ARDELYX, INC.
Form 10-Q
May 09, 2016
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2016

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER: 001-36485

ARDELYX, INC.

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	26-1303944
(STATE OR OTHER JURISDICTION	(I.R.S. EMPLOYER
OF INCORPORATION OR ORGANIZATION)	IDENTIFICATION NUMBER)

34175 Ardenwood Boulevard, Suite 200

Fremont, California 94555

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES, INCLUDING ZIPCODE)

(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 x 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 x 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 x
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 x

The number of issued and outstanding shares of the registrant s Common Stock, $0.0001 par value per share, as of May 5, 2016 was 34,630,148.

Table of Contents

Table of Contents

ARDELYX, INC.

	PAGE
PART I. FINANCIAL INFORMATION	
Item 1. Condensed Financial Statements:	2
Condensed Balance Sheets as of March 31, 2016 (unaudited) and December 31, 2015	2
Condensed Statements of Operations and Comprehensive Loss for the three months ended March 31, 2016 and 2015 (unaudited)	3
Condensed Statements of Cash Flows for the three months ended March 31, 2016 and 2015 (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	16
Item 4. Controls and Procedures	16
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	45
Item 3. Defaults Upon Senior Securities	45
Item 4. Mine Safety Disclosures	45
Item 5. Other Information	45
Item 6. Exhibits	46
Signatures	47

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)

	March 31, 2016 (Unaudited)	December 31, 2015 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 171,678	$ 107,004
Prepaid expenