commence after the Termination Effective Date. Ardelyx shall consider in good faith any request by AstraZeneca to commence new AZ Non-Clinical Work; *provided, that*, Ardelyx shall have the right to withhold its consent to the commencement of any new AZ Non-Clinical Work in its sole discretion. Any new AZ Non-Clinical Work approved by Ardelyx may be conducted by AstraZeneca at its sole cost and expense. All information, data and results from any AZ Non-Clinical Work shall be treated as AZ Product Data under the Agreement (regardless of when it arises) and subject to the provisions of Section 14.3 of the License Agreement.

AstraZeneca shall promptly disclose and provide to Ardelyx copies of any information, data and results from the AZ Non-Clinical Work.

**ARTICLE 4.
MANUFACTURING AND CTM SUPPLY; ADDITIONAL INITIAL
DELIVERABLES**

4.1 Manufacture and CTM Supply

(a) AstraZeneca will supply to Ardelyx, and Ardelyx will purchase from AstraZeneca, those quantities of Lead Licensed Product, Lead Licensed Compound and drug substance (the “**Clinical Trial Material**”, or “**CTM**”) described in Section 1 of **Exhibit A**.

(b) The Parties agree and acknowledge that a separate manufacturing and supply agreement (the “**MSA**”) is required to be entered into between the Parties to further govern the supply obligations undertaken by AstraZeneca hereunder. The Parties shall also enter into a separate Quality Assurance Agreement (the “**QAA**”) that shall define the manufacturing and supply quality responsibilities of the Parties for the Lead Licensed Compound and the Lead Licensed Product. The QAA shall further include provisions obligating AstraZeneca to report to Ardelyx any regulatory compliance issues with respect to AstraZeneca and/or its suppliers with respect to the Lead Licensed Compound and the Lead Licensed Product, as well as any critical quality non-conformances relating to the Lead Licensed Compound or Lead Licensed Product. The Parties entered into a Master Services Agreement and a Quality Assurance Agreement in connection with Ardelyx’s obligations with respect to the Initial Supply under the License Agreement, and the Parties agree that the MSA and the QAA entered into hereunder in connection with AstraZeneca’s obligations with respect to the CTM shall be in substantially the same form as those previously executed between the Parties, with only such changes as may be necessary to reflect AstraZeneca as the manufacturer and Ardelyx as the purchaser of the CTM. The MSA and QAA shall be executed as promptly as possible following the Termination Effective Date, but no later than thirty (30) days of the Termination Effective Date.

(c) In consideration of the delivery of the CTM, Ardelyx shall pay AstraZeneca a transfer price equal to the amounts paid by AstraZeneca to a Third Party for the Manufacture of the Licensed Compound utilized by AstraZeneca in the Manufacture of the CTM, plus a fee of ten percent (10%) of such amounts (the “**CTM Transfer Price**”); *provided, however*, that the total amount to be paid by Ardelyx for all CTM described in Section 1 of **Exhibit A** shall not exceed ten million U.S. dollars (U.S. \$10,000,000) in the aggregate. Within ten (10) days after the Termination Effective Date, AstraZeneca shall provide Ardelyx with an estimate of the CTM Transfer Price for the CTM described in Section 1 of **Exhibit A**, and shall also provide Ardelyx with documentation available at that time of the Third Party cost comprising the CTM Transfer Price. Ardelyx shall pay AstraZeneca seventy five percent (75%) of the estimated total CTM Transfer Price within forty-five (45) days after delivery of the CTM in Section 1(a) of **Exhibit A**. On or before December 1, 2015, AstraZeneca shall provide Ardelyx with documentation of the final CTM Transfer Price. Within forty-five (45) days after delivery of the CTM in Sections 1(b) and (c) of **Exhibit A**, Ardelyx shall pay AstraZeneca the remaining CTM Transfer Price; *provided, however*, that should the final CTM Transfer Price exceed the estimated CTM Transfer Price by more than ten percent (10%), Ardelyx shall not be obligated to pay any amounts in excess of such ten percent (10%) increase.

(d) As reimbursement to AstraZeneca for research and development expenses incurred by AstraZeneca under the License Agreement during 2015, and in consideration of the accelerated transfer of the AZ Product Data and INDs and the AstraZeneca resources necessary to manage and execute the delivery of the Initial Deliverables, all in order to facilitate the prompt start-up of Ardelyx planned development activities, Ardelyx shall pay to AstraZeneca ten million U.S. dollars (U.S.\$10,000,000) within ten (10) days of the Termination Effective Date.

(e) AstraZeneca shall as soon as reasonably practicable provide to Ardelyx, if Ardelyx so requests, all Information and Materials Controlled by AstraZeneca that are necessary or useful to Manufacture Licensed Compounds and Licensed Products. Such transfer shall take place as promptly as possible, but in any event shall be complete not later than July 1, 2015. In the event that Ardelyx elects not to obtain assignment of the Third Party contracts relating to the Manufacture of Licensed Compound, AstraZeneca shall cause its manufacturing contractors, to the extent reasonably possible, to provide to Ardelyx or its designee all reasonable assistance and transfer all Information and Materials Controlled by AstraZeneca that are necessary or useful to Manufacture the Licensed Compounds and the Licensed Products, including without limitation all production and quality control specifications and process and manufacturing technology, for the purpose of allowing Ardelyx or its designee to develop and establish such Manufacturing. Ardelyx shall have the right to disclose all such information to Third Parties for purposes of allowing Ardelyx to assess the feasibility of such Third Parties Manufacturing the Licensed Compounds and the Licensed Products and to allow such Manufacturing.

(f) The provisions of this Article 4 replace Section 8.4 of the License Agreement, which shall be deleted.

4.2 Additional Initial Deliverables. In addition to the delivery of the CTM, AstraZeneca will complete those activities and provide the Information and Materials described on **Exhibit A** (collectively, with the CTM, the “**Initial Deliverables**”). AstraZeneca agrees to use Commercially Reasonable Efforts to deliver the Initial Deliverables and perform the activities set forth in **Exhibit A** in such a manner and within such timelines as are set forth on **Exhibit A**.

4.3 Biological Material Storage. AstraZeneca shall, at least during an initial period of three (3) years, store, at its sole cost and expense, any non-clinical and human biological material obtained during the collaboration under the License Agreement. Both Parties shall be able to use the material for analysis, and AstraZeneca shall upon such request make the relevant material available to Ardelyx in a reasonable timeframe. Notwithstanding the above, AstraZeneca agrees that it will not use any biological materials obtained from clinical trial subjects treated with tenapanor for any analysis under this Section 4.3. After the initial storage period of three years, the Parties will discuss whether to continue the storage of the material, and any such continued storage shall require the written consent of both Parties.

ARTICLE 5. PUBLICATIONS AND PRESS RELEASE

5.1 Publications. AstraZeneca has provided Ardelyx with its proposed publication plan, which is set forth in **Exhibit C**, and Ardelyx and AstraZeneca agree to discuss the proposed publications in good faith. AstraZeneca agrees that it shall not publish or present any Confidential Information of Ardelyx or any AZ Product Data, other than in accordance with this Section 5.1. In the event that (i) Ardelyx agrees in principal to consent to a publication or presentation described on **Exhibit C**, (ii) a proposed publication is required by law, (iii) AstraZeneca determines, in good faith, that a proposed publication included in the "Clinical Trial" section on **Exhibit C** is required under either the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature announced on June 10, 2010 or the Good Publication Practice Guidelines issued by the International Society for Medical Publication Professionals, or (iv) the proposed publication is described on **Exhibit C** under the title "Real Work Evidence" and the subtitle "CKD US Kaiser," then AstraZeneca shall have the right to make such publication or presentation, subject to the following. AstraZeneca shall provide Ardelyx with the opportunity to review any such publication or presentation as early as practicable, but at least sixty (60) days prior to its intended submission for publication or presentation. Ardelyx shall respond to AstraZeneca regarding any proposed submission or presentation within thirty (30) days of its receipt from AstraZeneca. With respect to those publications or presentations covered only by subsection (i) above, AstraZeneca agrees not to make any submission for publication or to make such presentation until Ardelyx has provided its written consent, which shall not be unreasonably withheld. With respect to those publications or presentations described in subsection (ii) or subsection (iii) above, Ardelyx shall have the right to review and provide comments and suggestions as to the timing and content of such publication or presentation, but AstraZeneca shall not require Ardelyx's consent for such publication or presentation. In addition, Ardelyx shall have the right to review, but not to consent to, the publications described in subsection (iv) above. AstraZeneca agrees to consider any comments or suggestions provided by Ardelyx in good faith.

5.2 Press Release. Ardelyx intends to issue a press release regarding the termination of the License Agreement contemplated by this Termination Agreement, and Ardelyx agrees to provide a draft of the press release to AstraZeneca for comment before it is released. Any language in such press release relating to AstraZeneca must be approved by AstraZeneca prior to publication, with such consent not to be unreasonably withheld. For any other comments provided by AstraZeneca, such comments shall be considered in good faith by Ardelyx prior to publication.

ARTICLE 6.
REPRESENTATIONS, WARRANTIES AND COVENANTS

6.1 Representations, Warranties and Covenants.

(a) Each of the Parties hereby represents and warrants to the other Party that:

(i) this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery, and performance of the Agreement by such Party does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a Party or by which it is bound, nor violate any law or regulation of any court, Governmental Body, or administrative or other agency having jurisdiction over it;

(ii) it is not aware of any government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Laws, currently in effect, necessary for, or in connection with, the transaction contemplated by this Termination Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Termination Agreement and such other agreements (save for Regulatory Approvals, INDs and similar regulatory authorizations that may be necessary for the transfer of Regulatory Development as contemplated hereunder); and

(iii) such Party will at all times and in all material respects comply with all Applicable Laws relating to its activities under this Termination Agreement.

(b) AstraZeneca represents, warrants and covenants as of the Termination Effective Date (or as of such other /additional time as may be explicitly specified below) to Ardelyx that:

(i) AstraZeneca is the sole and exclusive owner of the entire right, title and interest in the Sole Program Know-How developed by, or on behalf of, AstraZeneca under the License Agreement. AstraZeneca has not permitted the Licensed Patents, Licensed Know-How, Sole Program Know-How developed by or on behalf of AstraZeneca, or the Joint Technology, to become subject to any encumbrance, lien or claim of ownership by any Third Party.

(ii) AstraZeneca has not filed any patent applications covering or claiming any Joint Technology or any Sole Program Know-How developed by, or on behalf of AstraZeneca.

(iii) To AstraZeneca's Knowledge, with the exception of the information provided to Ardelyx in writing prior to the Termination Effective Date regarding the prosecution of U.S. Patent Application Nos 14/421,451 and 14/421,454, the Licensed Patents existing as of the Termination Effective Date are being diligently prosecuted before the respective patent authorities in accordance with Applicable Law. All applicable fees due to patent authorities with respect to the filing and prosecution of the Listed Patents existing as of the Termination Effective Date have been paid on or before the due date for payment (as such due date may be extended in accordance with Applicable Laws or patent authority rules and regulations).

(iv) To AstraZeneca's Knowledge, the manufacture, use, sale, offer for sale or import of the Licensed Compounds or Licensed Products as they exist as of the Termination Effective Date will not infringe or misappropriate the Patents, other IPR or proprietary right of any Third Party.

(v) To AstraZeneca's Knowledge, the conception, development and reduction to practice of the Joint Technology, Sole Program Know-How, or AZ Background Technology developed by, or on behalf of AstraZeneca existing as of the Termination Effective Date have not constituted or involved the misappropriation of trade secrets or other proprietary rights of any Person.

(vi) AstraZeneca has not previously entered into any agreement, whether written or oral, with respect to, or otherwise assigned, transferred, licensed, conveyed or otherwise encumbered its right, title or interest in or to, the Licensed Patents, Licensed Know-How, Regulatory Documentation, Sole Program Know-How, Joint Technology, the Licensed Compounds or the Licensed Products, in each case existing as of the Termination Effective Date (including by granting any covenant not to sue with respect thereto), except agreements with CROs or CMOs in the ordinary course of business.

(vii) AstraZeneca covenants to Ardelyx that the CTM: (a) shall be manufactured in compliance with Applicable Laws; (b) conform to the applicable Specifications for such Licensed Compound or Licensed Product; (c) not be misbranded within the meaning of the FDCA; (d) not constitute an article that may not be introduced into interstate commerce under the provisions of Section 505 of the FDCA (21 U.S.C. §355); (e) conform to the certificates of analysis supplied with the shipment of such Licensed Product; and (f) shall be packaged and shipped in accordance with the applicable Specifications therefor in effect at the time of delivery.

ARTICLE 7. MISCELLANEOUS

7.1 Counterparts. This Termination Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

7.2 Entire Agreement. This Termination Agreement, together with the surviving provisions of the License Agreement, as expressly modified by this Termination Agreement, along with all exhibits attached hereto, sets forth all the covenants, promises, agreements, warranties, representations, conditions, and understandings between the Parties with respect to the AZ Triggered Termination of the License Agreement. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties other than as set forth in this Termination Agreement and the surviving provisions of the License Agreement, as expressly modified by this Termination Agreement. No subsequent alteration, amendment, change, or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

7.3 Assignment; Performance of Affiliates. The provisions of Section 17.1 of the License Agreement shall govern the assignment or performance by Affiliates of this Termination Agreement.

[SIGNATURE PAGE FOLLOWS]

In Witness Whereof, the Parties have executed this Termination Agreement in duplicate originals by their proper officers as of the date first written above.

Ardelyx, Inc.

By: /s/ Michael Raab

Title: CEO

AstraZeneca AB (publ)

By: /s/ Mats Berglund

Title: Vice President

**EXHIBIT A
INITIAL DELIVERABLES**

1. Clinical Trial Material

a. AstraZeneca shall complete the production of 360,000/50 mg tenapanor tablets and 420,000 placebo tablets and shall deliver all tablets to Ardelyx, or its designee on or before July 30,2015. The delivery of the tablets will be accompanied by delivery to Ardelyx or its designee of fully executed BSE/TSE statements and a list of any significant deviations. In addition, on or before August 31,2015, AstraZeneca shall deliver a draft of the Certificates of Analysis and a draft of the Certificates of Compliance for the tablets, and on or before September 30, 2015, AstraZeneca shall deliver the final Certificates of Analysis and the final Certificates of Compliance.

b. AstraZeneca shall complete the production of 240,000/50 mg tenapanor tablets and shall deliver all tablets to Ardelyx, or its designee on or before December 15,2015. The delivery of the tablets will be accompanied by delivery to Ardelyx or its designee of fully executed Certificates of Analysis; Certificates of Compliance, BSE/TSE statements and a list of any significant deviations.

c. AstraZeneca shall release to Ardelyx all remaining drug substance by November 30,2015, including any additional drug substance being stored at Irix. Campaign 4b is still in progress: the anticipated total of drug substance will be approximately 170 kg which will include 17 kg of campaign 4a. 65 kg of tenapanor free base will also be released to Ardelyx by November 30, 2015.

d. Within fifteen (15) business days of the Termination Effective Date, AstraZeneca shall provide Ardelyx with a written description of all Licensed Product and Licensed Compound that AstraZeneca holds in inventory (exclusive of the Licensed Product that is allocated for the tablet runs described in (a) and (b) above). Within thirty (30) days of receipt of such written description, Ardelyx shall provide AstraZeneca with written instructions regarding the shipment of any such inventory of Licensed Product or Licensed Compound to Ardelyx or its designee, and AstraZeneca shall ship any inventory requested by Ardelyx to Ardelyx or its designee for arrival on the date requested by Ardelyx. Any such shipment shall be accompanied by delivery to Ardelyx or its designee of fully executed Certificates of Analysis; Certificates of Compliance and BSE/TSE statements.

2. Additional CMC Commitments

a. On or before June 30, 2015, AstraZeneca shall deliver to Ardelyx a draft of each drug product analytical method and a draft of the validation data for each method. On or before September 30, 2015, AstraZeneca shall deliver each final drug product analytical method and the final validation report for each analytical method.

b. AstraZeneca shall transfer to Ardelyx the ongoing stability studies for the Phase 2b ESRD-Pi tablets by December 15, 2015.

- c. On or before July 1, 2015, AstraZeneca shall provide Ardelyx with the following:
 - i. All available information and data required by Ardelyx to complete the revised CMC section of the GI IND
 - ii. Drug Substance batch analysis tables that includes DS-9 and C4a
 - iii. Drug Product batch analysis tables
- d. Within twenty (20) days of receipt of the first draft of the Phase 3 IND, AstraZeneca shall provide Ardelyx with its written comments and suggestions on the CMC sections.
- e. AstraZeneca shall:
 - i. provide Ardelyx with a draft of the data generated in connection with the studies to determine the dissolution of the Phase 2b vs. Phase 3 tablets in HC1, buffer pH 4, FeSSIF and FaSSIF by August 31, 2015;
 - ii. provide Ardelyx with a final report of each study to determine the dissolution of the Phase 2b vs. Phase 3 tablets in HC1 buffer pH 4, FeSSIF and FaSSIF by September 30, 2015
 - iii. provide the results of the TIM1 gastrointestinal model with the Phase 2b and Phase 3 tablets by September 30, 2015.

3. Clinical and Regulatory Commitments

- a. On or before July 1, 2015, AstraZeneca shall deliver to Ardelyx the following information regarding MI:
 - i. Report of study of pIC50 against ratNHE3 (BS001370-01)
 - ii. SAR non-regulatory data
 - iii. MI supply and synthesis process iv. Synthesis and characterization of MI and other named impurities (Report and CoFA to be delivered)
- b. On or before July 1, 2015, AstraZeneca shall deliver to Ardelyx the following:
 - i. All clinical study reports, including, without limitation, the final clinical study report for D5613C00001
 - ii. Draft EU Application for Agreement of a Pediatric Investigation Plan for Tenapanor dated 18 Nov 2014 (i.e main text Sections B through E that includes all relevant information regarding treatment of hyperphosphataemia in pediatric patients with CKD on dialysis or not on dialysis that AstraZeneca has compiled).
- c. On or before September 1, 2015, AstraZeneca shall:
 - i. Deliver to Ardelyx reports for all M-I studies that are listed as ongoing or reporting on the attached Schedule A-I, and completed reports from any other M-I non-clinical studies not listed on Schedule A-I

ii. Complete the transfer of IND 120566 to Ardelyx

iii. Validated bioanalytical methods for MI in mouse, dog, and human; and reports containing analysis of plasma samples analyzed with such bioanalytical methods.

d. On or before June 15, 2015, AstraZeneca shall (i) provide Ardelyx with an overview of the work completed by Covance with respect to M-I studies and the validated bioanalytical methods, and (ii) make introductions to Ardelyx to the project manager at Covance responsible for the M-I studies and the bioanalytical methods, and shall execute such additional documentation as may be reasonably necessary to authorize Covance to conduct additional sample analysis for Ardelyx and to permit Ardelyx to access all of the M-I data generated for AstraZeneca prior to such date.

e. AstraZeneca and Ardelyx shall discuss in good faith and agree upon the format in which AstraZeneca shall deliver to Ardelyx the global safety database for tenapanor, and such database will be delivered to Ardelyx in the agreed upon format by September 1, 2015. In the event that by June 30, 2015, the Parties have not agreed upon the format for delivery, AstraZeneca shall deliver the global safety database to Ardelyx in Excel format by September 1, 2015.

SCHEDULE A-1

<u>Study Report No.</u>	<u>Study Title</u>	<u>Conducting Laboratory</u>	<u>Species, Strain (group size)</u>	<u>Dose, Route, Duration</u>	<u>GLP</u>	<u>Key Findings</u>
PHARMACOLOGY						
TBA (reporting) BS001370-01	Assessment the IC50 values of MI in the rat NHE3 stably expressed OK cell lines	AstraZeneca	NA	In vitro	no	MI is not active against NHE3 at the concentrations achieved in plasma and lacks substantial inhibitory activity against NHE3 in cell-based assays of NHE3 activity
TBA (reporting) 3534SV	Selectivity Screening in Radioligand Binding, Enzyme Activity and Functional Assays in vitro	Cerep, Le Bois l'Évêque, B.P. 30001, 86600 Celle l'Evescault, France	NA	In vitro	no	No interactions at clinically relevant concentrations
DMPK						
ADME-AZS-Wave3-150413 (ongoing)	BCRP inhibition	Pharmaron	NA	In vitro	no	TBD
ADME-AZS-Wave3-150412 (ongoing)	Pgp inhibition	Pharmaron	NA	In vitro	no	TBD
ADME-AZS-Wave3-150323 (ongoing)	CYP inhibition panel 1	Pharmaron	NA	In vitro	no	TBD
ADME-AZS-Wave3-150331 (ongoing)	Human B/P ratio	Pharmaron	NA	In vitro	no	TBD
ADME-AZS-Wave3-150415 (ongoing)	OATP1B1 Inhibition	Pharmaron	NA	In vitro	no	TBD
ADME-AZS-Wave3-150527 (ongoing)	CYP isoform ID	Pharmaron	NA	In vitro	no	TBD
ADME-AZS-Wave3-150417 (ongoing)	CYP inhibition panel 2	Pharmaron	NA	In vitro	no	TBD

<u>Study Report No.</u>	<u>Study Title</u>	<u>Conducting Laboratory</u>	<u>Species, Strain (group size)</u>	<u>Dose, Route, Duration</u>	<u>GLP</u>	<u>Key Findings</u>
ADME-AZS-Wave4-150318 (ongoing)	PPB	Pharmaron	NA	In vitro	no	TBD
Study Report No.	Study Title	Conducting Laboratory	Species, Strain (group size)	Dose, Route, Duration	GLP	Key Findings
15ASTRUKP1S4 (ongoing)	OATP1B3, OAT1, OAT3, MATE1, MATE2K and OCT2	Absorption System	NA	In vitro	no	TBD
TOXICOLOGY						
3521BV (AME00031) (reporting)	AZ13792925: Genetic Toxicity Evaluation using a Bacterial Reverse Mutation Test	Gentronix	Salmonella typhimurium LT2 strains TA1535, TA1537, TA98 and TA100, and Escherichia coli WP2 strain uvrA/pKM101	In vitro	no	negative
3521BV (8321467) (ongoing)	AZ13792925: Genetic Toxicity Evaluation Using the Bacterial Reverse Mutation Test in Salmonella typhimurium TA1535, TA100, TA1537 and TA98 and Escherichia coli WP2 uvrA pKM101	Covance	Salmonella typhimurium TA1535, TA100, TA1537 and TA98 and Escherichia coli WP2 uvrA pKM101	In vitro	yes	TBD
3522QV (8321468) (ongoing)	AZ 13792925: In Vitro L5178Y Mouse Lymphoma Cell Micronucleus Assay	Covance	L5178Y tk +/- (3.7.2C) mouse lymphoma cells	In vitro	yes	TBD
TBA (reporting)	Zebrafish	AstraZeneca	WIK	Compounds were assessed at a set, binary concentration range, between 0.1 to 100 μ M (0.1, 1, 10, 100 μ M).	no	Non-teratogenic

Study Report No.

0333DB (20069732) (reporting)

Study Title	Conducting Laboratory	Species, Strain (group size)	Dose, Route, Duration	GLP	Key Findings
AZD1722: Oral Dose Range-Finding Toxicity Study in the Non-Pregnant Rabbit	Charles River, Horsham, PA, USA	New Zealand white [Cr1 :KBL(NZ W)]	0 & 45 mg/kg/day, PO, 14 days	no	M1 detected in plasma

EXHIBIT B**Ongoing AZ Non-Clinical Work****Ongoing/to be completed pre-clinical studies**

These studies have or will have shortly completed in-life phase.

Ongoing work typically refers to sample analysis.

- 1) Rat dose response study of tenapanor on varying phosphate diets with expression analysis in GI and kidney tissues.
- 2) Rat dose response expression study on standard diet (study to generate replicate data of (1) to support publication).
- 3) Rat time course expression study looking at short term effects (2,3 and 4 days) and long term effects (4, 7 and 14 days +/- washout).
- 4) Rat salt diet study with extended diet adaption with expression analysis.
- 5) Rat phosphate diet study looking at expression changes in GI tract (in-life phase ending July 3rd)
- 6) ³³P absorption following acute/chronic +/- washout tenapanor treatments on different phosphate and sodium diets (some of these not yet performed, planned within the next 6 weeks)
- 7) ³³P absorption changes with tenapanor in combination with other intestinal transport inhibitors.
- 8) Expression and biomarker analysis in CV rat study.

Contract research studies still on-going

- 1) Ursula Seidler; completion of studies on intestinal fluid, sodium, phosphate, bicarbonate and electrogenic effects of tenapanor in wild-type and NHE3 KO mice.
- 2) Joanne Marks; Rat isolated loop studies following acute/chronic dosing +/- PFA to study phosphate transport.
- 3) Carsten Wagner; Effect of tenapanor on phosphate absorption in BBMV's from rat in different intestinal regions.

EXHIBIT C
Publication Plan

Pre Clinical

Mode of Action	Manuscript and potential abstracts	AstraZeneca	AZ data, study BS- 001370-02
NHE3 expression in dog	Manuscript and potential abstract	AstraZeneca	AZ data, study BS- 001370-03
Tenapanor is Vascular Protective in a Rat Model of CKD	ASN 2015 abstract, manuscript	AstraZeneca	AZ data, study PBI- 15-009
Tenapanors efficacy in rat is sensitive to dietary salt intake	ASN 2015 abstract (potential manuscript)	AstraZeneca	AZ data, study PBI- 14-055
Combination of tenapanor and eplerenone on UACR	Manuscript and potential abstract	AstraZeneca	AZ data, studies 14- 024-014 and 14-024-016
Salt accumulation in the skin of rats and effects of tenapanor	Manuscript and potential abstract	AstraZeneca	AZ data
Current Opinion Sodium Review	Review manuscript	Ardelyx/AstraZeneca	PO btw Ardelyx and OXP, 50% to be x- charged to AZ Ms already submitted
MIST (metabolite safety data)	Abstract and manuscript	AstraZeneca	AZ studies, 322009, D5613C00003, BS001370-01, BS000381-38, BS000381-39 and D5611C00007

Clinical

ESRD Fluid 2a	Manuscript	AstraZeneca	D5611C00001, near final ms
DDI Sevelamer	Manuscript	AstraZeneca	D5611C00006, near final ms
JSMAD	Manuscript	AstraZeneca	D5611C00005, near final ms
Food-effect	ASN 2015 abstract and manuscript	AstraZeneca	D5611C00003, pub dev ongoing
DDI midazolam	ASN 2015 abstract and manuscript	AstraZeneca	D5613C00003, pub dev ongoing

DDI cefadroxil	ASN 2015 abstract and manuscript	AstraZeneca	D5613C00004, pub dev ongoing
hADME	ASN 2015 abstract and manuscript	AstraZeneca	D5611C00007, pub dev ongoing
ESRD phosphate phase 2b	ASN 2015 abstract and manuscript	AstraZeneca	D5613C00001, pub dev ongoing
Phosphate 2b dose modelling	Manuscript and potential abstract	AstraZeneca	D5613C00001, pubs to be started
CKD phase 2a	ASN 2015 abstract and manuscript	AstraZeneca	D5610C00001, abstract started manuscript to be started
Genetics (preclin/clinical/epi)	Manuscript and potential abstracts	AstraZeneca	AZdata Pubs to be started
Real-World Evidence			
CKD US Kaiser	Manuscript x 2	AstraZeneca	In original contract btw Ardelyx and Kaiser
CKD US Kaiser	Manuscript x 1-2 and potential abstract	AstraZeneca	New contract btw AZ and Kaiser (additional work from above study)
Patient Interviews ESRD (from Fluid 2a study)	Manuscript	AstraZeneca	Manuscript is submitted (from D5611C00001)

ARDELYX, INC.

SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement (“Agreement”) is made as of June 2, 2015 (the “Effective Date”), by and among Ardelyx, Inc., a Delaware corporation (the “Company”), and each of those persons and entities, severally and not jointly, listed as a Purchaser on the Schedule of Purchasers attached as Exhibit A hereto (the “Schedule of Purchasers”). Such persons and entities are hereinafter collectively referred to herein as “Purchasers” and each individually as a “Purchaser.”

AGREEMENT

In consideration of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Company and each Purchaser (severally and not jointly) hereby agree as follows:

SECTION 1. AUTHORIZATION OF SALE OF SECURITIES.

The Company has authorized the sale and issuance of 7,242,992 shares of its Common Stock, par value \$0.0001 per share (the “Common Stock”) and warrants in the form of Exhibit B hereto to purchase an aggregate of 2,172,899 shares of Common Stock (each a “Warrant” and collectively the “Warrants”), on the terms and subject to the conditions set forth in this Agreement. The shares of Common Stock sold hereunder at the Closing (as defined below) shall be referred to as the “Shares.” The Shares and the Warrants are referred to collectively as the “Securities.”

SECTION 2. AGREEMENT TO SELL AND PURCHASE THE SECURITIES.

2.1 **Sale of Securities.** At the Closing (as defined in Section 3), the Company will sell to each Purchaser, and each Purchaser will purchase from the Company, (a) the number of Shares set forth opposite such Purchaser’s name on the Schedule of Purchasers at a purchase price of \$10.70 per Share and (b) a Warrant to purchase the number of shares of Common Stock set forth opposite such Purchaser’s name on the Schedule of Purchasers (such shares of Common Stock, the “Underlying Shares”), which Warrant shall have an exercise price equal to \$13.91 per Underlying Share, and which Warrant shall have a purchase price equal to \$0.125 per Underlying Share underlying such Warrant. The aggregate purchase price for the Shares and Warrants purchased by each Purchaser is set forth opposite such Purchaser’s name on the Schedule of Purchasers.

2.2 **Separate Agreement.** Each Purchaser shall severally, and not jointly, be liable for only the purchase of the Securities that appear on the Schedule of Purchasers that relate to such Purchaser. The Company’s agreement with each of the Purchasers is a separate agreement, and the sale of Securities to each of the Purchasers is a separate sale. The obligations of each Purchaser hereunder are expressly not conditioned on the purchase by any or all of the other Purchasers of the Securities such other Purchasers have agreed to purchase.

SECTION 3. CLOSING AND DELIVERY.

3.1 **Closing.** The closing of the purchase and sale of the Securities (which Securities are set forth in the Schedule of Purchasers) pursuant to this Agreement (the "Closing") shall be held on June 4, 2015 at the offices of Latham & Watkins LLP, 140 Scott Drive, Menlo Park, California 94025, or on such other date and place as may be agreed to by the Company and the Purchasers. At or prior to the Closing, each Purchaser shall execute any related agreements or other documents required to be executed hereunder, dated as of the date of the Closing (the "Closing Date").

3.2 **Issuance of the Securities at the Closing.** At the Closing, the Company shall issue or deliver to each Purchaser (a) evidence of a book entry position evidencing the Shares purchased by such Purchaser hereunder, registered in the name of such Purchaser, or in such nominee name(s) as designated by such Purchaser, representing the number of Shares to be purchased by such Purchaser at such Closing as set forth in the Schedule of Purchasers against payment of the purchase price for such Shares and (b) a Warrant registered in the name of such Purchaser, or in such nominee name(s) as designated by such Purchaser, representing the number of Underlying Shares as set forth in the Schedule of Purchasers. The name(s) in which the shares and Warrant are to be issued to each Purchaser are set forth in the Purchaser Questionnaire and the Selling Stockholder Notice and Questionnaire in the form attached hereto as Appendix I and II (the "Purchaser Questionnaire" and the "Selling Stockholder Questionnaire", respectively), as completed by each Purchaser, which shall be provided to the Company no later than the Closing Date. The Warrants shall be delivered to each Purchaser promptly following the Closing Date, but in any event within 10 business days following the Closing Date.

3.3 **Delivery of the Registration Rights Agreement.** At the Closing, the Company and each Purchaser shall execute and deliver the Registration Rights Agreement in the form attached hereto as Appendix III (the "Registration Rights Agreement"), with respect to the registration of the Shares and the Underlying Shares under the Securities Act of 1933, as amended (the "Securities Act").

3.4 **Delivery of Lock-Up Agreement.** At the Closing, the Company shall deliver Lock-Up Agreements, in form and substance reasonably acceptable to the Purchasers (the "Lock-Up Agreement") executed by each person listed on Exhibit C hereto, and each such Lock-Up Agreement shall be in full force and effect on the Closing Date.

SECTION 4. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE COMPANY.

Except as set forth on the Schedule of Exceptions delivered to the Purchasers concurrently with the execution of this Agreement (the "Schedule of Exceptions") or as otherwise described in the SEC Documents (as defined below), which disclosures qualify these representations and warranties in their entirety, the Company hereby represents and warrants as of the date hereof to, and covenants with, the Purchasers as follows:

4.1 **Organization and Standing.** The Company (i) has been duly incorporated and is validly existing as a corporation in good standing under the laws of Delaware, has with full

corporate power and authority to own or lease, as the case may be, and to operate its properties and conduct its business as presently conducted, and (ii) is duly qualified to do business as a foreign corporation and is in good standing under the laws of each jurisdiction which requires such qualification, except in the case of clause (ii) above, to the extent that the failure to be so qualified or be in good standing would not reasonably be expected to result in (i) a material adverse effect on the validity or enforceability of this Agreement, (ii) a material adverse effect on the condition (financial or otherwise), earnings, business or properties of the Company, or (iii) a material adverse effect on the Company's ability to perform in any material respect its obligations under this Agreement (any of (i), (ii) or (iii)) (a "Material Adverse Effect"). The Company has no subsidiaries.

4.2 Corporate Power; Authorization. The Company has all requisite corporate power and authority, and has taken all requisite corporate action, to execute and deliver this Agreement, the Warrants and the Registration Rights Agreement (as defined below and collectively, the "Transaction Documents"), sell and issue the Securities and carry out and perform all of its obligations under the Transaction Documents. Each Transaction Document constitutes the legal, valid and binding obligation of the Company, enforceable in accordance with its terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or affecting the enforcement of creditors' rights generally, (ii) as limited by equitable principles generally, including any specific performance and (iii) with respect to the Registration Rights Agreement, as rights to indemnity or contribution may be limited by state or federal laws or public policy underlying such laws.

4.3 Issuance and Delivery of the Securities. The Securities have been duly authorized and, when issued and paid for in compliance with the provisions of this Agreement, will be validly issued, fully paid and nonassessable. The Underlying Shares have been duly authorized and, upon exercise of the Warrants in accordance with their terms, including payment of the exercise price therefore, will be validly issued, fully paid and nonassessable. Assuming the accuracy of the representations made by each Purchaser in Section 5, the offer and issuance by the Company of the Securities is exempt from registration under the Securities Act.

4.4 SEC Documents; Financial Statements. The Company has filed in a timely manner all documents that the Company was required to file with the Securities and Exchange Commission (the "Commission") under Sections 13, 14(a) and 15(d) the Securities Exchange Act of 1934, as amended (the "Exchange Act"), since becoming subject to the requirements of the Exchange Act. As of their respective filing dates (or, if amended prior to the date of this Agreement, when amended), all documents filed by the Company with the Commission (the "SEC Documents") complied in all material respects with the requirements of the Exchange Act and the rules and regulations of the Commission promulgated thereunder. None of the SEC Documents as of their respective dates contained any untrue statement of material fact or omitted to state a material fact required to be stated therein or necessary to make the statements made therein, in light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Documents (the "Financial Statements") present fairly the financial condition, results of operations and cash flows of the Company as of the dates and for the periods indicated, comply as to form with the applicable accounting requirements of the Act and have been prepared in conformity with generally accepted accounting principles applied on a consistent basis throughout the periods involved (except as otherwise noted therein).

Ernst & Young LLP, who have certified certain financial statements of the Company delivered their report with respect to the audited consolidated financial statements and schedules included in the SEC Documents, are independent public accountants with respect to the Company within the meaning of the Act and the applicable published rules and regulations thereunder.

4.5 Capitalization. The authorized capital stock of the Company consists of 300,000,000 shares of common stock and 5,000,000 shares of undesignated Preferred Stock. As of the Effective Date, there are no shares of Preferred Stock issued and outstanding and there are 18,651,835 shares of Common Stock issued and outstanding, of which no shares are owned by the Company. There are no other shares of any other class or series of capital stock of the Company issued or outstanding. The Company has no capital stock reserved for issuance, except that, as of the Effective Date, there are (i) 2,973,599 shares of Common Stock reserved for issuance pursuant to the Company's stock incentive plans, of which 1,231,671 shares are issuable upon the exercise of stock options outstanding on the date hereof and (ii) 369,040 shares of Common Stock reserved for issuance pursuant to the Company's employee stock purchase plan. There are no bonds, debentures, notes or other indebtedness having general voting rights (or convertible into securities having such rights) ("Voting Debt") of the Company issued and outstanding. Except as stated above, there are no existing options, warrants, calls, subscriptions or other rights, agreements, arrangements or commitments relating to the issued or unissued capital stock of the Company, obligating the Company to issue, transfer, sell, redeem, purchase, repurchase or otherwise acquire or cause to be issued, transferred, sold, redeemed, purchased, repurchased or otherwise acquired any capital stock or Voting Debt of, or other equity interest in, the Company or securities or rights convertible into or exchangeable for such shares or equity interests or obligations of the Company to grant, extend or enter into any such option, warrant, call, subscription or other right, agreement, arrangement or commitment. The issuance of Common Stock or other securities pursuant to any provision of this Agreement or the Warrant will not give rise to any preemptive rights or rights of first refusal on behalf of any Person or result in the triggering of any anti-dilution rights. There are no agreements or arrangements under which the Company or any of its Subsidiaries is obligated to register the sale of any of their securities under the Securities Act.

4.6 Litigation. No action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or its property is pending or, to the best knowledge of the Company, threatened that will have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

4.7 Governmental Consents. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state, or local governmental authority on the part of the Company is required in connection with the consummation of the transactions contemplated by this Agreement or the Registration Rights Agreement except for (a) the filing of a Form D with the Commission under the Securities Act and compliance with the securities and blue sky laws in the states and other jurisdictions in which shares of Common Stock are offered and/or sold, which compliance will be effected in accordance with such laws, (b) the approval by the NASDAQ Global Market of the listing of the Shares and the Underlying Shares and (c) the filing of one or more registration statements and all amendments thereto with the Commission as contemplated by the Registration Rights Agreement.

4.8 No Default or Consents. Neither the execution, delivery or performance of the Transaction Documents by the Company nor the consummation of any of the transactions contemplated thereby (including, without limitation, the issuance and sale by the Company of the Securities and the Underlying Shares) will conflict with, result in a breach or violation of, or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to, (i) the charter or by-laws of the Company, (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which the Company is a party or bound or to which its or their property is subject, or (iii) any statute, law, rule, regulation, judgment, order or decree applicable to the Company of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or any of its properties, except in the case of clauses (ii) and (iii) above, for any conflict, breach or violation of, or imposition that would not, individually or in the aggregate, have a Material Adverse Effect.

4.9 No Material Adverse Change. Since March 31, 2015, there have not been any changes in the authorized capital, assets, liabilities, financial condition, business, Material Agreements or operations of the Company from that reflected in the Financial Statements except changes in the ordinary course of business which have not been, either individually or in the aggregate, materially adverse to the business, properties, financial condition or results of operations of the Company.

4.10 No General Solicitation. Neither the Company nor any Person acting on its behalf, has engaged in any form of general solicitation or general advertising (within the meaning of Regulation D promulgated under the Securities Act) in connection with the offer or sale of the Securities.

4.11 No Integrated Offering. Neither of the Company or any Person acting on its behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any Company security, under circumstances that would adversely affect reliance by the Company on Section 4(a)(2) of the Securities Act or require registration of any of the Securities under the Securities Act or cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of the Securities Act.

4.12 Sarbanes-Oxley Act. There is and has been no failure on the part of the Company and any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith, including, without limitation, Section 402 relating to loans.

4.13 Intellectual Property. The Company owns, possesses, licenses or has other rights to use, on reasonable terms, all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, technology, know-how and other intellectual property (collectively, the "Intellectual Property") necessary for the conduct of the Company's business as now conducted or as proposed in the SEC Documents to be conducted (the "Company Intellectual Property"). To the knowledge of the Company, there are no rights of third parties to any Company Intellectual Property, other than as licensed by the Company. To the knowledge of the Company, there is no infringement by third parties of any Company Intellectual Property. There is no pending or, to the Company's

knowledge, threatened action, suit, proceeding or claim by others challenging the Company's rights in or to any Company Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any Company Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company infringes or otherwise violates any patent, trademark, copyright, trade secret or other proprietary rights of others. The Company is not aware of any facts required to be disclosed to the U.S. Patent and Trademark Office ("USPTO") which have not been disclosed to the USPTO and which would preclude the grant of a patent in connection with any patent application of the Company Intellectual Property or could form the basis of a finding of invalidity with respect to any issued patents of the Company Intellectual Property.

4.14 Compliance with NASDAQ Continued Listing Requirements. The Company is in compliance with applicable NASDAQ continued listing requirements. There are no proceedings pending or, to the Company's knowledge, threatened against the Company relating to the continued listing of the Common Stock on NASDAQ and the Company has not received any notice of, nor to the Company's knowledge is there any reasonable basis for, the delisting of the Common Stock from NASDAQ.

4.15 Disclosure. The Company understands and confirms that the Purchasers will rely on the foregoing representations in effecting transactions in securities of the Company. To the knowledge of the executive officers of the Company, all due diligence materials regarding the Company, its business and the transactions contemplated hereby, furnished by or on behalf of the Company to the Purchasers upon their request are, when taken together with the SEC Documents and the Schedule of Exceptions, true and correct in all material respects and do not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading.

4.16 Contracts. Each franchise, contract or other document of a character required to be described in the SEC Documents or to be filed as an exhibit to the SEC Documents under the Securities Act and the rules and regulations promulgated thereunder (collectively, the "Material Contracts") is so described or filed.

4.17 Properties and Assets. The Company owns or leases all such properties as are necessary to the conduct of its operations as presently conducted.

4.18 Compliance. Except as would not, individually or in the aggregate, result in a Material Adverse Effect: (i) the Company is and has been in compliance with statutes, laws, ordinances, rules and regulations applicable to the Company for the ownership, testing, development, manufacture, packaging, processing, use, labeling, storage, or disposal of any product manufactured by or on behalf of the Company or out-licensed by the Company (a "Company Product"), including without limitation, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., the Public Health Service Act, 42 U.S.C. § 262, similar laws of other governmental entities and the regulations promulgated pursuant to such laws (collectively, "Applicable Laws"); (ii) the Company possesses all licenses, certificates, approvals, authorizations, permits and supplements or amendments thereto required by any such Applicable

Laws and/or for the ownership of its properties or the conduct of its business as it relates to a Company Product and as described in the SEC Documents (collectively, "Authorizations") and such Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Authorizations; (iii) the Company has not received any written notice of adverse finding, warning letter or other written correspondence or notice from the U.S. Food and Drug Administration (the "FDA") or any other governmental entity alleging or asserting noncompliance with any Applicable Laws or Authorizations relating to a Company Product; (iv) the Company has not received written notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental entity or third party alleging that any Company Product, operation or activity related to a Company Product is in violation of any Applicable Laws or Authorizations or has any knowledge that any such governmental entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, nor, to the Company's knowledge, has there been any noncompliance with or violation of any Applicable Laws by the Company that would reasonably be expected to require the issuance of any such written notice or result in an investigation, corrective action, or enforcement action by the FDA or similar governmental entity with respect to a Company Product; (v) the Company has not received written notice that any governmental entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations or has any knowledge that any such governmental entity has threatened or is considering such action with respect to a Company Product; and (vi) the Company has filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete, correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission). To the Company's knowledge, neither the Company nor any of its directors, officers, employees or agents, has made, or caused the making of, any false statements on, or material omissions from, any other records or documentation prepared or maintained to comply with the requirements of the FDA or any other governmental entity.

4.19 Taxes. The Company has filed all tax returns that are required to be filed or has requested extensions thereof (except in any case in which the failure so to file would not have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business, except as contemplated in the SEC Documents) and has paid all taxes required to be paid by it and any other assessment, fine or penalty levied against it, to the extent that any of the foregoing is due and payable, except for any such assessment, fine or penalty that is currently being contested in good faith or as would not have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business, except as contemplated in the SEC Documents.

4.20 Transfer Taxes. There are no transfer taxes or other similar fees or charges under Federal law or the laws of any state, or any political subdivision thereof, required to be paid in connection with the execution and delivery of this Agreement or the issuance by the Company or sale by the Company of the Securities.

4.21 **Investment Company.** The Company is not and, after giving effect to the offering and sale of the Securities, will not be an “investment company” as defined in the Investment Company Act of 1940, as amended.

4.22 **Insurance.** The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are reasonable and customary in the business in which it is engaged; all policies of insurance and fidelity or surety bonds insuring the Company or its businesses, assets, employees, officers and directors are in full force and effect; the Company is in compliance with the terms of such policies and instruments in all material respects; and there are no claims by the Company under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; the Company has not been refused any insurance coverage sought or applied for; and the Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

4.23 **Price of Common Stock.** The Company has not taken, directly or indirectly, any action designed to cause or result in, or that has constituted or that might reasonably be expected to constitute the stabilization or manipulation of the price of any securities of the Company to facilitate the sale or resale of the Shares, Underlying Shares and the Warrants.

4.24 **Governmental Permits, Etc.** The Company possesses all licenses, certificates, permits and other authorizations issued by all applicable authorities necessary to conduct its business, and the Company has not received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business.

4.25 **Internal Control over Financial Reporting; Sarbanes-Oxley Matters.** The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management’s general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company’s internal controls over financial reporting are effective 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 and the Company is not aware of any material weakness in its internal controls over financial reporting. The Company maintains “disclosure controls and procedures” (as such term is defined in Rule 13a-15(e) under the Exchange Act); such disclosure controls and procedures are effective.

4.26 **Foreign Corrupt Practices.** The Company is not nor, to the knowledge of the Company, any director, officer, agent, or employee of the Company is aware of or has taken any

action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the “FCPA”), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any “foreign official” (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA; and the Company.

4.27 **Labor.** No labor problem or dispute with the employees of the Company exists or, to the knowledge of the Company, is threatened, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers or contractors, that could have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business, except as contemplated in the SEC Documents.

4.28 **ERISA.** None of the following events has occurred or exists: (i) a failure to fulfill the obligations, if any, under the minimum funding standards of Section 302 of the United States Employee Retirement Income Security Act of 1974, as amended (“ERISA”), and the regulations and published interpretations thereunder with respect to a Plan that is required to be funded, determined without regard to any waiver of such obligations or extension of any amortization period; (ii) an audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other federal or state governmental agency or any foreign regulatory agency with respect to the employment or compensation of employees by any of the Company that could have a Material Adverse Effect; (iii) any breach of any contractual obligation, or any violation of law or applicable qualification standards, with respect to the employment or compensation of employees by the Company that would reasonably be expected to have a Material Adverse Effect. None of the following events has occurred or is reasonably likely to occur: (i) a material increase in the aggregate amount of contributions required to be made to all Plans in the current fiscal year of the Company compared to the amount of such contributions made in the most recently completed fiscal year of the Company; (ii) a material increase in the “accumulated post-retirement benefit obligations” (within the meaning of Statement of Financial Accounting Standards 106) of the Company compared to the amount of such obligations in the most recently completed fiscal year of the Company; (iii) any event or condition giving rise to a liability under Title IV of ERISA that could have a Material Adverse Effect; or (iv) the filing of a claim by one or more employees or former employees of the Company related to their employment that could have a Material Adverse Effect. For purposes of this paragraph, the term “Plan” means a plan (within the meaning of Section 3(3) of ERISA) subject to Title IV of ERISA with respect to which the Company may have any liability.

4.29 **Environmental Laws.** The Company (i) is in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (“Environmental Laws”), (ii) has received and is in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct its business and (iii) has not received notice of any actual or potential liability under any environmental law, except where such non-compliance with Environmental Laws, failure to receive required permits, licenses or other approvals, or liability would not, individually or in the

aggregate, have a Material Adverse Effect, whether or not arising from transactions in the ordinary course of business. The Company has not been named as a “potentially responsible party” under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

4.30 Money Laundering Laws. The operations of the Company are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements and the money laundering statutes and the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “Money Laundering Laws”) and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

4.31 OFAC. The Company is not nor, to the knowledge of the Company, any director, officer, agent or employee of the Company (i) is currently subject to any sanctions administered or imposed by the United States (including any administered or enforced by the Office of Foreign Assets Control of the U.S. Treasury Department, the U.S. Department of State, or the Bureau of Industry and Security of the U.S. Department of Commerce), the United Nations Security Council, the European Union, or the United Kingdom (including sanctions administered or controlled by Her Majesty’s Treasury) (collectively, “Sanctions”) and such persons, “Sanction Persons”) or (ii) will, directly or indirectly, use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person in any manner that will result in a violation of any economic Sanctions by, or could result in the imposition of Sanctions against, any person (including any person participating in the offering, whether as underwriter, advisor, investor or otherwise). The Company is not nor, to the knowledge of the Company, any director, officer, agent, or employee of the Company or any of its subsidiaries, is a person that is, or is 50% or more owned or otherwise controlled by a person that is: (i) the subject of any Sanctions; or (ii) located, organized or resident in a country or territory that is, or whose government is, the subject of Sanctions that broadly prohibit dealings with that country or territory (currently, Cuba, Iran, North Korea, Sudan, and Syria) (collectively, “Sanctioned Countries” and each, a “Sanctioned Country”). Except as has been disclosed to the Purchasers or is not material to the analysis under any Sanctions, the Company has not engaged in any dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country, in the preceding 3 years, nor does the Company have any plans to increase its dealings or transactions with Sanctioned Persons, or with or in Sanctioned Countries.

4.32 Compliance in Clinical Trials. The clinical studies and tests conducted by the Company or on behalf of the Company, have been and, if still pending, are being conducted in all material respects pursuant to all Applicable Laws and Authorizations; the descriptions of the results of such clinical studies and tests contained in the SEC Documents are accurate and complete in all material respects and fairly present the data derived from such clinical studies and tests; the Company is not aware of any clinical studies or tests, the results of which the Company believes reasonably call into question the research, nonclinical or clinical study or test results described or referred to in the SEC Documents when viewed in the context in which such results are described; and the Company has not received any written notices or correspondence from any governmental entity requiring the termination, suspension or material modification of any clinical study or test conducted by or on behalf of the Company.

SECTION 5. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE PURCHASERS.

5.1 Each Purchaser, severally and not jointly, represents and warrants to and covenants with the Company that:

(a) Such Purchaser (if an entity) is a validly existing corporation, limited partnership or limited liability company and has all requisite corporate, partnership or limited liability company power and authority to enter into and consummate the transactions contemplated by the Transaction Documents and to carry out its obligations hereunder and thereunder, and to invest in the Securities pursuant to this Agreement.

(b) Such Purchaser acknowledges that it can bear the economic risk and complete loss of its investment in the Securities and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment contemplated hereby. Such Investor has had an opportunity to receive, review and understand all information related to the Company requested by it and to ask questions of and receive answers from the Company regarding the Company, its business and the terms and conditions of the offering of the Securities, and has conducted and completed its own independent due diligence. Such Purchaser acknowledges that the Company has made available the SEC Documents. Based on the information such Purchaser has deemed appropriate, and without reliance upon any Placement Agent, it has independently made its own analysis and decision to enter into the Transaction Documents. Such Purchaser is relying exclusively on its own sources of information, investment analysis and due diligence (including professional advice it deems appropriate) with respect to the execution, delivery and performance of the Transaction Documents, the Securities and the business, condition (financial and otherwise), management, operations, properties and prospects of the Company, including but not limited to all business, legal, regulatory, accounting, credit and tax matters.

(c) The Securities to be received by such Purchaser hereunder will be acquired for such Purchaser's own account, not as nominee or agent, and not with a view to the resale or distribution of any part thereof in violation of the Securities Act, and such Purchaser has no present intention of selling, granting any participation in, or otherwise distributing the same in violation of the Securities Act without prejudice, however, to such Purchaser's right at all times to sell or otherwise dispose of all or any part of such Securities in compliance with applicable federal and state securities laws. Such Purchaser is not a broker-dealer registered with the SEC under the Exchange Act or an entity engaged in a business that would require it to be so registered. Such Purchaser understands that the Securities are characterized as "restricted securities" under the U.S. federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances. Purchaser will not, directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise acquire or take a pledge of) any of the securities purchased hereunder except in compliance with the Securities Act, applicable blue sky laws, and the rules and regulations promulgated thereunder.

(d) Such Purchaser is an “accredited investor” within the meaning of Rule 501(a) under the Securities Act. Such Purchaser has determined based on its own independent review and such professional advice as it deems appropriate that its purchase of the Securities and participation in the transactions contemplated by the Transaction Documents (i) are fully consistent with its financial needs, objectives and condition, (ii) comply and are fully consistent with all investment policies, guidelines and other restrictions applicable to such Purchaser, (iii) have been duly authorized and approved by all necessary action, (iv) do not and will not violate or constitute a default under such Purchaser’s charter, by-laws or other constituent document or under any law, rule, regulation, agreement or other obligation by which such Purchaser is bound and (v) are a fit, proper and suitable investment for such Purchaser, notwithstanding the substantial risks inherent in investing in or holding the Securities.

(e) The execution, delivery and performance by such Purchaser of the Transaction Documents to which such Purchaser is a party have been duly authorized and each has been duly executed and when delivered will constitute the valid and legally binding obligation of such Purchaser, enforceable against such Purchaser in accordance with their respective terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and similar laws of general applicability, relating to or affecting creditors’ rights generally.

(f) Purchaser is not a broker or dealer registered pursuant to Section 15 of the Exchange Act (a “registered broker-dealer”) and is not affiliated with a registered broker dealer. Purchaser is not party to any agreement for distribution of any of the Securities.

(g) Purchaser shall have completed or caused to be completed and delivered to the Company at no later than the Closing Date, the Purchaser Questionnaire and the Selling Stockholder Questionnaire for use in preparation of the Registration Statement, and the answers to the Purchaser Questionnaire and the Selling Stockholder Questionnaire are true and correct in all material respects as of the date of this Agreement and will be true and correct as of the Closing Date and the effective date of the Registration Statement; provided that the Purchasers shall be entitled to update such information by providing notice thereof to the Company before the effective date of such Registration Statement.

(h) Such Purchaser understands that no United States federal or state agency, or similar agency of any other country, has reviewed, approved, passed upon, or made any recommendation or endorsement of the Company or the purchase of the Securities.

(i) Such Purchaser has no present intent to effect a “change of control” of the Company as such term is understood under the rules promulgated pursuant to Section 13(d) of the Exchange Act.

(j) Such Purchaser has not taken any of the actions set forth in, and is not subject to, the disqualification provisions of Rule 506(d)(1) of the Securities Act.

(k) Such Purchaser did not learn of the investment in the Securities as a result of any general solicitation or general advertising.

(l) Such Purchaser's residence (if an individual) or offices in which its investment decision with respect to the Securities was made (if an entity) are located at the address immediately below such Purchaser's name on its signature page hereto.

(m) Such Purchaser (including any person controlling, controlled by, or under common control with such Purchaser, as the term "control" is defined pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and its implementing regulations (the "HSR Act")) in connection with the consummation of the transactions contemplated by this Agreement will not be required to and will not complete a filing with the U.S. government pursuant to the HSR Act.

5.2 Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly executed any purchases or sales, including all "short sales" as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include the location and/or reservation of borrowable shares of Common Stock) ("Short Sales"), of the securities of the Company during the period commencing as of the time that such Purchaser was first contacted by the Company, Leerink Partners LLC or any other person regarding the transactions contemplated hereby and ending immediately prior to the Effective Date. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other persons party to this Agreement, such Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to the identification of the availability of, or securing of, available shares to borrow in order to effect Short Sales or similar transactions in the future.

5.3 Purchaser understands that nothing in this Agreement or any other materials presented to Purchaser in connection with the purchase and sale of the Securities constitutes legal, tax or investment advice. Purchaser has consulted such legal, tax and investment advisors as it, in its sole discretion, has deemed necessary or appropriate in connection with its purchase of the Securities.

5.4 Legends.

(a) Purchaser understands that, until such time as the Shares have been sold pursuant to the Registration Statement or the Securities may be sold pursuant to Rule 144 under the Securities Act (“Rule 144”) without any restriction as to the number of securities as of a particular date that can then be immediately sold, the book entry notations evidencing the Shares and the Underlying Shares may bear one or more legends in substantially the following form and substance:

“THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), OR ANY OTHER APPLICABLE SECURITIES LAWS AND HAVE BEEN ISSUED IN RELIANCE UPON AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND SUCH OTHER SECURITIES LAWS. NEITHER THIS SECURITY NOR ANY INTEREST OR PARTICIPATION HEREIN MAY BE REOFFERED, SOLD, ASSIGNED, TRANSFERRED, PLEDGED, ENCUMBERED, HYPOTHECATED OR OTHERWISE DISPOSED OF, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO A TRANSACTION WHICH IS EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION, IN EACH CASE IN ACCORDANCE WITH ALL APPLICABLE SECURITIES LAWS, AND IN THE CASE OF A TRANSACTION EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION, UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO IT THAT SUCH TRANSACTION DOES NOT REQUIRE REGISTRATION UNDER THE SECURITIES ACT AND SUCH OTHER APPLICABLE LAWS.”

It is understood that the Warrants may bear one or more legends in substantially the following form and substance:

“THE SECURITIES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), OR ANY OTHER APPLICABLE SECURITIES LAWS AND HAVE BEEN ISSUED IN RELIANCE UPON AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND SUCH OTHER SECURITIES LAWS. NEITHER THIS SECURITY NOR ANY INTEREST OR PARTICIPATION HEREIN MAY BE REOFFERED, SOLD, ASSIGNED, TRANSFERRED, PLEDGED, ENCUMBERED, HYPOTHECATED OR OTHERWISE DISPOSED OF, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO A TRANSACTION WHICH IS EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION, IN EACH CASE IN ACCORDANCE WITH ALL APPLICABLE SECURITIES LAWS, AND IN THE CASE OF A TRANSACTION EXEMPT FROM, OR NOT SUBJECT TO, SUCH REGISTRATION, UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO IT THAT SUCH TRANSACTION DOES NOT REQUIRE REGISTRATION UNDER THE SECURITIES ACT AND SUCH OTHER APPLICABLE LAWS.”

In addition, book entry notations representing the Securities or the Underlying Shares may contain:

- (i) Any legend required by the laws of the State of California, including any legend required by the California Department of Corporations.
- (ii) Any legend required by the blue sky laws of any other state to the extent such laws are applicable to the sale of such Securities or Underlying Shares hereunder.
- (iii) A legend regarding affiliate status of the Purchasers set forth in Schedule 1 hereto, in the form included therein.

(b) The Company agrees that at such time as such legend is no longer required under this Section, it will, no later than three business days following the delivery by a Purchaser to the Company or the Company's transfer agent of a certificate representing Shares or Underlying Shares, as applicable and if such Shares are certificated, issued with a restrictive legend, together with such representations and covenants of such Purchaser or such Purchaser's executing broker as the Company may reasonably require in connection therewith, deliver or cause to be delivered to such Purchaser a book entry position representing such shares that is free from any legend referring to the Securities Act. The Company shall not make any notation on its records or give instructions to any transfer agent of the Company that enlarge the restrictions on transfer set forth in this Section. Certificates for Securities subject to legend removal hereunder shall be transmitted by the transfer agent of the Company to the Purchasers by crediting the account of such Purchaser's prime broker with the Depository Trust Company. All costs and expenses related to the removal of the legends and the reissuance of any Securities shall be borne by the Company.

(c) The restrictive legend set forth in this section above shall be removed and the Company shall issue a certificate or book entry position without such restrictive legend or any other restrictive legend to the holder of the applicable shares upon which it is stamped or issue to such holder by electronic delivery with the applicable balance account at the Depository Trust Company ("DTC") or in physical certificated shares, if appropriate, if (i) such Shares and Underlying Shares are registered for resale under the Securities Act (provided that, if the Purchaser is selling pursuant to the effective registration statement registering the Securities for resale, the Purchaser agrees to only sell such Shares during such time that such registration statement is effective and such Purchaser is not aware or has not been notified by the Company that such registration statement has been withdrawn or suspended, and only as permitted by such registration statement); (ii) such Shares are sold or transferred pursuant to Rule 144 (if the transferor is not an affiliate of the Company); or (iii) such Shares are eligible for sale without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such securities and without volume or manner-of-sale restrictions. Subject to receipt of such representations, and covenants as are contemplated hereby, following the earlier of (i) the effective date of the Registration Statement or (ii) Rule 144 becoming available for the resale of the Shares and Underlying Shares, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to the Shares and Underlying Shares and without volume or manner-of-sale restrictions, the Company shall issue to the Company's transfer agent the instructions with respect to legend removal consistent with this Section. Any fees (with respect to the transfer agent, the Company's counsel or otherwise) associated with the issuance of such opinion or the removal of such legend shall be borne by the Company.

5.5 Restricted Securities. Purchaser understands that the Securities are characterized as “restricted securities” under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such Securities may be resold without registration under the Securities Act only in certain limited circumstances. In this connection, such Purchaser represents that it is familiar with Rule 144, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act.

5.6 Exculpation Among Purchasers. Purchaser acknowledges that it is not relying upon any other Purchaser, or any officer, director, employee, agent, partner, member or affiliate of any such other Purchaser, in making its investment or decision to invest in the Company. Purchaser agrees that neither any Purchaser nor the respective controlling Persons, officers, directors, partners, agents, or employees of any Purchaser shall be liable to any other Purchaser for any action heretofore taken or omitted to be taken by any of them in connection with the purchase of the Securities.

SECTION 6. CONDITIONS TO COMPANY’S OBLIGATIONS AT THE CLOSING.

The Company’s obligation to complete the sale and issuance of the Securities and deliver Securities to each Purchaser, individually, as set forth in the Schedule of Purchasers at the Closing shall be subject to the following conditions to the extent not waived by the Company:

6.1 Receipt of Payment. The Company shall have received payment, by wire transfer of immediately available funds, in the full amount of the purchase price for the number of Securities being purchased by such Purchaser at the Closing as set forth in the Schedule of Purchasers.

6.2 Representations and Warranties. The representations and warranties made by the Purchasers in Section 5 hereof shall be true and correct in all material respects when made, and shall be true and correct in all material respects on the Closing Date with the same force and effect as if they had been made on and as of said date. The Purchaser shall have performed in all material respects all obligations and covenants herein required to be performed by them on or prior to the Closing Date.

6.3 Receipt of Executed Documents. Such Purchaser shall have executed and delivered to the Company the Registration Rights Agreement, the Purchaser Questionnaire and the Selling Stockholder Questionnaire.

SECTION 7. CONDITIONS TO PURCHASERS' OBLIGATIONS AT THE CLOSING.

Each Purchaser's obligation to accept delivery of the Securities and to pay for the Securities shall be subject to the following conditions to the extent not waived by such Purchaser:

7.1 Representations and Warranties Correct. The representations and warranties made by the Company in Section 4 hereof shall be true and correct in all material respects as of, and as if made on, the date of this Agreement and as of the Closing Date, except to the extent any such representation or warranty expressly speaks as of an earlier date, in which case such representation or warranty shall be true and correct as of such earlier date. The Company shall have performed in all material respects all obligations and covenants herein required to be performed by it on or prior to the Closing Date.

7.2 Receipt of Executed Registration Rights Agreement. The Company shall have executed and delivered to the Purchasers the Registration Rights Agreement.

7.3 Legal Opinion. The Purchasers shall have received an opinion of Latham & Watkins LLP, special counsel to the Company, dated as of the Closing Date, in form and substance reasonably acceptable to the Purchasers.

7.4 Certificate. Each Purchaser shall have received a certificate signed by the Chief Executive Officer or the Chief Financial Officer to the effect that the representations and warranties of the Company in Section 4 hereof are true and correct in all material respects as of, and as if made on, the date of this Agreement and as of the Closing Date and that the Company has satisfied in all material respects all of the conditions set forth in this Section 7.

7.5 Good Standing. The Company is validly existing as a corporation in good standing under the laws of Delaware.

7.6 Nasdaq Approval. The Company shall have filed with Nasdaq a Notification Form: Listing of Additional Shares for the listing of the Shares and the Underlying Shares.

7.7 Judgments. No judgment, writ, order, injunction, award or decree of or by any court, or judge, justice or magistrate, including any bankruptcy court or judge, or any order of or by any governmental authority, shall have been issued, and no action or proceeding shall have been instituted by any governmental authority, enjoining or preventing the consummation of the transactions contemplated hereby.

7.8 Stop Orders. No stop order or suspension of trading shall have been imposed by the NASDAQ Global Market, the SEC or any other governmental regulatory body with respect to public trading in the Common Stock.

SECTION 8. TERMINATION OF OBLIGATIONS TO EFFECT CLOSING; EFFECTS.

8.1 The obligations of the Company, on the one hand, and the Purchasers, on the other hand, to effect the Closing shall terminate as follows:

(a) upon the mutual written consent of the Company and Purchasers that agreed to purchase a majority of the Securities to be issued and sold pursuant to this Agreement;

(b) by the Company if any of the conditions set forth in Section 6 shall have become incapable of fulfillment, and shall not have been waived by the Company; or

(c) by a Purchaser (with respect to itself only) if any of the conditions set forth in Section 7 shall have become incapable of fulfillment, and shall not have been waived by the Purchaser;

provided, however, that, except in the case of clauses (b) and (c) above, the party seeking to terminate its obligation to effect the Closing shall not then be in breach of any of its representations, warranties, covenants or agreements contained in this Agreement or the other Transaction Documents if such breach has resulted in the circumstances giving rise to such party's seeking to terminate its obligation to effect the Closing.

8.2 Nothing in this Section 8 shall be deemed to release any party from any liability for any breach by such party of the terms and provisions of this Agreement or the other Transaction Documents or to impair the right of any party to compel specific performance by any other party of its obligations under this Agreement or the other Transaction Documents.

SECTION 9. BROKER'S FEES.

The Company and each Purchaser (severally and not jointly) acknowledge and agree that Leerink Partners LLC is acting as the Company's placement agent for the sale of certain of the Securities being offered hereby and will be compensated solely by the Company in such capacity. Except as set forth in the preceding sentence, the Company and each Purchaser (severally and not jointly) hereby represent that there are no other brokers or finders entitled to compensation in connection with the sale of the Securities, and shall indemnify each other for any such fees for which they are responsible.

SECTION 10. ADDITIONAL AGREEMENTS OF THE PARTIES.

10.1 **Nasdaq Listing.** The Company will use commercially reasonable efforts to continue the listing and trading of its Common Stock on Nasdaq and, in accordance, therewith, will use commercially reasonable efforts to comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of such market or exchange, as applicable.

10.2 **Access to Information.** From the date hereof until the Closing, the Company will make reasonably available to the Purchasers' representatives, consultants and their respective counsels for inspection, such information and documents as the Purchasers reasonably request, and will make available at reasonable times and to a reasonable extent officers and employees of the Company to discuss the business and affairs of the Company.

10.3 **Termination of Covenants.** The provisions of Section 10.1-10.2 shall terminate and be of no further force and effect on the date on which the Company's obligations under the Registration Rights Agreement to register or maintain the effectiveness of any registration covering the Registrable Securities (as such term is defined in the Registration Rights Agreement) shall terminate.

10.4 **Form D; Blue Sky Filings.** The Company agrees to timely file a Form D with respect to the Securities and to provide a copy thereof, promptly upon request of any Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Securities for, sale to the Purchaser at the Closing under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of any Purchaser.

10.5 Integration. The Company shall not, and shall use its commercially reasonable efforts to ensure that no affiliate of the Company shall, sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that will be integrated with the offer or sale of the Securities in a manner that would require the registration under the Securities Act of the sale of the Securities to the Purchasers, or that will be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any trading market such that it would require stockholder approval prior to the closing of such other transaction unless stockholder approval is obtained before the closing of such subsequent transaction.

10.6 Short Sales and Confidentiality After the Date Hereof. Each Purchaser covenants that neither it nor any affiliates acting on its behalf or pursuant to any understanding with it will execute any Short Sales during the period from the date hereof until the earlier of such time as (i) after the transactions contemplated by this Agreement are first publicly announced or (ii) this Agreement is terminated in full. Each Purchaser covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company, such Purchaser will maintain the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Each Purchaser understands and acknowledges that the SEC currently takes the position that coverage of short sales of shares of the Common Stock “against the box” prior to effectiveness of a resale registration statement with securities included in such registration statement would be a violation of Section 5 of the Securities Act, as set forth in Item 239.10 of the Securities Act Rules Compliance and Disclosure Interpretations compiled by the Office of Chief Counsel, Division of Corporation Finance.

10.7 Securities Laws Disclosure; Publicity. By 5:00 P.M., New York City time, on the trading day immediately following the Effective Date, the Company shall issue a press release reasonably acceptable to Leerink Partners LLC disclosing the material terms of the transactions contemplated hereby. On or before 9:00 A.M., New York City time, on the third trading day immediately following the execution of this Agreement, the Company will file a Current Report on Form 8-K (the “8-K”) with the Commission describing the terms of the Transaction Documents (and including as exhibits to such Current Report on Form 8-K the agreements required to be filed in connection therewith). Notwithstanding the foregoing, the Company shall not publicly disclose the name of any Purchaser, or include the name of any Purchaser in any public filing with the Commission or any regulatory agency or NASDAQ, without the prior written consent of such Purchaser, which consent shall not be unreasonably withheld, conditioned or delayed, except: (a) as required by federal securities law in connection with (i) any registration statement contemplated by the Registration Rights Agreement and (ii) the filing of final Transaction Documents with the Commission; (b) the filing of a Form D with the Commission under the Securities Act and (c) to the extent such disclosure is required by law or NASDAQ regulations, in which case the Company shall provide the Purchasers with prior notice of such disclosure permitted under this clause (c). As of the time of the filing of the 8-K, no Purchaser shall be in possession of any material, non-public information received from the Company, any subsidiary of the Company or any of their respective officers, directors, employees or agents, pursuant to the transactions contemplated by this Agreement that is not disclosed in the 8-K, press release or other disclosure by the Company that complies with the requirements of Regulation FD.

10.8 Subsequent Equity Sales. From the date hereof until the later of (i) 90 days after the Effective Date and (ii) the date immediately following the date on which the initial Registration Statement required by Section 2(a) of the Registration Rights Agreement is first declared effective by the Commission, neither the Company nor any subsidiary of the Company shall issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents. Notwithstanding the foregoing, in no event shall this Section 10.8 prohibit the Company from (A) issuing shares of Common Stock or Common Stock Equivalents (i) in connection with a transaction with an third party that includes a bona fide commercial relationship with the Company (including any joint venture, marketing or distribution arrangement, strategic alliance, collaboration agreement or corporate partnering or intellectual property license agreement with the Company), (ii) upon the exercise of any options, equity awards or warrants outstanding on the date hereof, or (iii) to employees, directors, consultants or service providers pursuant to any stock option or equity incentive or employee stock purchase plan or otherwise for bona fide equity compensation purposes; provided, however, that the aggregate number of shares of Common Stock or Common Stock Equivalents issued pursuant to clause (i) during the restricted period specified in this Section 10.8 shall not exceed 10% of the total number of shares of Common Stock issued and outstanding immediately following the Closing, or (B) filing a registration statement on Form S-3 with the Commission to register equity securities of the Company to be sold on a primary basis following the Effective Date. For purposes of this section, "Common Stock Equivalents" means any securities of the Company or any subsidiary of the Company which would entitle the holder thereof to acquire Common Stock, including, without limitation, any debt, preferred stock, rights, options, warrants or other instrument that is convertible into or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock or other securities that entitle the holder to receive, directly or indirectly, Common Stock.

SECTION 11. INDEMNIFICATION.

11.1 Indemnification by the Company. The Company agrees to indemnify and hold harmless each of the Purchasers and each Person, if any, who controls any Purchaser within the meaning of the Securities Act (each, an "Indemnified Party"), against any losses, claims, damages, liabilities or expenses, joint or several, to which such Indemnified Party may become subject under the Securities Act, the Exchange Act, or any other federal or state statutory law or regulation, or at common law (including in settlement of any litigation, if such settlement is effected with the written consent of the Company), insofar as such losses, claims, damages, liabilities or expenses (or actions in respect thereof as contemplated below) arise out of or are based in whole or in part on any inaccuracy in the representations and warranties of the Company contained in this Agreement or any failure of the Company to perform its obligations hereunder, and will reimburse each Indemnified Party for legal and other expenses reasonably incurred as such expenses are reasonably incurred by such Indemnified Party in connection with investigating, defending, settling, compromising or paying such loss, claim, damage, liability, expense or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage, liability or expense arises out of or is based upon (i) the failure of such Indemnified Party to comply with the covenants and agreements contained in Section 6 above respecting sale of the Securities (including the Underlying Shares), or (ii) the inaccuracy of any representations made by such Indemnified Party herein.

11.2 Indemnification by Purchasers. Each Purchaser shall severally, and not jointly, indemnify and hold harmless the other Purchasers and the Company, each of its directors, and each Person, if any, who controls the Company within the meaning of the Securities Act, against any losses, claims, damages, liabilities or expenses to which the Company, each of its directors or each of its controlling Persons may become subject, under the Securities Act, the Exchange Act, or any other federal or state statutory law or regulation, or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Purchaser) insofar as such losses, claims, damages, liabilities or expenses (or actions in respect thereof as contemplated below) arise out of or are based upon (i) any failure by such Purchaser to comply with the covenants and agreements contained in Sections 5 and 10.6 above respecting the sale of the Securities (including the Underlying Shares) unless such failure by such Purchaser is directly caused by the Company's failure to provide written notice of a Suspension to such Purchaser or (ii) the inaccuracy of any representation made by such Purchaser herein, in each case to the extent, and will reimburse the Company, each of its directors, and each of its controlling Persons for any legal and other expense reasonably incurred, as such expenses are reasonably incurred by the Company, each of its directors, and each of its controlling Persons in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. No Purchaser shall be liable for the indemnification obligations of any other Purchaser.

SECTION 12. NOTICES.

All notices, requests, consents and other communications hereunder shall be in writing, shall be sent by confirmed facsimile or electronic mail, or mailed by first-class registered or certified airmail, or nationally recognized overnight express courier, postage prepaid, and shall be deemed given when so sent in the case of facsimile or electronic mail transmission, or when so received in the case of mail or courier, and addressed as follows:

if to the Company, to:

Ardelyx, Inc.
34175 Ardenwood Blvd.
Fremont, California
Attention: Chief Executive Officer
Facsimile: (510) 745-0493
E-Mail: mraab@ardelyx.com

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

Latham & Watkins LLP
140 Scott Drive
Menlo Park, California 94025
Attention: Mark Roeder
Facsimile: (650) 463-2600
E-Mail: mark.roeder@lw.com

or to such other person at such other place as the Company shall designate to the Purchasers in writing; and

(a) if to the Purchasers, at the address as set forth at the end of this Agreement, or at such other address or addresses as may have been furnished to the Company in writing.

SECTION 13. MISCELLANEOUS.

13.1 Waivers and Amendments. Neither this Agreement nor any provision hereof may be changed, waived, discharged, terminated, modified or amended except upon the written consent of the Company and holders of at least a majority of the Shares and the Underlying Shares (assuming the exercise of the then-outstanding Warrants).

13.2 Headings. The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be part of this Agreement.

13.3 Severability. In case any provision contained in this Agreement should be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby.

13.4 Replacement of Shares or Warrants. If the Shares are certificated and any certificate or instrument evidencing any Shares or Warrants is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof, or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company and the Company's transfer agent of such loss, theft or destruction and the execution by the holder thereof of a customary lost certificate affidavit of that fact and an agreement to indemnify and hold harmless the Company and the Company's transfer agent for any losses in connection therewith or, if required by the transfer agent, a bond in such form and amount as is required by the transfer agent. The applicants for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs associated with the issuance of such replacement Shares or Warrant. If a replacement certificate or instrument evidencing any Shares or Warrant is requested due to a mutilation thereof, the Company may require delivery of such mutilated certificate or instrument as a condition precedent to any issuance of a replacement.

13.5 Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under this Agreement are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance of the obligations of any other Purchaser under this Agreement. Nothing contained herein and no action taken by any Purchaser pursuant hereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group, or are deemed affiliates (as such term is defined under the Exchange Act) with respect to such obligations or the transactions contemplated by this Agreement. Each Purchaser shall be entitled to independently protect and

enforce its rights, including without limitation the rights arising out of this Agreement, and it shall not be necessary for any other Purchaser to be joined as an additional party in any proceeding for such purpose.

13.6 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of California, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of San Francisco. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City San Francisco for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law.

13.7 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, but all of which, when taken together, shall constitute but one instrument, and shall become effective when one or more counterparts have been signed by each party hereto and delivered to the other parties.

13.8 Successors and Assigns. Except as otherwise expressly provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors, assigns, heirs, executors and administrators of the parties hereto.

13.9 Entire Agreement. This Agreement and other documents delivered pursuant hereto, including the exhibit and the Schedule of Exceptions, constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof and thereof.

13.10 Payment of Fees and Expenses. Each of the Company and the Purchasers shall bear its own expenses and legal fees incurred on its behalf with respect to this Agreement and the transactions contemplated hereby. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

13.11 **Survival.** The representations, warranties, covenants and agreements made in this Agreement shall survive any investigation made by the Company or the Purchasers and the Closing.

[signature pages follow]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

ARDELYX, INC.

By: /s/ Michael Raab

Name: Michael Raab

Title: President and Chief Executive Officer

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

PURCHASERS:

**New Enterprise Associates 12,
Limited Partnership**

By: /s/ Louis S. Citron

Name: Louis S. Citron

Title: Chief Legal Officer

Address: c/o New Enterprise Associates
1954 Greenspring Drive, Suite 600
Timonium, MD 21093

Fax: 410-842-4115

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

PURCHASERS:

NEA 15 Opportunity Fund, L.P.

By: /s/ Louis S. Citron

Name: Louis S. Citron

Title: Chief Legal Officer

Address: c/o New Enterprise Associates
1954 Greenspring Drive, Suite 600
Timonium, MD 21093

Fax: 410-842-4115

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

PURCHASERS:

New Enterprise Associates 15, L.P.

By: /s/ Louis S. Citron

Name: Louis S. Citron

Title: Chief Legal Officer

Address: c/o New Enterprise Associates
1954 Greenspring Drive, Suite 600
Timonium, MD 21093

Fax: 410-842-4115

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

PURCHASERS:

RA CAPITAL HEALTHCARE FUND, L.P.

By: RA Capital Management, LLC
Its: General Partner

By: /s/ Rajeev Shah

Name: Rajeev Shah

Title: Authorized Signatory

Address: 20 Park Plaza
Suite 1200
Boston, MA 02116

Fax: _____

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

PURCHASERS:

Blackwell Partners LLC—Series A

By: /s/ Eric M. Koehrsen /s/ Jannine Lall

Name: Eric M. Koehrsen/ Jannine Lall

Title: Authorized Signatory/ Authorized Signatory

Address: 280 S. Mangum Street, Suite 210
Durham, NC 27701

Fax: 919-668-9926

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

PURCHASERS:

FORESITE CAPITAL FUND II, LP

by: FORESITE CAPITAL MANAGEMENT II, LLC,
General Partner

By: /s/ Dennis D. Ryan

Name: Dennis D. Ryan

Title: CFO

Address: 101 California Street, Suite 4100
San Francisco, CA 94111

Fax: (530) 787-3805

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

PURCHASERS:

Broadfin Healthcare Master Fund, Ltd.

By: /s/ Jason Abrams

Name: Jason Abrams

Title: CFO

Address: 300 Park Avenue, 25 Floor
New York, NY 10022

Fax: 212-808-2464

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

PURCHASERS:

ROCK SPRINGS CAPITAL MASTER FUND LP

By: Rock Springs GP LLC
Its: General Partner

By: /s/ Graham McPhail

Name: Graham McPhail

Title: Managing Director

Address: Rock Springs Capital
650 S. Exeter St., Suite 1070
Baltimore, MD 21202

Fax: 410-220-0144

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

PURCHASERS:

Cormorant Global Healthcare Master Fund, LP

By: /s/ Jay Scollins

Name: Jay Scollins

Title: CFO/COO

Address: 200 Clarendon Street 52nd Floor
Boston, MA 02116

Fax: 617-509-5905

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

PURCHASERS:

Sabby Healthcare Master Fund, Ltd.

By: /s/ Robert Grundstein

Name: Robert Grundstein

Title: COO of Investment Management

Address: c/o Sabby Management, LLC

10 Mountainview Road, Suite 205

Upper Saddle River, NJ 27458

Fax: _____

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

PURCHASERS:

By: /s/ Peter Schultz

Name: Peter Schultz

Title: Professor

Address: _____

Fax: 858-242-1001

SIGNATURE PAGES TO
SECURITIES PURCHASE AGREEMENT

**EXHIBIT A
SCHEDULE OF PURCHASERS**

<u>Name and Address</u>	<u>Number of Shares</u>	<u>Number of Shares Underlying Warrants</u>	<u>Aggregate Purchase Price of Warrants and Shares</u>
New Enterprise Associates 12, Limited Partnership c/o New Enterprise Associates 1954 Greenspring Drive, Suite 600 Timonium, MD 21093	1,869,159	560,748	\$ 20,070,094.80
NEA 15 Opportunity Fund, L.P. c/o New Enterprise Associates 1954 Greenspring Drive, Suite 600 Timonium, MD 21093	1,401,869	420,561	\$ 15,052,568.43
New Enterprise Associates 15, L.P. c/o New Enterprise Associates 1954 Greenspring Drive, Suite 600 Timonium, MD 21093	1,401,869	420,561	\$ 15,052,568.43
RA Capital Healthcare Fund, L.P. 20 Park Plaza Suite 1200 Boston, MA 02116	459,813	137,944	\$ 4,937,242.10
Blackwell Partners LLC - Series A 280 S. Mangum Street, Suite 210 Durham, NC 27701	100,935	30,281	\$ 1,083,789.63
Foresite Capital Fund II, LP 101 California Street Suite 4100 San Francisco, CA 94111	467,290	140,187	\$ 5,017,526.38
Broadfin Healthcare Master Fund, Ltd. 300 Park Avenue 25th Floor New York, NY 10022	467,290	140,187	\$ 5,017,526.38
Rock Springs Capital Master Fund LP Rock Springs Capital 650 S. Exeter St. Suite 1070 Baltimore, MD 21202	467,290	140,187	\$ 5,017,526.38
Cormorant Global Healthcare Master Fund, LP 200 Clarendon Street 52nd Floor Boston, MA 02116	467,290	140,187	\$ 5,017,526.38
Sabby Healthcare Master Fund, Ltd. c/o Sabby Management LLC 10 Mountainview Road Suite 205 Upper Saddle River, NJ 07458	93,458	28,037	\$ 1,003,505.23
Peter Schultz 1650 la Jolla Rancho Rd La Jolla, CA 92037	46,729	14,019	\$ 501,752.68
TOTAL	<u>7,242,992</u>	<u>2,172,899</u>	<u>\$ 77,771,626.82</u>

EXHIBIT B
FORM OF WARRANT

THIS WARRANT AND THE SECURITIES ISSUABLE UPON THE EXERCISE HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION IS NOT REQUIRED UNDER SUCH ACT OR UNLESS SOLD IN ACCORDANCE WITH RULE 144 UNDER SUCH ACT.

WARRANT NO. 2015-
DATE OF ISSUANCE: June , 2015
EXPIRATION DATE: June , 2020

NUMBER OF SHARES:
(subject to adjustment hereunder)

WARRANT TO PURCHASE SHARES
OF COMMON STOCK OF

ARDELYX, INC.

This Warrant is issued to , or its registered assigns (including any successors or assigns, the "Purchaser"), pursuant to that certain Securities Purchase Agreement, dated as of June 2, 2015, among Ardelyx, Inc., a Delaware corporation (the "Company"), the Purchaser and certain other purchasers thereunder (the "Purchase Agreement") and is subject to the terms and conditions of the Purchase Agreement.

1. EXERCISE OF WARRANT.

(a) Number and Exercise Price of Warrant Shares; Expiration Date. Subject to the terms and conditions set forth herein and set forth in the Purchase Agreement, the Purchaser is entitled to purchase from the Company up to shares of the Company's Common Stock, \$0.0001 par value per share (the "Common Stock") (as adjusted from time to time pursuant to the provisions of this Warrant) (the "Warrant Shares"), at a purchase price of \$13.91 per share (the "Exercise Price"), on or before 5:00 p.m. New York City time on June , 2020 (the "Expiration Date") (subject to earlier termination of this Warrant as set forth herein).

(b) Method of Exercise. While this Warrant remains outstanding and exercisable in accordance with Section 1(a) above, the Purchaser may exercise this Warrant by surrendering this Warrant at the principal office of the Company and paying the Exercise Price by either:

- (1) wire transfer to the Company or cashier's check drawn on a United States bank made payable to the order of the Company, or
- (2) exercising of the right to credit the Exercise Price against the Fair Market Value of the Warrant Shares (as defined below) at the time of exercise (the "Net Exercise") pursuant to Section 1(c).

(c) Net Exercise. If the Company shall receive written notice from the Purchaser at the time of exercise of this Warrant that the holder elects to Net Exercise the Warrant, the Company shall deliver to such Purchaser (without payment by the Purchaser of any exercise price in cash) that number of Warrant Shares computed using the following formula:

$$X = \frac{Y(A - B)}{A}$$

Where

- X = The number of Warrant Shares to be issued to the Purchaser.
- Y = The number of Warrant Shares purchasable under this Warrant or, if only a portion of the Warrant is being exercised, the portion of the Warrant being cancelled (at the date of such calculation).
- A = The Fair Market Value of one (1) share of Common Stock (at the date of such calculation).
- B = The Exercise Price (as adjusted to the date of such calculations).

The "Fair Market Value" of one share of Common Stock shall mean (x) the last reported sale price and, if there are no sales, the last reported bid price, of the Common Stock on the business day prior to the date of exercise on the NASDAQ Global Market as reported by Bloomberg Financial Markets (or a comparable reporting service of national reputation selected by the Company and reasonably acceptable to the holder if Bloomberg Financial Markets is not then reporting sales prices of the Common Stock) (collectively, "Bloomberg") or (y) or if the foregoing does not apply, the last sales price of the Common Stock in the over-the-counter market on the pink sheets or bulletin board for such security as reported by Bloomberg, and, if there are no sales, the last reported bid price of the Common Stock as reported by Bloomberg or, if fair market value cannot be calculated as of such date on either of the foregoing bases, the price determined in good faith by the Company's Board of Directors.

(d) Deemed Exercise. In the event that immediately prior to the close of business on the Expiration Date, the Fair Market Value of one share of Common Stock (as determined in accordance with Section 1(c) above) is greater than the then applicable Exercise Price, this Warrant shall be deemed to be automatically exercised on a net exercise issue basis pursuant to Section 1(c) above, and the Company shall deliver the applicable number of shares of Common Stock to the Holder pursuant to the provisions of Section 1(c) above and this Section 1(d).

2. CERTAIN ADJUSTMENTS.

(a) Adjustment of Number of Warrant Shares and Exercise Price. The number and kind of Warrant Shares purchasable upon exercise of this Warrant and the Exercise Price shall be subject to adjustment from time to time as follows:

(1) Subdivisions, Combinations and Other Issuances. If the Company shall at any time after the Date of Issuance but prior to the Expiration Date subdivide its shares of

capital stock of the same class as the Warrant Shares, by split-up or otherwise, or combine such shares of capital stock, or issue additional shares of capital stock as a dividend with respect to any shares of such capital stock, the number of Warrant Shares issuable on the exercise of this Warrant shall forthwith be proportionately increased in the case of a subdivision or stock dividend, or proportionately decreased in the case of a combination. Appropriate adjustments shall also be made to the Exercise Price payable per share, but the aggregate Exercise Price payable for the total number of Warrant Shares purchasable under this Warrant (as adjusted) shall remain the same. Any adjustment under this Section 2(a)(1) shall become effective at the close of business on the date the subdivision or combination becomes effective, or as of the record date of such dividend, or in the event that no record date is fixed, upon the making of such dividend.

(2) Reorganizations or Mergers. In case of any reclassification, capital reorganization or change in the capital stock of the Company (other than as a result of a subdivision, combination or stock dividend provided for in Section 2(a)(1) above) that occurs after the Date of Issuance, then, as a condition of such reclassification, reorganization or change, lawful provision shall be made, and duly executed documents evidencing the same from the Company or its successor shall be delivered to the Purchaser, so that the Purchaser shall thereafter have the right at any time prior to the expiration of this Warrant to purchase, at a total price equal to that payable upon the exercise of this Warrant, the kind and amount of shares of stock and/or other securities or property (including, if applicable, cash) receivable in connection with such reclassification, reorganization or change by a holder of the same number and type of securities as were purchasable as Warrant Shares by the Purchasers immediately prior to such reclassification, reorganization or change. In any such case appropriate provisions shall be made with respect to the rights and interest of the Purchaser so that the provisions hereof shall thereafter be applicable with respect to any shares of stock or other securities or property deliverable upon exercise hereof, and appropriate adjustments shall be made to the Exercise Price payable hereunder, provided the aggregate Exercise Price shall remain the same (and, for the avoidance of doubt, this Warrant shall be exclusively exercisable for such shares of stock and/or other securities or property from and after the consummation of such reclassification or other change in the capital stock of the Company).

(b) Notice to Holder. If, while this Warrant is outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including, without limitation, any granting of rights or warrants to subscribe for or purchase any capital stock of the Company or any subsidiary, (ii) authorizes or approves, enters into any agreement contemplating or solicits stockholder approval for any Change of Control or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then the Company shall deliver to a holder a notice of such transaction at least 15 business days prior to the applicable record or effective date on which a person would need to hold Common Stock in order to participate in or vote with respect to such transaction; provided, however, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice.

(c) Calculations. All calculations under this Section 2 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 2, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(d) Treatment of Warrant upon a Change of Control.

(1) In the event of a Change of Control in which the consideration to be received by the Company's stockholders consists solely of cash, solely of Marketable Securities (as defined below) or a combination of cash and Marketable Securities (a "Cash/Public Change of Control"), if this Warrant is outstanding upon the consummation of such Cash/Public Change of Control then (i) if the Fair Market Value of one share of Common Stock (as determined in accordance with Section 1(c)) is greater than the then applicable Exercise Price, this Warrant shall be deemed to be automatically exercised on a net exercise issue basis pursuant to Section 1(c) as of immediately prior to such Cash/Public Change of Control and (ii) if the Fair Market Value of one share of Common Stock (as determined in accordance with Section 1(c)) is less than or equal to the then applicable Exercise Price, this Warrant will expire immediately prior to the consummation of such Change of Control.

(2) If, at any time while this Warrant is outstanding, the Company consummates a Change of Control that is not a Cash/Public Change of Control, then a holder shall have the right thereafter to receive, upon exercise of this Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Change of Control if it had been, immediately prior to such Change of Control, a holder of the number of Warrant Shares then issuable upon exercise in full of this Warrant (the "Alternate Consideration"). The Company shall not effect any such Change of Control unless prior to or simultaneously with the consummation thereof, any successor to the Company, surviving entity or the corporation purchasing or otherwise acquiring such assets or other appropriate corporation or entity shall assume the obligation to deliver to the holder, such Alternate Consideration as, in accordance with the foregoing provisions, the holder may be entitled to purchase, and the other obligations under this Warrant.

(3) As used in this Warrant, a "Change of Control" shall mean (i) a merger or consolidation of the Company with another corporation (other than a merger effected exclusively for the purpose of changing the domicile of the Company), (ii) the sale, assignment, transfer, conveyance or other disposal of all or substantially all of the properties or assets or all or a majority of the outstanding voting shares of capital stock of the Company, (iii) a purchase, tender or exchange offer accepted by the holders of a majority of the outstanding voting shares of capital stock of the Company, or (iv) a "person" or "group" (as these terms are used for purposes of Section 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) is or shall become the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly at least a majority of the voting power of the capital stock of the Company.

(4) As used in this Warrant, "Marketable Securities" means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act, and is then current in its filing of all required reports and other information under the Securities Act of 1933, as amended (the "Securities Act"), and the Exchange Act; (ii) the class and series of shares or other

security of the issuer that would be received by the holder in connection with the Change of Control were the holder to exercise this Warrant on or prior to the closing thereof is then traded or quoted on a nationally recognized securities exchange, inter-dealer quotation system or over-the-counter market, and (iii) following the closing of such Change of Control, the holder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by the holder in such Change of Control were the holder to exercise or convert this Warrant in full on or prior to the closing of such Change of Control, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six months from the closing of such Change of Control.

2. NO FRACTIONAL SHARES. No fractional Warrant Shares or scrip representing fractional shares will be issued upon exercise of this Warrant. In lieu of any fractional shares which would otherwise be issuable, the Company shall pay cash equal to the product of such fraction multiplied by the Fair Market Value of one Warrant Share.

3. NO STOCKHOLDER RIGHTS. Until the exercise of this Warrant or any portion of this Warrant, the Purchaser shall not have, nor exercise, any rights as a stockholder of the Company (including without limitation the right to notification of stockholder meetings or the right to receive any notice or other communication concerning the business and affairs of the Company) except as provided in Section 9 below.

4. RESERVATION OF STOCK. The Company covenants that during the period this Warrant is exercisable, the Company will reserve from its authorized and unissued Common Stock a sufficient number of shares of Common Stock (or other securities, if applicable) to provide for the issuance of Warrant Shares (or other securities) upon the exercise of this Warrant.

5. MECHANICS OF EXERCISE.

(a) Delivery of Warrant Shares Upon Exercise. This Warrant may be exercised by the holder hereof, in whole or in part, by the surrender of this Warrant and the Notice of Exercise attached hereto as Exhibit A duly completed and executed on behalf of the holder hereof, at the principal office of the Company together with payment in full of the Exercise Price (unless the Purchaser has elected to Net Exercise) then in effect with respect to the number of Warrant Shares as to which the Warrant is being exercised. This Warrant shall be deemed to have been exercised immediately prior to the close of business on the date of its surrender for exercise as provided above, and the person entitled to receive the Warrant Shares issuable upon such exercise shall be treated for all purposes as the holder of such shares of record as of the close of business on such date. Warrant Shares purchased hereunder shall be transmitted by the Company's transfer agent to the holder by crediting the account of the holder's prime broker with The Depository Trust Company through its Deposit or Withdrawal at Custodian system if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the holder or (B) the shares are eligible for resale by the holder without volume or manner-of-sale limitations pursuant to Rule 144, and otherwise by physical delivery to the address specified by the holder in the Notice of Exercise by the end of the day on the date that is three trading days from the delivery to the Company of the Notice of Exercise, surrender of this Warrant and

payment of the aggregate Exercise Price (unless exercised by means of a cashless exercise pursuant to Section 1(c). The Warrant Shares shall be deemed to have been issued, and the holder or any other person so designated to be named therein shall be deemed to have become a holder of record of such shares for all purposes, as of the date the Warrant has been exercised, with payment to the Company of the Exercise Price (or by Net Exercise) and all taxes required to be paid by the holder, if any, prior to the issuance of such shares, having been paid.

(b) Holder's Exercise Limitations.¹ A holder shall not have the right to exercise this Warrant, pursuant to Section 1 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the holder (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by the holder and its affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the holder or any of its affiliates and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other convertible notes or convertible preferred stock or warrants) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the holder or any of its affiliates. Except as set forth in the preceding sentence, for purposes of this section, beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the holder that the Company is not representing to the holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this section 5(b) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the holder together with any affiliates) and of which portion of this Warrant is exercisable shall be in the sole discretion of the holder, and the submission of a Notice of Exercise shall be deemed to be the holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the holder together with any affiliates) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercise of the Warrant that are not in compliance with the Beneficial Ownership Limitation. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 5(b), in determining the number of outstanding shares of Common Stock, a holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Company's transfer agent setting forth the number of shares of Common Stock outstanding. Upon the written request of a holder, the Company shall within

¹ **Note to Form:** This Section 5(b) will be included for all Purchasers other than Purchasers affiliated with New Enterprise Associates.

three trading days confirm in writing to the holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the holder or its affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. Any such increase or decrease will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 5(b) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

6. CERTIFICATE OF ADJUSTMENT. Whenever the Exercise Price or number or type of securities issuable upon exercise of this Warrant is adjusted, as herein provided, the Company shall, at its expense, promptly deliver to the Purchaser a certificate of an officer of the Company setting forth the nature of such adjustment and showing in detail the facts upon which such adjustment is based.

7. COMPLIANCE WITH SECURITIES LAWS.

(a) The Purchaser understands that this Warrant and the Warrant Shares are characterized as "restricted securities" under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations this Warrant and the Warrant Shares may be resold without registration under the Securities Act only in certain limited circumstances. In this connection, the Purchaser represents that it is familiar with Rule 144 under the Securities Act, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act.

(b) Prior and as a condition to the sale or transfer of the Warrant Shares issuable upon exercise of this Warrant, the Purchaser shall furnish to the Company such certificates, representations, agreements and other information, including an opinion of counsel, as the Company or the Company's transfer agent reasonably may require to confirm that such sale or transfer is being made pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act, unless such Warrant Shares are being sold or transferred pursuant to an effective registration statement.

(c) The Purchaser acknowledges that the Company may place a restrictive legend on the Warrant Shares issuable upon exercise of this Warrant in order to comply with applicable securities laws, unless such Warrant Shares are otherwise freely tradable under Rule 144 of the Securities Act.

8. REPLACEMENT OF WARRANTS. On receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant and, in the case of any such loss, theft or destruction of this Warrant, on delivery of an indemnity agreement reasonably

satisfactory in form and amount to the Company or, in the case of any such mutilation, on surrender and cancellation of such Warrant, the Company at its expense will execute and deliver, in lieu thereof, a new Warrant of like tenor.

9. NO IMPAIRMENT. Except to the extent as may be waived by the holder of this Warrant, the Company will not, by amendment of its charter or through a Change of Control, dissolution, sale of assets or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such action as may be necessary or appropriate in order to protect the rights of the Purchaser against impairment.

10. TRADING DAYS. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall be other than a day on which the Common Stock is traded on the Nasdaq Global Market, or, if the Nasdaq Global Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock is then traded, then such action may be taken or such right may be exercised on the next succeeding day on which the Common Stock is so traded.

11. TRANSFERS; EXCHANGES. (a) Subject to compliance with applicable federal and state securities laws and Section 8 hereof, this Warrant may be transferred by the Purchaser with respect to any or all of the Warrant Shares purchasable hereunder. For a transfer of this Warrant as an entirety by Purchaser, upon surrender of this Warrant to the Company, together with the Notice of Assignment in the form attached hereto as Exhibit B duly completed and executed on behalf of the Purchaser, the Company shall issue a new Warrant of the same denomination to the assignee. For a transfer of this Warrant with respect to a portion of the Warrant Shares purchasable hereunder, upon surrender of this Warrant to the Company, together with the Notice of Assignment in the form attached hereto as Exhibit B duly completed and executed on behalf of the Purchaser, the Company shall issue a new Warrant to the assignee, in such denomination as shall be requested by the Purchaser, and shall issue to the Purchaser a new Warrant covering the number of shares in respect of which this Warrant shall not have been transferred.

(b) This Warrant is exchangeable, without expense, at the option of the Purchaser, upon presentation and surrender hereof to the Company for other warrants of different denominations entitling the holder thereof to purchase in the aggregate the same number of shares of Common Stock purchasable hereunder. This Warrant may be divided or combined with other warrants that carry the same rights upon presentation hereof at the principal office of the Company together with a written notice specifying the denominations in which new warrants are to be issued to the Purchaser and signed by the Purchaser hereof. The term "Warrants" as used herein includes any warrants into which this Warrant may be divided or exchanged.

12. MISCELLANEOUS. This Agreement shall be governed by and construed in accordance with the internal laws of the State of California, without the application of principles of conflicts of laws that would result in any law other than the laws of the State of California. All notices, requests, consents and other communications hereunder shall be in writing, shall be sent by confirmed facsimile or electronic mail, or mailed by first-class registered or certified

airmail, or nationally recognized overnight express courier, postage prepaid, and shall be deemed given when so sent in the case of facsimile or electronic mail transmission, or when so received in the case of mail or courier, and addressed as follows: (a) if to the Company, at 34175 Ardenwood Blvd., Fremont, California, Attention: Chief Executive Officer, Facsimile: (510) 745-0493, Email: mraab@ardelyx.com; with a copy to (which shall not constitute notice) Latham & Watkins LLP, 140 Scott Drive, Menlo Park, California 94025, Attention: Mark Roeder, Facsimile: (650) 463-2600, E-Mail: mark.roeder@lw.com and (b) if to the Purchaser, at such address or addresses (including copies to counsel) as may have been furnished by the Purchaser to the Company in writing. The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provisions.

[Signature Page Follows]

IN WITNESS WHEREOF, this Common Stock Purchase Warrant is issued effective as of the date first set forth above.

ARDELYX, INC.

By: _____
Name: Michael Raab
Title: President and Chief Executive Officer

Signature Page to Warrant No. 2015-[Warrant No.]

EXHIBIT A

NOTICE OF INTENT TO EXERCISE
(To be signed only upon exercise of Warrant)

To: Ardelyx, Inc.

The undersigned, the Purchaser of the attached Warrant, hereby irrevocably elects to exercise the purchase right represented by such Warrant for, and to purchase thereunder, _____ (_____) shares of Common Stock of Ardelyx, Inc. and (choose one)

_____ herewith makes payment of _____ Dollars (\$_____) thereof

or

_____ elects to Net Exercise the Warrant pursuant to Section 1(b)(2) thereof.

The undersigned requests that the certificates or book entry position evidencing the shares to be acquired pursuant to such exercise be issued in the name of, and delivered to _____, whose address is _____

By its signature below the undersigned hereby represents and warrants that it is an "accredited investor" as defined in Rule 501(a) of Regulation D promulgated under the Securities Act of 1933, as amended, and agrees to be bound by the terms and conditions of the attached Warrant as of the date hereof, including Section 9 thereof.

DATED: _____

(Signature must conform in all respects to name of the Purchaser as specified on the face of the Warrant)

[Purchaser]
Address: _____

EXHIBIT B

NOTICE OF ASSIGNMENT FORM

FOR VALUE RECEIVED, [Purchaser] (the "Assignor") hereby sells, assigns and transfers all of the rights of the undersigned Assignor under the attached Warrant with respect to the number of shares of common stock of Ardelyx, Inc. (the "Company") covered thereby set forth below, to the following "Assignee" and, in connection with such transfer, represents and warrants to the Company that the transfer is in compliance with Section 9 of the Warrant and applicable federal and state securities laws:

NAME OF ASSIGNEE

ADDRESS/FAX NUMBER

Number of shares: _____

Dated: _____ Signature: _____

Witness: _____

ASSIGNEE ACKNOWLEDGMENT

The undersigned Assignee acknowledges that it has reviewed the attached Warrant and by its signature below it hereby represents and warrants that it is an "accredited investor" as defined in Rule 501(a) of Regulation D promulgated under the Securities Act of 1933, as amended, and agrees to be bound by the terms and conditions of the Warrant as of the date hereof, including Section 9 thereof.

Signature: _____

By: _____

Its: _____

Address:

EXHIBIT C
LIST OF PERSONS EXECUTING LOCK-UP AGREEMENTS

Peter Schultz
David Mott
NEA Ventures 2008, Limited Partnership
New Enterprise Associates 12, Limited Partnership
New Enterprise Associates 15, L.P.
NEA 15 Opportunity Fund, L.P.

APPENDIX I

PURCHASER QUESTIONNAIRE

To: Ardelyx, Inc.

This Purchaser Questionnaire ("*Questionnaire*") must be completed by each potential investor in connection with the offer and sale of the shares of the common stock, par value \$0.0001 per share, and shares of common stock that may be issued upon exercise of certain warrants (collectively, the "*Securities*"), of Ardelyx, Inc., a Delaware corporation (the "*Corporation*"). The Securities are being offered and sold by the Corporation without registration under the Securities Act of 1933, as amended (the "*Securities Act*"), and the securities laws of certain states, in reliance on the exemptions contained in Section 4(a)(2) of the Securities Act and on Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. The Corporation must determine that a potential investor meets certain suitability requirements before offering or selling the Securities to such investor. The purpose of this Questionnaire is to assure the Corporation that each investor will meet the applicable suitability requirements. The information supplied by you will be used in determining whether you meet such criteria, and reliance upon the private offering exemptions from registration is based in part on the information herein supplied.

This Questionnaire does not constitute an offer to sell or a solicitation of an offer to buy any security. By signing this Questionnaire, you will be authorizing the Corporation to provide a completed copy of this Questionnaire to such parties as the Corporation deems appropriate in order to ensure that the offer and sale of the Securities will not result in a violation of the Securities Act or the securities laws of any state and that you otherwise satisfy the suitability standards applicable to purchasers of the Securities. All potential investors must answer all applicable questions and complete, date and sign this Questionnaire. Please print or type your responses and attach additional sheets of paper if necessary to complete your answers to any item.

PART A. BACKGROUND INFORMATION

Name of Beneficial Owner of the Securities: _____

Business Address: _____
(Number and Street)

City: _____ State: _____ Zip Code: _____

Telephone Number: _____

If a corporation, partnership, limited liability company, trust or other entity:

Type of entity: _____

State of formation: _____ Approximate Date of formation: _____

Were you formed for the purpose of investing in the securities being offered?

Yes No

If an individual:

Residence Address:

(Number and Street)

City: _____ State: _____ Zip Code: _____

Telephone Number: _____

Age: _____ Citizenship: _____ Where registered to vote: _____

Set forth in the space provided below the state(s), if any, in the United States in which you maintained your residence during the past two years and the dates during which you resided in each state:

Are you a director or executive officer of the Corporation?

Yes No

Social Security or Taxpayer Identification No.: _____

PART B. ACCREDITED INVESTOR QUESTIONNAIRE

In order for the Corporation to offer and sell the Securities in conformance with state and federal securities laws, the following information must be obtained regarding your investor status. Please initial each category applicable to you as a purchaser of Securities of the Corporation.

- (1) A bank as defined in Section 3(a)(2) of the Securities Act, or any savings and loan association or other institution as defined in Section 3(a)(5) (A) of the Securities Act whether acting in its individual or fiduciary capacity;
- (2) A broker or dealer registered pursuant to Section 15 of the Securities Exchange Act of 1934, as amended (the "Exchange Act");
- (3) An insurance company as defined in Section 2(13) of the Securities Act;
- (4) An investment company registered under the Investment Company Act of 1940 or a business development company as defined in Section 2(a)(48) of that act;
- (5) A Small Business Investment Company licensed by the U.S. Small Business Administration under Section 301(c) or (d) of the Small Business Investment Act of 1958;

-
- (6) A plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has total assets in excess of \$5,000,000;
 - (7) An employee benefit plan within the meaning of the Employee Retirement Income Security Act of 1974, if the investment decision is made by a plan fiduciary, as defined in Section 3(21) of such act, which is either a bank, savings and loan association, insurance company or registered investment adviser, or if the employee benefit plan has total assets in excess of \$5,000,000 or, if a self-directed plan, with investment decisions made solely by persons that are accredited investors;
 - (8) A private business development company as defined in Section 202(a)(22) of the Investment Advisers Act of 1940;
 - (9) An organization described in Section 501(c)(3) of the Internal Revenue Code, a corporation, Massachusetts or similar business trust, or partnership, not formed for the specific purpose of acquiring the Securities, with total assets in excess of \$5,000,000;
 - (10) A trust, with total assets in excess of \$5,000,000, not formed for the specific purpose of acquiring the Securities, whose purchase is directed by a sophisticated person who has such knowledge and experience in financial and business matters that such person is capable of evaluating the merits and risks of investing in the Corporation;
 - (11) A natural person whose individual net worth, or joint net worth with that person's spouse, at the time of his purchase exceeds \$1,000,000 (exclusive of the value of that person's primary residence);
 - (12) A natural person who had an individual income in excess of \$200,000 in each of the two most recent years, or joint income with that person's spouse in excess of \$300,000, in each of those years, and has a reasonable expectation of reaching the same income level in the current year;
 - (13) An executive officer or director of the Corporation;
 - (14) An entity in which all of the equity owners qualify under any of the above subparagraphs. If the undersigned belongs to this investor category only, list the equity owners of the undersigned, and the investor category which each such equity owner satisfies.

PART C. BAD ACTOR QUESTIONNAIRE

1. During the past ten years, have you been convicted of any felony or misdemeanor that is related to any securities matter?

Yes (If yes, please continue to Question 1.a)

No (If no, please continue to Question 2)

- a) If your answer to Question 1 was “yes”, was the conviction related to: (i) the purchase or sale of any security; (ii) the making of any false filing with the Securities and Exchange Commission (the “SEC”); or (iii) the conduct of an underwriter, broker, dealer, municipal securities dealer, investment adviser or paid solicitor of purchasers of securities?

Yes No

2. Are you subject to any court injunction or restraining order entered during the past five years that is related to any securities matter?

Yes (If yes, please continue to Question 2.a)

No (If no, please continue to Question 3)

- a) If your answer to Question 2 was “yes”, does the court injunction or restraining order currently restrain or enjoin you from engaging or continuing to engage in any conduct or practice related to: (i) the purchase or sale of any security; (ii) the making of any false filing with the SEC; or (iii) the conduct of an underwriter, broker, dealer, municipal securities dealer, investment adviser or paid solicitor of purchasers of securities?

Yes No

3. Are you subject to any final order² of any governmental commission, authority, agency or officer³⁽²⁾ related to any securities, insurance or banking matter?

Yes (If yes, please continue to Question 3.a)

No (If no, please continue to Question 4)

- a) If your answer to Question 3 was “yes”:

i) Does the order currently bar you from: (i) associating with an entity regulated by such commission, authority, agency or officer; (ii)

² A “final order” is defined under Rule 501(g) as a written directive or declaratory statement issued by a federal or state agency described in Rule 506(d)(1) (iii) under applicable statutory authority that provides for notice and an opportunity for a hearing, and that constitutes a final disposition or action by such federal or state agency.

³ You may limit your response to final orders of: (i) state securities commissions (or state agencies/officers that perform a similar function); (ii) state authorities that supervise or examine banks, savings associations or credit unions; (iii) state insurance commissions (or state agencies/officers that perform a similar function); (iv) federal banking agencies; (v) the U.S. Commodity Futures Trading Commission; or (vi) the U.S. National Credit Union Administration.

engaging in the business of securities, insurance or banking; or (iii) engaging in savings association or credit union activities?

Yes No

- ii) Was the order (i) entered within the past ten years and (ii) based on a violation of any law or regulation that prohibits fraudulent, manipulative or deceptive conduct?

Yes No

4. Are you subject to any SEC disciplinary order?⁴(3)

Yes (If yes, please continue to Question 4.a)

No (If no, please continue to Question 5)

- a) If your answer to Question 4 was “yes”, does the order currently: (i) suspend or revoke your registration as a broker, dealer, municipal securities dealer or investment adviser; (ii) place limitations on your activities, functions or operations; or (iii) bar you from being associated with any particular entity or class of entities or from participating in the offering of any penny stock?

5. Are you subject to any SEC cease and desist order entered within the past five years?

Yes (If yes, please continue to Question 5.a)

No (If no, please continue to Question 6)

- a) If your answer to Question 5 was “yes”, does the order currently require you to cease and desist from committing or causing a violation or future violation of (i) any knowledge-based anti-fraud provision of the U.S. federal securities laws⁵ or (ii) Section 5 of the Securities Act?

Yes No

6. Have you been suspended or expelled from membership in, or suspended or barred from association with a member of, a registered national securities exchange or a registered national or affiliated securities association?

⁴ You may limit your response to disciplinary orders issued pursuant to Sections 15(b) or 15B(c) of the Exchange Act or Section 203(e) or (f) of the Investment Advisers Act of 1940 (the “Advisers Act”).

⁵ Including (but not limited to) Section 17(a)(1) of the Securities Act, Section 10(b) of the Exchange Act and Rule 10b-5 thereunder, Section 15(c)(1) of the Exchange Act, and Section 206(1) of the Advisers Act or any other rule or regulation thereunder.

Yes (If yes, please describe the basis of any such suspension or expulsion and any related details in the space provided under Question 10 below)⁶

No (If no, please continue to Question 7)

7. Have you registered a securities offering with the SEC, made an offering under Regulation A or been named as an underwriter in any registration statement or Regulation A offering statement filed with the SEC?

Yes (If yes, please continue to Question 7.a)

No (If no, please continue to Question 8)

a) If your answer to Question 7 was “yes”:

i) During the past five years, was any such registration statement or Regulation A offering statement the subject of a refusal order, stop order or order suspending the Regulation A exemption?

Yes No

ii) Is any such registration statement or Regulation A offering statement currently the subject of an investigation or proceeding to determine whether a stop order or suspension order should be issued?

Yes No

8. Are you subject to a U.S. Postal Service false representation order entered within the past five years?

Yes No

9. Are you currently subject to a temporary restraining order or preliminary injunction with respect to conduct alleged by the U.S. Postal Service to constitute a scheme or device for obtaining money or property through the mail by means of false representations?

Yes No

10. Describe any facts or circumstances that caused you to answer “yes” to any Question (indicating the corresponding Question number). Attach additional pages if necessary.

A. FOR EXECUTION BY AN INDIVIDUAL:

⁶ In providing additional information, please explain whether or not the suspension or expulsion resulted from “any act or omission to act constituting conduct inconsistent with just and equitable principles of trade.”

By: _____

Print Name: _____

Date

B. FOR EXECUTION BY AN ENTITY:

Entity Name: _____

By: _____

Print Name: _____

Title: _____

Date

C. ADDITIONAL SIGNATURES (if required by partnership, corporation or trust document):

Entity Name: _____

By: _____

Print Name: _____

Title: _____

Date

Entity Name: _____

By: _____

Print Name: _____

Title: _____

Date

APPENDIX II

APPENDIX II

SELLING STOCKHOLDER NOTICE AND QUESTIONNAIRE

Name of Selling Stockholder (please print)

ARDELYX, INC.

QUESTIONNAIRE FOR SELLING STOCKHOLDERS

IMPORTANT: IMMEDIATE ATTENTION REQUIRED

This Questionnaire is being furnished to all persons or entities (the "Purchasers") electing to purchase shares of Common Stock ("Common Stock") of Ardelyx, Inc. (the "Company") pursuant to the Securities Purchase Agreement by and among the Company and the Purchasers (the "Purchase Agreement") to which this Questionnaire is an Appendix. This Questionnaire relates to certain information required to be disclosed in the Registration Statement on Form S-3 being prepared by the Company for filing with the United States Securities and Exchange Commission (the "SEC") pursuant to the Registration Rights Agreement entered into by and among the Company and the Purchasers (the "Registration Rights Agreement") in connection with the Purchase Agreement. **The Company must receive a completed Questionnaire from each Purchaser in order to include such Purchaser's shares of Common Stock in the Registration Statement.**

The furnishing of accurate and complete responses to the questions posed in this Questionnaire is an extremely important part of the registration process. The inclusion of inaccurate or incomplete disclosures in the Registration Statement can result in potential liabilities, both civil and criminal, to the Company and to the individuals who furnish the information. Accordingly, Purchasers are advised to consult their own securities law counsel regarding the consequences of being named or not being named as a selling securityholder in the Registration Statement and related prospectus.

PLEASE GIVE A RESPONSE TO EVERY QUESTION, indicating "None" or "Not Applicable" where appropriate. **Please complete, sign, and return one copy of this Questionnaire by facsimile, email or overnight courier as soon as possible.**

Latham & Watkins
140 Scott Drive
Menlo Park, CA 94025
Attn: John Williams
Fax: (650) 463-2600
john.williams@lw.com

Unless stated otherwise, answers should be given as of the date you complete this Questionnaire. However, it is your responsibility to inform us of any changes that may occur to

your situation. If there is any situation about which you have any doubt, or if you are uncertain as to the meaning of any terms used in this Questionnaire, please contact John Williams at: (650) 470-4887.

PART I—STOCK OWNERSHIP

Item 1. Beneficial Ownership.

a. Deemed Beneficial Ownership. Please state the amount of securities of the Company you own on the date you complete this Questionnaire. (If none, please so state in each case.)

<u>Amount Beneficially Owned</u> ¹	<u>Number of Shares of Common Stock Owned</u>
Please state the number of shares owned by you or by family members, trusts and other organizations with which you have a relationship, and any other shares of which you may be deemed to be the "beneficial owner" ¹ :	
Total Shares:	_____
Of such shares:	_____
Shares as to which you have <u>sole</u> voting power:	_____
Shares as to which you have <u>shared</u> voting power:	_____
Shares as to which you have <u>sole</u> investment power:	_____
Shares as to which you have <u>shared</u> investment power:	_____
Shares which you will have a right to acquire before 60 days after the date you complete this questionnaire through the exercise of options, warrants or otherwise:	_____

Do you have any present plans to exercise options or otherwise acquire, dispose of or to transfer shares of Common Stock of the Company between the date you complete this Questionnaire and the date which is 60 days after the date in which the Registration Statement is filed?

Answer:

If so, please describe.

b. Pledged Securities. If any of such securities have been pledged or otherwise deposited as collateral or are the subject matter of any voting trust or other similar agreement or of any contract providing for the sale or other disposition of such securities, please give the details thereof.

Answer:

c. Disclaimer of Beneficial Ownership. Do you wish to disclaim beneficial ownership¹ of any of the shares reported in response to Item 1(a)?

Answer:

If the answer is "Yes", please furnish the following information with respect to the person or persons who should be shown as the beneficial owner(s)¹ of the shares in question.

<u>Name and Address of Actual Beneficial Owner</u>	<u>Relationship of Such Person To You</u>	<u>Number of Shares Beneficially Owned</u>
--	---	--

d. Shared Voting or Investment Power over Securities. Will any person be deemed to have beneficial ownership over any of the Securities purchased by you pursuant to the Purchase Agreement?

Answer:

If the answer is "Yes", please furnish the following information with respect to the person or persons who should be shown as the beneficial owner(s)¹ of the Securities in question.

<u>Name and Address of Beneficial Owner</u>	<u>Relationship of Such Person To You</u>	<u>Number of Shares Beneficially Owned</u>
---	---	--

Item 2. Major Shareholders. Please state below the names of persons or groups known by you to own beneficially¹ more than 5% of the Company's Common Stock.

Answer:

Item 3. Change of Control. Do you know of any contractual arrangements, including any pledge of securities of the Company, the operation of which may at a subsequent date result in a change of control of the Company?

Answer:

Item 4. Relationship with the Company. Please state the nature of any position, office or other material relationship you have, or have had within the past three years, with the Company or its affiliates.

Name

Nature of
Relationship

Item 5. Broker-Dealer Status. Is the Purchaser a broker-dealer registered pursuant to Section 15 of the Exchange Act?

Yes.

No.

Note that the Company will be required to identify any registered broker-dealer as an underwriter in the prospectus.

If so, please answer the remaining questions in this section.

a. If the Purchaser is a registered broker-dealer, please indicate whether the Purchaser purchased its Common Stock for investment or acquired them as transaction-based compensation for investment banking or similar services.

Answer:

Note: if the Purchaser is a registered broker-dealer and received its Common Stock other than as transaction-based compensation, the Company is required to identify the Purchaser as an underwriter in the Registration Statement and related prospectus.

b. Is the Purchaser an affiliate of a registered broker-dealer? For purposes of this Question, an “affiliate” of a specified person or entity means a person or entity that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, the person or entity specified.

Yes.

No.

If so, please answer the remaining questions in this section.

i. Please describe the affiliation between the Purchaser and any registered broker-dealers:

ii. If the Common Stock were received by the Purchaser other than in the ordinary course of business, please describe the circumstances:

iii. If the Purchaser, at the time of its receipt of Common Stock, has had any agreements or understandings, directly or indirectly, with any person to distribute the Common Stock, please describe such agreements or understandings:

Note that if the Purchaser is an affiliate of a broker-dealer and did not receive its Common Stock in the ordinary course of business or at the time of receipt had any agreements or understandings, directly or indirectly, to distribute the securities, the Company must identify the Purchaser as an underwriter in the prospectus.

Item 6. Nature of Beneficial Holding. The purpose of this question is to identify the ultimate natural person(s) or publicly held entity that exercise(s) sole or shared voting or dispositive power over the Registrable Securities (as defined in the Registration Rights Agreement).

a. Is the Purchaser a natural person?

Yes.

No.

b. Is the Purchaser required to file, or is it a wholly owned subsidiary of a company that is required to file, periodic and other reports (for example, Form 10-K, 10-Q, 8-K) with the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act?

Yes.

No.

c. Is the Purchaser an investment company, or a subsidiary of an investment company, registered under the Investment Company Act of 1940, as amended?

Yes.

No.

If a subsidiary, please identify the publicly held parent entity:

d. If you answered “no” to questions (a), (b) and (c) above, please identify the controlling person(s) of the Purchaser (the “Controlling Entity”). If the Controlling Entity is not a natural person or a publicly held entity, please identify each controlling person(s) of such Controlling Entity. This process should be repeated until you reach natural persons or a publicly held entity that exercises sole or shared voting or dispositive power over the Registrable Securities:

*****PLEASE NOTE THAT THE SEC REQUIRES THAT THESE NATURAL PERSONS BE NAMED IN THE PROSPECTUS*****

PART II—CERTAIN TRANSACTIONS

Item 7. Transactions with the Company. If you, any of your associates², or any member of your immediate family³ had or will have any direct or indirect material interest in any transactions⁴ or series of transactions to which the Company or any of its subsidiaries was a party at any time since June 1, 2013, or in any currently proposed transactions or series of transactions in which the Company or any of its subsidiaries will be a party, in which the amount involved exceeds \$120,000, please specify (a) the names of the parties to the transaction(s) and their relationship to you, (b) the nature of the interest in the transaction, (c) the amount involved in the transaction, and (d) the amount of the interest in the transaction. If the answer is “none”, please so state.

Answer:

Item 8. Third Party Payments. Please describe any compensation paid to you by a third party pursuant to any arrangement between the Company and any such third party.

Answer:

PART III—PLAN OF DISTRIBUTION

The selling stockholders and any of their pledgees, donees, transferees, assignees or other successors-in-interest may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. The selling stockholders may use one or more of the following methods when disposing of the shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

-
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
 - through brokers, dealers or underwriters that may act solely as agents;
 - purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
 - an exchange distribution in accordance with the rules of the applicable exchange;
 - privately negotiated transactions;
 - through the writing or settlement of options or other hedging transactions entered into after the effective date of the registration statement of which this prospectus is a part, whether through an options exchange or otherwise;
 - broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
 - a combination of any such methods of disposition; and
 - any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended, or Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of common stock from time to time under this prospectus, or under a supplement or amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

Upon being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the

participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In addition, upon being notified in writing by a selling stockholder that a donee or pledge intends to sell more than 500 shares of common stock, we will file a supplement to this prospectus if then required in accordance with applicable securities law.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of the shares of common stock or interests in shares of common stock, the selling stockholders may enter into hedging transactions after the effective date of the registration statement of which this prospectus is a part with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of common stock short after the effective date of the registration statement of which this prospectus is a part and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions after the effective date of the registration statement of which this prospectus is a part with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The maximum commission or discount to be received by any member of the Financial Industry Regulatory Authority (FINRA) or independent broker-dealer will not be greater than 8% of the initial gross proceeds from the sale of any security being sold.

We have advised the selling stockholders that they are required to comply with Regulation M promulgated under the Securities and Exchange Act during such time as they may be engaged in a distribution of the shares. The foregoing may affect the marketability of the common stock.

The aggregate proceeds to the selling securityholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling securityholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering.

We are required to pay all fees and expenses incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act or otherwise.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (a) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or (b) the date on which the shares of common stock covered by this prospectus may be sold by non-affiliates without any volume limitations or pursuant to Rule 144 of the Securities Act.

* * *

The undersigned has reviewed the Plan of Distribution set forth above and does not have a present intention of effecting a sale in a manner not described therein.

_____ Agree _____ Disagree
(If left blank, response will be deemed to be "Agree".)

The undersigned hereby represents that the undersigned understands, pursuant to Interpretation A.65 in the Securities and Exchange Commission, Division of Corporation Finance, Manual of Publicly Available Telephone Interpretations dated July 1997, a copy of which is attached hereto as Exhibit 1, that the undersigned may not make any short sale of the Common Stock prior to the effectiveness of the Registration Statement, and further covenants to the Company that the undersigned will not engage in any short sales of such stock to be registered under the Registration Statement prior to its effectiveness.

SIGNATURE

The undersigned understands that the Company anticipates filing the Registration Statement within the time frame set forth in the Registration Rights Agreement. If at any time any of the information set forth in my responses to this Questionnaire has materially changed due to passage of time, or any development occurs which requires a change in any of my answers, or has for any other reason become incorrect, the undersigned agrees to furnish as soon as practicable to the individual to whom a copy of this Questionnaire is to be sent, as indicated and at the address shown on the first page hereof, any necessary or appropriate correcting information. Otherwise, the Company is to understand that the above information continues to be, to the best of my knowledge, information and belief, complete and correct.

Upon any sale of Common Stock pursuant to the Registration Statement, the undersigned hereby agrees to deliver to the Company and the Company's transfer agent the Certificate of Subsequent Sale set forth in Exhibit I hereto.

The undersigned understands that the information that the undersigned is furnishing to the Company herein will be used by the Company in the preparation of the Registration Statement.

Date: _____, 2015

Name of Purchaser: _____

Signature: _____

Print Name: _____

Title (if applicable): _____

Address: _____

_____ Street

_____ City State Zip Code

_____ Telephone Number

_____ Facsimile Number

FOOTNOTES

1. **Beneficial Ownership.** You are the beneficial owner of a security, as defined in Rule 13d-3 under the Securities Exchange Act of 1934 (the “Exchange Act”), if you, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise have or share: (1) voting power, which includes the power to vote, or to direct the voting of, such security, and/or (2) investment power, which includes the power to dispose, or to direct the disposition of, such security. You are also the beneficial owner of a security if you, directly or indirectly, create or use a trust, proxy, power of attorney, pooling arrangement or any other contract, arrangement or device with the purpose or effect of divesting yourself of beneficial ownership of a security or preventing the vesting of such beneficial ownership.

You are deemed to be the beneficial owner of a security if you have the right to acquire beneficial ownership of such security at any time within 60 days including, but not limited to, any right to acquire such security (a) through the exercise of any option, warrant or right, (b) through the conversion of a security, or (c) pursuant to the automatic termination of, or the power to revoke a trust, discretionary account, or similar arrangement.

Ordinarily, shares held in the name of your spouse or minor child should be considered as beneficially owned by you absent special circumstances to indicate that you do not have, as a practical matter, voting power or investment power over such shares. Similarly, absent countervailing facts, securities held in the name of relatives who share your home are to be reported as being beneficially owned by you. In addition, securities held for your benefit in the name of others, such as nominees, trustees and other fiduciaries, securities held by a partnership of which you are a partner, and securities held by a corporation controlled by you should be regarded as beneficially owned by you.

This definition of beneficial ownership is very broad; therefore, even though you may not actually have or share voting or investment power with respect to securities owned by persons in your family or living in your home, you should include such shares in your beneficial ownership disclosure and may then disclaim beneficial ownership of such securities.

2. **Associate.** The term “associate”, as defined in Rule 14a-1 under the Exchange Act, means (a) any corporation or organization (other than the Company or any of its majority owned subsidiaries) of which you are an officer or partner or are, directly or indirectly, the beneficial owner of 10% or more of any class of equity securities, (b) any trust or other estate in which you have a substantial beneficial interest or as to which you serve as trustee or in a similar capacity, and (c) your spouse, or any relative of yours or relative of your spouse living in your home or who is a director or officer of the Company or of any subsidiary. The term “relative of yours” as used in this Questionnaire refers to any relative or spouse of yours, or any relative of such spouse, who has the same home as you or who is a director or officer of any subsidiary of the Company.

Please identify your associate referred to in your answer and indicate your relationship.

-
3. Immediate Family. The members of your “immediate family” are deemed to include the following: your spouse; your parents; your children; your siblings; your mother-in-law or father-in-law; your sons- and daughters-in-law; and your brothers- and sisters-in-law.
 4. Transactions. The term “transaction” is to be understood in its broadest sense, and includes the direct or indirect receipt of anything of value. Please note that indirect as well as direct material interests in transactions are to be disclosed. Transactions in which you would have a direct interest would include your purchasing or leasing anything (stock in a business acquired by the Company, office space, plants, Company apartments, computers, raw materials, finished goods, etc.) from or selling or leasing anything to, or borrowing or lending cash or other property from or to, the Company, or any subsidiary.

Securities Act Sections Compliance and Disclosure Interpretations Section 239.10: “An issuer filed a Form S-3 registration statement for a secondary offering of common stock which is not yet effective. One of the selling shareholders wanted to do a short sale of common stock “against the box” and cover the short sale with registered shares after the effective date. The issuer was advised that the short sale could not be made before the registration statement becomes effective, because the shares underlying the short sale are deemed to be sold at the time such sale is made. There would, therefore, be a violation of Section 5 if the shares were effectively sold prior to the effective date.”

CERTIFICATE OF SUBSEQUENT SALE

American Stock Transfer & Trust Company, LLC

RE: Sale of Shares of Common Stock of Ardelyx, Inc. (the "Company") pursuant to the Company's Prospectus dated _____, _____ (the "Prospectus")

Dear Sir/Madam:

The undersigned hereby certifies, in connection with the sale of shares of Common Stock of the Company included in the table of Selling Stockholders in the Prospectus, that the undersigned has sold the shares pursuant to the Prospectus and in a manner described under the caption "Plan of Distribution" in the Prospectus and that such sale complies with all securities laws applicable to the undersigned, including, without limitation, the Prospectus delivery requirements of the Securities Act of 1933, as amended.

Selling Stockholder (the beneficial owner): _____

Record Holder (e.g., if held in name of nominee): _____

Book Entry Position or Restricted Stock Certificate No.(s): _____

Number of Shares Sold: _____

Date of Sale: _____

In the event that you receive a stock certificate(s) or evidence of a book entry position representing more shares of Common Stock than have been sold by the undersigned, then you should return to the undersigned a newly issued certificate or book entry position for such excess shares in the name of the Record Holder and **BEARING A RESTRICTIVE LEGEND**. Further, you should place a stop transfer on your records with regard to such certificate. Notwithstanding the foregoing, in the event that the undersigned executes and delivers to you and to the Company the certification set forth on Annex I, upon instructions from the Company, you should return to the undersigned a newly issued certificate or book entry position for such excess shares of Common Stock in the name of the Record Holder without any restrictive legend. In addition, no subsequent certification will be required to be delivered to you by the undersigned provided that the representations and warranties set forth on Annex I have been delivered to you and continue to be accurate.

Dated: _____

Very truly yours,

By: _____

Print Name: _____

Title: _____

cc: Ardelyx, Inc.
34175 Ardenwood Blvd.
Suite 200
Fremont, CA 94555
Attn: General Counsel

In connection with any excess shares to be returned to the Selling Stockholder upon a sale of shares of Common Stock of Ardelyx, Inc. (the "Company") included in the table of Selling Stockholders in the Prospectus, the undersigned hereby certifies to the Company and American Stock Transfer & Trust Company, LLC, that:

1. In connection with the sale by the undersigned stockholder of any of the shares of Common Stock, the undersigned stockholder will deliver a copy of the Prospectus included in the Registration Statement to the purchaser directly or through the undersigned stockholder's broker-dealer in compliance with the requirements of the Securities Act of 1933 and the Securities Exchange Act of 1934.

2. Any such sale will be made only in the manner described under "Plan of Distribution" in the Prospectus.

3. The undersigned stockholder will only sell the shares of Common Stock while the Registration Statement is effective, unless another exemption from registration is available.

4. The Company and its attorneys may rely on this letter to the same extent as if it were addressed to them.

5. The undersigned stockholder agrees to notify you immediately of any development or occurrence which to his, her or its knowledge would render any of the foregoing representations and agreements inaccurate.

All terms not defined herein are as defined in the Securities Purchase Agreement entered into in June 2015 among the Company and the Purchasers.

Very truly yours,

Dated: _____

By: _____

Print Name: _____

Title: _____

APPENDIX III

REGISTRATION RIGHTS AGREEMENT

This Registration Rights Agreement (this “Agreement”) is made and entered into as of June 2, 2015, by and among Ardelyx, Inc., a Delaware corporation (the “Company”), and the investors signatory hereto (each a “Purchaser” and collectively, the “Purchasers”).

This Agreement is made pursuant to the Securities Purchase Agreement, dated as of June 2, 2015, among the Company and the Purchasers (the “Purchase Agreement”).

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Company and the Purchasers agree as follows:

1. Definitions. Capitalized terms used and not otherwise defined herein that are defined in the Purchase Agreement shall have the meanings given such terms in the Purchase Agreement. As used in this Agreement, the following terms shall have the respective meanings set forth in this Section 1:

“Affiliate” means, with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, Controls, is controlled by or is under common control with such Person, as such terms are used in and construed under Rule 405 under the Securities Act.

“Advice” shall have the meaning set forth in Section 7(d).

“Control” (including the terms “controlling”, “controlled by” or “under common control with”) means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

“Commission” means the United States Securities and Exchange Commission, or any successor entity or entities, including, if applicable, the staff of the Commission.

“Common Stock” means the common stock, par value \$0.0001 per share, of the Company.

“Effectiveness Date” means: (a) with respect to the Initial Registration Statement required to be filed hereunder, the 90th day following the Closing Date (or the 120th day following the Closing Date in the event the Initial Registration Statement is reviewed by the Commission), (b) with respect to any additional Registration Statements which may be required pursuant to Section 2, the 90th day following the date on which the Company first knows, or reasonably should have known, that such additional Registration Statement is required under such Section (or the 120th day following such date in the event such additional Registration Statement is reviewed by the Commission). If the Effectiveness Date falls on a Saturday, Sunday or other date that the Commission is closed for business, the Effectiveness Date shall be extended to the next day on which the Commission is open for business.

“Effectiveness Period” shall have the meaning set forth in Section 2(a).

“Exchange Act” means the Securities Exchange Act of 1934, as amended.

“Filing Date” means: (a) with respect to the Initial Registration Statement, the 45th calendar day following the Closing Date, and (b) with respect to any additional Registration Statements that may be required pursuant to Section 2 hereof, the 45th day following the date on which the Company first knows, or reasonably should have known, that such additional Registration Statement is required under such Section.

“Holder” or “Holders” means the holder or holders, as the case may be, from time to time of Registrable Securities.

“Indemnified Party” shall have the meaning set forth in Section 6(c).

“Indemnifying Party” shall have the meaning set forth in Section 6(c).

“Initial Registration Statement” shall mean the initial Registration Statement required to be filed to cover the resale by the Holders of the Registrable Securities pursuant to Section 2(a).

“Losses” shall have the meaning set forth in Section 6(a).

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, an investigation or partial proceeding, such as a deposition), whether commenced or threatened.

“Prospectus” means the prospectus included in a Registration Statement (including, without limitation, a prospectus that includes any information previously omitted from a prospectus filed as part of an effective registration statement in reliance upon Rule 430A or Rule 430B promulgated by the Commission pursuant to the Securities Act), as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Securities covered by a Registration Statement, and all other amendments and supplements to the Prospectus, including post-effective amendments, and all material incorporated by reference or deemed to be incorporated by reference in such Prospectus.

“Reduction Securities” shall have the meaning set forth in Section 2(b).

“Registrable Securities” means (i) the Shares issued pursuant to the Purchase Agreement, (ii) the Underlying Shares issuable upon exercise of the Warrants issued pursuant to the Purchase Agreement and (iii) any other shares of Common Stock issued as (or issuable upon conversion or exercise of any warrant, right or other security which is issued as) a dividend or other distribution with respect to, in exchange for or in replacement of the Shares or the Underlying Shares; provided, however, that any such Registrable Securities shall cease to be Registrable Securities (and the Company shall not be required to maintain the effectiveness of any, or file another, Registration Statement hereunder with respect thereto) for so long as (a) a

Registration Statement with respect to the sale of such Registrable Securities is declared effective by the Commission under the Securities Act and such Registrable Securities have been disposed of by the Holder in accordance with such effective Registration Statement, (b) such Registrable Securities have been previously sold in accordance with Rule 144, or (c) such securities become eligible for resale without volume or manner-of-sale restrictions and without current public information pursuant to Rule 144 as set forth in a written opinion letter to such effect, addressed, delivered and acceptable to the Company's transfer agent and the affected Holders (assuming that such securities and any securities issuable upon exercise, conversion or exchange of which, or as a dividend upon which, such securities were issued or are issuable, were at no time held by any Affiliate of the Company), as reasonably determined by the Company, upon the advice of counsel to the Company.

“Registration Statement” means each of the following: (i) an initial registration statement which is required to register the resale of the Registrable Securities, and (ii) each additional registration statement, if any, contemplated by Section 2, and including, in each case, the Prospectus, amendments and supplements to each such registration statement or Prospectus, including pre- and post-effective amendments, all exhibits thereto, and all material incorporated by reference or deemed to be incorporated by reference in such registration statement.

“Rule 144” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

“Rule 415” means Rule 415 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

“Rule 424” means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same effect as such Rule.

“Securities Act” means the Securities Act of 1933, as amended.

“Shares” shall have the meaning set forth in the Purchase Agreement.

“Trading Day” means any day on which the Common Stock is traded on the Nasdaq Global Market, or, if the Nasdaq Global Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock is then traded.

“Transaction Documents” shall have the meaning set forth in the Purchase Agreement.

“Underlying Shares” shall have the meaning set forth in the Purchase Agreement.

“Warrants” shall have the meaning set forth in the Purchase Agreement.

2. Registration.

(a) On or prior to each Filing Date, the Company shall prepare and file with the Commission a Registration Statement covering the resale of all of the Registrable Securities that are not then registered on an existing and effective Registration Statement for an offering to be made on a continuous basis pursuant to Rule 415. The Registration Statement filed hereunder shall be on Form S-3 (except if the Company is not then eligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on another appropriate form in accordance herewith) and shall contain (except if otherwise required pursuant to written comments received from the Commission upon a review of such Registration Statement) the “Plan of Distribution” in substantially the form attached hereto as Annex A. The Company shall use its commercially reasonable efforts to cause a Registration Statement filed under this Agreement to be declared effective under the Securities Act promptly but, in any event, no later than the Effectiveness Date for such Registration Statement, and shall, subject Section 7(d) hereof, use its commercially reasonable efforts to keep the Registration Statement continuously effective under the Securities Act until the earlier of (i) the date that is three years after the Closing Date and (ii) the date on which all securities under such Registration Statement have ceased to be Registrable Securities (the “Effectiveness Period”). Notwithstanding the foregoing, the Company shall be entitled to suspend the effectiveness of the Registration Statement at any time prior to the expiration of the Effectiveness Period for up to an aggregate of 30 consecutive Trading Days or an aggregate of 60 Trading Days (which need not be consecutive) in any given 360-day period. It is agreed and understood that the Company shall, from time to time, be obligated to file one or more additional Registration Statements to cover any Registrable Securities which are not registered for resale pursuant to a pre-existing Registration Statement.

(b) Notwithstanding anything contained herein to the contrary, in the event that the Commission limits the amount of Registrable Securities that may be included and sold by Holders in any Registration Statement, including the Initial Registration Statement, pursuant to Rule 415 or any other basis, the Company may reduce the number of Registrable Securities included in such Registration Statement on behalf of the Holders in whole or in part (in case of an exclusion as to a portion of such Registrable Securities, such portion shall be allocated pro rata among such Holders first in proportion to the respective numbers of Registrable Securities represented by Underlying Shares requested to be registered by each such Holder over the total amount of Registrable Securities represented by Underlying Shares, and second in proportion to the respective numbers of Registrable Securities represented by Shares requested to be registered by each such Holder over the total amount of Registrable Securities represented by Shares) (such Registrable Securities, the “Reduction Securities”). In such event the Company shall give the Holders prompt notice of the number of such Reduction Securities excluded and the Company will not be liable for any damages under this Agreement in connection with the exclusion of such Reduction Securities. The Company shall use its commercially reasonable efforts at the first opportunity that is permitted by the Commission to register for resale the Reduction Securities. Such new Registration Statement shall be on Form S-3 (except if the Company is not then eligible to register for resale the Reduction Securities on Form S-3, in which case such registration shall be on another appropriate form for such purpose) and shall contain (except if otherwise required pursuant to written comments received from the Commission upon a review of such Registration Statement) the “Plan of Distribution” in substantially the form attached

hereto as Annex A. The Company shall use its commercially reasonable efforts to cause each such Registration Statement to be declared effective under the Securities Act as soon as possible but, in any event, no later than the Effectiveness Date, and shall use its commercially reasonable efforts to keep such Registration Statement continuously effective under the Securities Act during the entire Effectiveness Period, subject to Section 7(d) hereof. Notwithstanding the foregoing, the Company shall be entitled to suspend the effectiveness of such Registration Statement at any time prior to the expiration of the Effectiveness Period for an aggregate of no more than 30 consecutive Trading Days or an aggregate of 50 Trading Days (which need not be consecutive) in any given 360-day period.

(c) If: (i) the Initial Registration Statement is not filed with the Commission on or prior to the Filing Date, (ii) the Initial Registration Statement is not declared effective by the Commission (or otherwise does not become effective) on or prior to the Effectiveness Date or (iii) after the date it is declared effective by the Commission and except as provided in Sections 2(e) and (f) and Section 3(h), (A) such Registration Statement ceases for any reason (including without limitation by reason of a stop order, or the Company's failure to update the Registration Statement), to remain continuously effective as to all Registrable Securities included in such Registration Statement or (B) the Holders are not permitted to utilize the Prospectus therein to resell such Registrable Securities for any reason (other than due to a change in the "Plan of Distribution" or the inaccuracy of any information regarding the Holders) in each case for more than an aggregate of thirty (30) consecutive Trading Days or sixty (60) Trading Days (which need not be consecutive) in any given 360-day period (other than as a result of a breach of this Agreement by such Holder), or (iv) the Company fails to satisfy the current public information requirement pursuant to Rule 144(c)(1) as a result of which the Holders who are not affiliates are unable to sell Registrable Securities without restriction under Rule 144 (or any successor thereto), (any such failure or breach in clauses (i) through (iv) above being referred to as an "Event," and, for purposes of clauses (i), (ii) or (iv), the date on which such Event occurs, or for purposes of clause (iii), the date on which such thirty (30) or fifty (60) Trading Day period is exceeded, being referred to as an "Event Date"), then in addition to any other rights the Holders may have hereunder or under applicable law, on each such Event Date and on each monthly anniversary of each such Event Date (if the applicable Event shall not have been cured by such date) until the earlier of (1) the applicable Event is cured or (2) the Registrable Securities are eligible for resale pursuant to Rule 144 without manner of sale or volume restrictions or the current public information requirement, the Company shall pay to each Holder an amount in cash, as liquidated damages and not as a penalty ("Liquidated Damages"), equal to one percent (1%) of the aggregate purchase price paid by such Holder pursuant to the Purchase Agreement for any unregistered Registrable Securities then held by such Holder. The parties agree that (1) notwithstanding anything to the contrary herein or in the Purchase Agreement, no Liquidated Damages shall be payable with respect to any period after the expiration of the Effectiveness Period (except in respect of an Event described in Section 2(c)(iv) herein), (it being understood that this sentence shall not relieve the Company of any Liquidated Damages accruing prior to the Effectiveness Deadline) and in no event shall, the aggregate amount of Liquidated Damages (excluding Liquidated Damages payable in respect of an Event described in Section 2(c)(iv) herein) payable to a Holder exceed, in the aggregate, five percent (5%) of the aggregate purchase price paid by such Holder pursuant to the Purchase Agreement) and (2) in no event shall the Company be liable in any thirty (30) day period for Liquidated Damages under this Agreement in excess of one percent (1%) of the aggregate purchase price paid by the

Holders pursuant to the Purchase Agreement. The Liquidated Damages pursuant to the terms hereof shall apply on a daily pro-rata basis for any portion of a month prior to the cure of an Event, except in the case of the first Event Date. The Company shall not be liable for Liquidated Damages under this Agreement as to any Registrable Securities which are not permitted by the Commission to be included in a Registration Statement. In such case, the Liquidated Damages shall be calculated to only apply to the percentage of Registrable Securities which are permitted to be included in such Registration Statement. The Effectiveness Deadline for a Registration Statement shall be extended without default or Liquidated Damages hereunder in the event that the Company's failure to obtain the effectiveness of the Registration Statement on a timely basis results from the failure of a Purchaser to timely provide the Company with information requested by the Company and necessary to complete the Registration Statement in accordance with the requirements of the Securities Act (in which the Effectiveness Deadline would be extended with respect to Registrable Securities held by such Purchaser).

3. Registration Procedures.

In connection with the Company's registration obligations hereunder, the Company shall:

(a) Not less than three Trading Days prior to the filing of a Registration Statement or any related Prospectus or any amendment or supplement thereto, the Company shall furnish to the Holders copies of all such documents proposed to be filed (other than those incorporated by reference). Notwithstanding the foregoing, the Company shall not be required to furnish to the Holders any prospectus supplement being prepared and filed solely to name new or additional selling securityholders unless such Holders are named in such prospectus supplement. In addition, in the event that any Registration Statement is on Form S-1 (or other form which does not permit incorporation by reference), the Company shall not be required to furnish to the Holders any prospectus supplement containing information included in a report or proxy statement filed under the Exchange Act that would be incorporated by reference in such Registration Statement if such Registration Statement were on Form S-3 (or other form which permits incorporation by reference). The Company shall duly consider any comments made by Holders and received by the Company not later than two Trading Days prior to the filing of the Registration Statement, but shall not be required to accept any such comments to which it reasonably objects.

(b) (i) Prepare and file with the Commission such amendments, including post-effective amendments, to each Registration Statement and the Prospectus used in connection therewith as may be necessary to keep such Registration Statement continuously effective as to the applicable Registrable Securities for its Effectiveness Period and prepare and file with the Commission such additional Registration Statements in order to register for resale under the Securities Act all of the Registrable Securities; (ii) cause the related Prospectus to be amended or supplemented by any required Prospectus supplement, and as so supplemented or amended to be filed pursuant to Rule 424; (iii) respond as promptly as reasonably possible to any comments received from the Commission with respect to each Registration Statement or any amendment thereto and, as promptly as reasonably possible provide the Holders true and complete copies of all correspondence from and to the Commission relating to such Registration Statement that pertains to the Holders as Selling Stockholders but not any comments that would result in the disclosure to the Holders of material and non-public information concerning the

Company; and (iv) comply in all material respects with the provisions of the Securities Act and the Exchange Act with respect to the Registration Statements and the disposition of all Registrable Securities covered by each Registration Statement.

(c) Notify the Holders as promptly as reasonably possible (and, in the case of (i)(A) below, not less than three Trading Days prior to such filing) and (if requested by any such Person) confirm such notice in writing no later than one Trading Day following the day: (i)(A) when a Prospectus or any prospectus supplement (but only to the extent notice is required under Section 3(a) above) or post-effective amendment to a Registration Statement is proposed to be filed; (B) when the Commission notifies the Company whether there will be a "review" of such Registration Statement and whenever the Commission comments in writing on such Registration Statement (in which case the Company shall provide true and complete copies thereof and all written responses thereto to each of the Holders that pertain to the Holders as a Selling Stockholder or to the Plan of Distribution, but not information which the Company believes would constitute material and non-public information); and (C) with respect to each Registration Statement or any post-effective amendment, when the same has been declared effective; (ii) of any request by the Commission or any other Federal or state governmental authority for amendments or supplements to a Registration Statement or Prospectus or for additional information that pertains to the Holders as Selling Stockholders or the Plan of Distribution; (iii) of the issuance by the Commission of any stop order suspending the effectiveness of a Registration Statement covering any or all of the Registrable Securities or the initiation of any Proceedings for that purpose; (iv) of the receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Registrable Securities for sale in any jurisdiction, or the initiation or threatening of any Proceeding for such purpose; (v) of the occurrence of any event or passage of time that makes the financial statements included or incorporated by reference in a Registration Statement ineligible for inclusion or incorporation by reference therein or any statement made in such Registration Statement or Prospectus or any document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires any revisions to such Registration Statement, Prospectus or other documents so that, in the case of such Registration Statement or the Prospectus, as the case may be, it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading; and (vi) of the occurrence or existence of any pending corporate development with respect to the Company that the Company believes may be material and that, in the determination of the Company, makes it not in the best interest of the Company to allow continued availability of a Registration Statement or Prospectus; provided, that any and all of such information shall remain confidential to each Holder until such information otherwise becomes public, unless disclosure by a Holder is required by law; provided, further, that notwithstanding each Holder's agreement to keep such information confidential, each such Holder makes no acknowledgement that any such information is material, non-public information.

(d) Use its reasonable best efforts to avoid the issuance of, or, if issued, obtain the withdrawal of (i) any order suspending the effectiveness of a Registration Statement, or (ii) any suspension of the qualification (or exemption from qualification) of any of the Registrable Securities for sale in any jurisdiction, at the earliest practicable moment.

(e) Furnish to each Holder, without charge, at least one conformed copy of each Registration Statement and each amendment thereto and all exhibits to the extent reasonably requested by such Person (including those previously furnished or incorporated by reference) promptly after the filing of such documents with the Commission; provided, that the Company shall have no obligation to provide any document pursuant to this clause that is available on the EDGAR system.

(f) Promptly deliver to each Holder, without charge, as many copies of each Prospectus or Prospectuses (including each form of prospectus) and each amendment or supplement thereto as such Persons may reasonably request. Subject to Section 7(d) hereof, the Company hereby consents to the use of such Prospectus and each amendment or supplement thereto by each of the selling Holders in connection with the offering and sale of the Registrable Securities covered by such Prospectus and any amendment or supplement thereto.

(g) Prior to any public offering of Registrable Securities, use its commercially reasonable efforts to register or qualify or cooperate with the selling Holders in connection with the registration or qualification (or exemption from such registration or qualification) of such Registrable Securities for offer and sale under the securities or Blue Sky laws of those jurisdictions within the United States as any Holder reasonably requests in writing to keep each such registration or qualification (or exemption therefrom) effective during the Effectiveness Period and to do any and all other acts or things necessary or advisable to enable the disposition in such jurisdictions of the Registrable Securities covered by the Registration Statements; provided, that the Company shall not be required to qualify generally to do business in any jurisdiction where it is not then so qualified or subject the Company to any material tax in any such jurisdiction where it is not then so subject.

(h) Cooperate with the Holders to facilitate the timely preparation and delivery of certificates representing Registrable Securities to be delivered to a transferee pursuant to the Registration Statements, which certificates shall be free, to the extent permitted by the Purchase Agreement, of all restrictive legends, and to enable such Registrable Securities to be in such denominations and registered in such names as any such Holders may request.

(i) Upon the occurrence of any event contemplated by Section 3(c)(v), as promptly as reasonably possible, prepare a supplement or amendment, including a post-effective amendment, to the affected Registration Statements or a supplement to the related Prospectus or any document incorporated or deemed to be incorporated therein by reference, and file any other required document so that, as thereafter delivered, no Registration Statement nor any Prospectus will contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

(j) The Company may require each selling Holder to furnish to the Company a certified statement as to the number of shares of Common Stock beneficially owned by such Holder and any Affiliate thereof, the natural persons thereof that have voting and dispositive control over the shares and any other information with respect to such Holder as the Commission requests.

4. Holder's Obligations. Each Holder agrees, by acquisition of the Registrable Securities, that no Holder shall be entitled to sell any of such Registrable Securities pursuant to a Registration Statement or to receive a Prospectus relating thereto, unless such Holder has furnished the Company with all material information required to be set forth in the Purchaser Questionnaire and Selling Stockholder Questionnaire pursuant to the Purchase Agreement. Any sale of any Registrable Securities by any Holder shall constitute a representation and warranty by such Holder that the information regarding such Holder is as set forth in the Prospectus delivered by such Holder in connection with such disposition, and that such Prospectus does not as of the time of such sale contain any untrue statement of a material fact regarding such Holder or omit to state any material fact regarding such Holder necessary to make the statements in such Prospectus, in the light of the circumstances under which they were made, not misleading, solely to the extent such facts are based upon information regarding such Holder furnished in writing to the Company by such Holder for use in such Prospectus.

5. Registration Expenses. All fees and expenses incident to the Company's performance of or compliance with its obligations under this Agreement (excluding any underwriting discounts and selling commissions) shall be borne by the Company whether or not any Registrable Securities are sold pursuant to a Registration Statement. The fees and expenses referred to in the foregoing sentence shall include, without limitation, (i) all registration and filing fees (including, without limitation, fees and expenses (A) with respect to filings required to be made with the Principal Market on which the Common Stock is then listed for trading, and (B) in compliance with applicable state securities or Blue Sky laws), (ii) printing expenses (including, without limitation, expenses of printing certificates for Registrable Securities and of printing prospectuses if the printing of prospectuses is reasonably requested by the holders of a majority of the Registrable Securities included in the Registration Statement), (iii) messenger, telephone and delivery expenses, (iv) reasonable fees and disbursements of counsel for the Company, (v) reasonable fees and disbursements of counsel to the Holders, in an amount not to exceed \$35,000, (vi) Securities Act liability insurance, if the Company so desires such insurance, and (vii) reasonable fees and expenses of all other Persons retained by the Company in connection with the consummation of the transactions contemplated by this Agreement. In addition, the Company shall be responsible for all of its internal expenses incurred in connection with the consummation of the transactions contemplated by this Agreement (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), the expense of any annual audit and the fees and expenses incurred in connection with the listing of the Registrable Securities on any securities exchange as required hereunder. In no event shall the Company be responsible for any broker or similar commissions of any Holder or, except to the extent provided for in the Transaction Documents, any legal fees or other costs of the Holders.

6. Indemnification.

(a) Indemnification by the Company. The Company shall, notwithstanding any termination of this Agreement, indemnify and hold harmless each Holder, the officers, directors, agents, partners, members, stockholders and employees of each Holder, each Person who controls any such Holder (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) and the officers, directors, agents, partners, members, stockholders and employees of each such controlling Person, to the fullest extent permitted by applicable law,

from and against any and all losses, claims, damages, liabilities, costs (including, without limitation, reasonable costs of preparation and reasonable attorneys' fees) and expenses (collectively, "Losses"), as incurred, arising out of or relating to any untrue or alleged untrue statement of a material fact contained in any Registration Statement, any Prospectus or any form of prospectus or in any amendment or supplement thereto (it being understood that the Holder has approved Annex A hereto for this purpose), or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus or form of prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading, except to the extent, but only to the extent, that (1) such untrue statements, alleged untrue statements, omissions or alleged omissions are based solely upon information regarding such Holder furnished in writing to the Company by such Holder expressly for use therein, or to the extent that such information relates to such Holder or such Holder's proposed method of distribution of Registrable Securities and was reviewed and expressly approved in writing by such Holder expressly for use in the Registration Statement, such Prospectus or such form of Prospectus or in any amendment or supplement thereto (it being understood that the Holder has approved Annex A hereto for this purpose) or (2) in the case of an occurrence of an event of the type specified in Section 3(c)(ii)-(v), the use by such Holder of an outdated or defective Prospectus after the Company has validly notified such Holder in writing (in accordance with Section 7(h) below) that the Prospectus is outdated or defective and prior to the receipt by such Holder of an Advice (as defined below) or an amended or supplemented Prospectus, but only if and to the extent that following the receipt of the Advice or the amended or supplemented Prospectus the misstatement or omission giving rise to such Loss would have been corrected. The Company shall notify the Holders promptly of the institution, threat or assertion of any Proceeding of which the Company is aware in connection with the transactions contemplated by this Agreement.

(b) Indemnification by Holders. Each Holder shall, notwithstanding any termination of this Agreement, severally and not jointly, indemnify and hold harmless the Company, its directors, officers, agents and employees, each Person who controls the Company (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, agents, partners, members, stockholders or employees of such controlling Persons, to the fullest extent permitted by applicable law, from and against all Losses, as incurred, arising solely out of or based solely upon: (x) for so long as the Company is not a "Seasoned Issuer" and the prospectus delivery requirements of the Securities Act apply to sales by such Holder, such Holder's failure to comply with the prospectus delivery requirements of the Securities Act or (y) any untrue statement of a material fact contained in any Registration Statement, any Prospectus, or any form of prospectus, or in any amendment or supplement thereto, or arising solely out of or based solely upon any omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus, or any form of prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading to the extent, but only to the extent that, (1) such untrue statements or omissions are based solely upon information regarding such Holder furnished in writing to the Company by such Holder expressly for use therein, or to the extent that such information relates to such Holder or such Holder's proposed method of distribution of Registrable Securities and was reviewed and expressly approved in writing by such Holder expressly for use in the Registration Statement, such Prospectus or such form of Prospectus or in any amendment or supplement thereto (it being understood that the Holder has approved Annex A hereto for this

purpose) or (2) in the case of an occurrence of an event of the type specified in Section 3(c)(ii)-(v), the use by such Holder of an outdated or defective Prospectus after the Company has validly notified such Holder in writing (in accordance with Section 7(h) below) that the Prospectus is outdated or defective and prior to the receipt by such Holder of an Advice or an amended or supplemented Prospectus, but only if and to the extent that following the receipt of the Advice or the amended or supplemented Prospectus the misstatement or omission giving rise to such Loss would have been corrected. In no event shall the liability of any selling Holder hereunder be greater in amount than the dollar amount of the net proceeds received by such Holder upon the sale of the Registrable Securities giving rise to such indemnification obligation.

(c) Conduct of Indemnification Proceedings. If any Proceeding shall be brought or asserted against any Person entitled to indemnity hereunder (an "Indemnified Party"), such Indemnified Party shall promptly notify the Person from whom indemnity is sought (the "Indemnifying Party") in writing, and the Indemnifying Party shall assume the defense thereof, including the employment of counsel reasonably satisfactory to the Indemnified Party and the payment of all fees and expenses incurred in connection with defense thereof; provided, that the failure of any Indemnified Party to give such notice shall not relieve the Indemnifying Party of its obligations or liabilities pursuant to this Agreement, except (and only) to the extent that it shall be finally determined by a court of competent jurisdiction (which determination is not subject to appeal or further review) that such failure shall have proximately and materially adversely prejudiced the Indemnifying Party.

An Indemnified Party shall have the right to employ separate counsel in any such Proceeding and to participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnified Party or Parties unless: (1) the Indemnifying Party has agreed in writing to pay such fees and expenses; (2) the Indemnifying Party shall have failed promptly to assume the defense of such Proceeding and to employ counsel reasonably satisfactory to such Indemnified Party in any such Proceeding; or (3) the named parties to any such Proceeding (including any impleaded parties) include both such Indemnified Party and the Indemnifying Party, and such Indemnified Party shall have been advised by counsel that a conflict of interest is likely to exist if the same counsel were to represent such Indemnified Party and the Indemnifying Party (in which case, if such Indemnified Party notifies the Indemnifying Party in writing that it elects to employ separate counsel at the expense of the Indemnifying Party, the Indemnifying Party shall not have the right to assume the defense thereof and such counsel shall be at the expense of the Indemnifying Party); provided, that the Indemnifying Party shall not be liable for the fees and expenses of more than one separate firm of attorneys at any time for all Indemnified Parties pursuant to this Section 6(c). The Indemnifying Party shall not be liable for any settlement of any such Proceeding effected without its written consent, which consent shall not be unreasonably withheld. No Indemnifying Party shall, without the prior written consent of the Indemnified Party, effect any settlement of any pending Proceeding in respect of which any Indemnified Party is a party, unless such settlement includes an unconditional release of such Indemnified Party from all liability on claims that are the subject matter of such Proceeding. Each Indemnified Party shall furnish such information regarding itself or the claim in question as an Indemnifying Party may reasonably request in writing and as shall be reasonably required in connection with defense of such claim and litigation resulting therefrom.

All fees and expenses of the Indemnified Party (including reasonable fees and expenses to the extent incurred in connection with investigating or preparing to defend such Proceeding in a manner not inconsistent with this Section) shall be paid to the Indemnified Party, as incurred, within ten Trading Days of written notice thereof to the Indemnifying Party (regardless of whether it is ultimately determined that an Indemnified Party is not entitled to indemnification hereunder; provided, that the Indemnifying Party may require such Indemnified Party to undertake to reimburse all such fees and expenses to the extent it is finally judicially determined that such Indemnified Party is not entitled to indemnification hereunder).

(d) Contribution. If a claim for indemnification under Section 6(a) or 6(b) is unavailable to an Indemnified Party (by reason of public policy or otherwise), then each Indemnifying Party, in lieu of indemnifying such Indemnified Party, shall contribute to the amount paid or payable by such Indemnified Party as a result of such Losses, in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party and Indemnified Party in connection with the actions, statements or omissions that resulted in such Losses as well as any other relevant equitable considerations. The relative fault of such Indemnifying Party and Indemnified Party shall be determined by reference to, among other things, whether any action in question, including any untrue or alleged untrue statement of a material fact or omission or alleged omission of a material fact, has been taken or made by, or relates to information supplied by, such Indemnifying Party or Indemnified Party, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such action, statement or omission. The amount paid or payable by a party as a result of any Losses shall be deemed to include, subject to the limitations set forth in Section 6(c), any reasonable attorneys' or other reasonable fees or expenses incurred by such party in connection with any Proceeding to the extent such party would have been indemnified for such fees or expenses if the indemnification provided for in this Section was available to such party in accordance with its terms.

The parties hereto agree that it would not be just and equitable if contribution pursuant to this Section 6(d) were determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to in the immediately preceding paragraph. Notwithstanding the provisions of this Section 6(d), no Holder shall be required to contribute, in the aggregate, any amount in excess of the amount by which the proceeds actually received by such Holder from the sale of the Registrable Securities subject to the Proceeding exceeds the amount of any damages that such Holder has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

The indemnity and contribution agreements contained in this Section 6 are in addition to any liability that the Indemnifying Parties may have to the Indemnified Parties and are not in diminution or limitation of the indemnification provisions under the Purchase Agreement.

7. Miscellaneous.

(a) Remedies. In the event of a breach by the Company or by a Holder, of any of their obligations under this Agreement, each Holder or the Company, as the case may be, in addition to being entitled to exercise all rights granted by law and under this Agreement, including recovery of damages, will be entitled to specific performance of its rights under this Agreement. The Company and each Holder agree that monetary damages would not provide adequate compensation for any losses incurred by reason of a breach by it of any of the provisions of this Agreement and hereby further agree that, in the event of any action for specific performance in respect of such breach, it shall waive the defense that a remedy at law would be adequate.

(b) Compliance. Each Holder covenants and agrees that it will comply with the prospectus delivery requirements of the Securities Act as applicable to it in connection with sales of Registrable Securities pursuant to the Registration Statement.

(c) Subsequent Registration Rights. Until the Initial Registration Statement required hereunder is declared effective by the Commission, the Company shall not enter into any agreement granting any registration rights with respect to any of its securities to any Person without the written consent of Holders representing no less than a majority of the then outstanding Registrable Securities; provided, that this Section 7(c) shall not prohibit the Company from fulfilling its obligations under any other registration rights agreements existing as of the date hereof.

(d) Discontinued Disposition. Each Holder agrees by its acquisition of such Registrable Securities that, upon receipt of a notice from the Company of the occurrence of any event of the kind described in Section 3(c), such Holder will forthwith discontinue disposition of such Registrable Securities under the Registration Statement until such Holder's receipt of the copies of the supplemented Prospectus and/or amended Registration Statement or until it is advised in writing (the "Advice") by the Company that the use of the applicable Prospectus may be resumed, and, in either case, has received copies of any additional or supplemental filings that are incorporated or deemed to be incorporated by reference in such Prospectus or Registration Statement. The Company may provide appropriate stop orders to enforce the provisions of this paragraph.

(e) Furnishing of Information. Each Holder shall furnish in writing to the Company such information regarding itself, the Registrable Securities held by it and the intended method of disposition of the Registrable Securities held by it, as shall be reasonably requested by the Company to effect the registration of such Registrable Securities and shall execute such documents in connection with such registration as the Company may reasonably request.

(f) Piggy-Back Registrations. If at any time during the Effectiveness Period, except as contemplated by Section 2(b) hereof, there is not an effective Registration Statement covering all of the Registrable Securities and the Company shall determine to prepare and file with the Commission a registration statement relating to an offering for its own account or the account of others under the Securities Act of any of its equity securities, other than on Form S-4 or Form S-8 (each as promulgated under the Securities Act) or their then equivalents relating to

equity securities to be issued solely in connection with any acquisition of any entity or business or equity securities issuable in connection with the stock option or other employee benefit plans, then the Company shall send to each Holder a written notice of such determination and, if within 15 days after the date of such notice, any such Holder shall so request in writing, the Company shall include in such registration statement all or any part of such Registrable Securities such Holder requests to be registered; provided, however, that the Company shall not be required to register any Registrable Securities pursuant to this Section 7(f) that are eligible for resale pursuant to Rule 144 promulgated under the Securities Act without volume limitation or that are the subject of a then effective Registration Statement; provided, further, however, if there is not an effective Registration Statement covering all of the Registrable Securities during the Effectiveness Period, the Company may file a registration statement with the Commission to register equity securities of the Company to be sold on a primary basis, provided that the Company does not sell any such shares until there is an effective Registration Statement covering all of the Registrable Securities. The Company shall have the right to terminate or withdraw any registration initiated by it under this Section 7(f) prior to the effectiveness of such registration whether or not any Holder has elected to include securities in such registration.

(g) Amendments and Waivers. No provision of this Agreement may be waived or amended except in a written instrument signed by the Company and the Holder or Holders (as applicable) of no less than a majority of the then outstanding Registrable Securities. The Company shall provide prior notice to all Holders of any proposed waiver or amendment. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of either party to exercise any right hereunder in any manner impair the exercise of any such right.

(i) Termination of Registration Rights. For the avoidance of doubt, it is expressly agreed and understood that (i) in the event that there are no Registrable Securities outstanding as of a Filing Date, then the Company shall have no obligation to file, caused to be declared effective or to keep effective any Registration Statement hereunder (including any Registration Statement previously filed pursuant to this Agreement) and (ii) all registration rights granted to the Holders hereunder (including the rights set forth in Sections 7(c) and 7(f)), shall terminate in their entirety effective on the first date on which there shall cease to be any Registrable Securities outstanding. If not previously terminated pursuant to the foregoing sentence, it is expressly agreed and understood that all registration rights granted to the Holder pursuant to this Agreement shall terminate as to the Holder on the earlier of (a) such time following the date that is five (5) years following the date of this Agreement that the Holders own in the aggregate less than 25% of the number of Registrable Securities that the Holders owned in the aggregate as of the date hereof (as adjusted for stock splits, combinations, dividends, recapitalizations and the like) and (b) the date that is ten (10) years following the date of this Agreement.

(h) Notices. All notices, requests, consents and other communications hereunder shall be in writing, shall be sent by confirmed facsimile or electronic mail, or mailed by first-class registered or certified airmail, or nationally recognized overnight express courier, postage prepaid, and shall be deemed given when so sent in the case of facsimile or electronic mail transmission, or when so received in the case of mail or courier, and addressed as follows:

if to the Company, to:

Ardelyx, Inc.
34175 Ardenwood Blvd.
Fremont, California
Attention: Chief Executive Officer
Facsimile: (510) 745-0493
E-Mail: mraab@ardelyx.com

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

Latham & Watkins LLP
140 Scott Drive
Menlo Park, California 94025
Attention: Mark Roeder
Facsimile: (650) 463-2600
E-Mail: mark.roeder@lw.com

If to a Purchaser: To the address set forth under such Purchaser's name on the signature pages hereto

If to any other Person who is then the registered Holder: To the address of such Holder as it appears in the stock transfer books of the Company

or such other address as may be designated in writing hereafter, in the same manner, by such Person.

(i) Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the successors and permitted assigns of each of the parties and shall inure to the benefit of each Holder. Each Holder may assign its respective rights hereunder in the manner and to the Persons as permitted under the Purchase Agreement.

(j) Execution and Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and, all of which taken together shall constitute one and the same Agreement. In the event that any signature is delivered by facsimile transmission, such signature shall create a valid binding obligation of the party executing (or on whose behalf such signature is executed) the same with the same force and effect as if such facsimile signature were the original thereof.

(k) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by and construed and enforced in accordance with the internal laws of the State of California, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the

interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of San Francisco. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of San Francisco for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law.

(l) Cumulative Remedies. The remedies provided herein are cumulative and not exclusive of any remedies provided by law.

(m) Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their reasonable best efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

(n) Use of Terms. The parties agree and acknowledge that when, in this Agreement, the Company is required to use its reasonable best efforts to perform any covenant under this Agreement, such requirement shall not obligate the Company, in the reasonable judgment of the disinterested members of its Board of Directors, to perform any act that will have a material adverse effect on the Company.

(o) Headings. The headings in this Agreement are for convenience of reference only and shall not limit or otherwise affect the meaning hereof.

(p) Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser hereunder is several and not joint with the obligations of any other Purchaser hereunder, and no Purchaser shall be responsible in any way for the performance of the obligations of any other Purchaser hereunder. The decision of each Purchaser to purchase Securities pursuant to the Transaction Documents has been made independently of any other Purchaser. Nothing contained herein or in any other agreement or document delivered at any closing, and no action taken by any Purchaser pursuant hereto or thereto, shall be deemed to

constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert with respect to such obligations or the transactions contemplated by this Agreement. Each Purchaser acknowledges that no other Purchaser has acted as agent for such Purchaser in connection with making its investment hereunder and that no Purchaser will be acting as agent of such Purchaser in connection with monitoring its investment in the Securities or enforcing its rights under the Transaction Documents. Each Purchaser shall be entitled to protect and enforce its rights, including without limitation the rights arising out of this Agreement, and it shall not be necessary for any other Purchaser to be joined as an additional party in any proceeding for such purpose.

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

ARDELYX, INC.

By: _____

Name: Michael Raab

Title: President and Chief Executive Officer

Signature Pages to Registration Rights Agreement

PURCHASERS:

By: _____

Name: _____

Title: _____

Address: _____

Fax: _____

Email: _____

Signature Pages to Registration Rights Agreement

ANNEX A

PLAN OF DISTRIBUTION

The selling stockholders and any of their pledgees, donees, transferees, assignees or other successors-in-interest may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. The selling stockholders may use one or more of the following methods when disposing of the shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- through brokers, dealers or underwriters that may act solely as agents;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- through the writing or settlement of options or other hedging transactions entered into after the effective date of the registration statement of which this prospectus is a part, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of disposition; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended, or Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of common stock from time to time under this prospectus, or under a supplement or amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

Upon being notified in writing by a selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling stockholder and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In addition, upon being notified in writing by a selling stockholder that a donee or pledge intends to sell more than 500 shares of common stock, we will file a supplement to this prospectus if then required in accordance with applicable securities law.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of the shares of common stock or interests in shares of common stock, the selling stockholders may enter into hedging transactions after the effective date of the registration statement of which this prospectus is a part with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of common stock short after the effective date of the registration statement of which this prospectus is a part and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions after the effective date of the registration statement of which this prospectus is a part with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The maximum commission or discount to be received by any member of the Financial Industry Regulatory Authority (FINRA) or independent broker-dealer will not be greater than 8% of the initial gross proceeds from the sale of any security being sold.

We have advised the selling stockholders that they are required to comply with Regulation M promulgated under the Securities and Exchange Act during such time as they may be engaged in a distribution of the shares. The foregoing may affect the marketability of the common stock.

The aggregate proceeds to the selling securityholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling securityholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering.

We are required to pay all fees and expenses incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act or otherwise.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (a) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement or (b) the date on which the shares of common stock covered by this prospectus may be sold by non-affiliates without any volume limitations or pursuant to Rule 144 of the Securities Act.

SCHEDULE OF EXCEPTIONS

June 2, 2015

This Schedule of Exceptions is being furnished by Ardelyx, Inc., a Delaware corporation, (the "Company"), to the Purchasers listed on Exhibit A to that certain Securities Purchase Agreement of even date herewith by and among the Company and such Purchasers (the "Agreement") in connection with the execution and delivery of the Agreement, pursuant to Section 4 of the Agreement. Unless the context otherwise requires, all capitalized terms used in this Schedule of Exceptions shall have the respective meanings ascribed to such terms in the Agreement.

This Schedule of Exceptions and the information, descriptions and disclosures included herein is intended to set forth exceptions to the representations and warranties of the Company contained in the Agreement. The contents of all agreements and other documents referred to in a particular section of this Schedule of Exceptions are incorporated by reference into such particular section as though fully set forth in such section.

4.9 No Material Adverse Change

On or about the date hereof, the Company has entered into a Termination Agreement with AstraZeneca AB, a Material Contract.

4.16 Contracts

On or about the date hereof, the Company has entered into a Termination Agreement with AstraZeneca AB which the Company expects to describe on a Current Report on Form 8-K within the time period required by the SEC.

SCHEDULE 1

Name

Peter Schultz
New Enterprise Associates 12, Limited Partnership
New Enterprise Associates 15, L.P.
NEA 15 Opportunity Fund, L.P.

Form of Affiliate Legend

“THE SHARES REPRESENTED BY THIS CERTIFICATE ARE HELD BY AN AFFILIATE OF THE ISSUER AS DEFINED IN RULE 144 PROMULGATED UNDER THE SECURITIES ACT OF 1933 AND MAY ONLY BE SOLD OR OTHERWISE TRANSFERRED IN COMPLIANCE WITH THE REQUIREMENTS OF RULE 144 OR PURSUANT TO A REGISTRATION STATEMENT UNDER SAID ACT OR AN EXEMPTION FROM SUCH REGISTRATION.”

CERTIFICATION

I, Michael Raab, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ardelyx, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the small business issuer 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)) 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 small business issuer, 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) 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
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2015

By: _____ /s/ Michael Raab

Name

Michael Raab

**President Chief Executive Officer and Director
(Principal Executive Officer)**

CERTIFICATION

I, Mark Kaufmann, 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 small business issuer 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)) 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 small business issuer, 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) 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
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2015

By: _____ /s/ Mark Kaufmann

Name
Mark Kaufmann
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 Quarterly Report of Ardelyx, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2015, 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 Mark Kaufmann, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 12, 2015

By: _____ /s/ Michael Raab

**Name
Michael Raab
President Chief Executive Officer and Director
(Principal Executive Officer)**

Date: August 12, 2015

By: _____ /s/ Mark Kaufmann

**Name
Mark Kaufmann
Chief Financial Officer
(Principal Financial Officer)**

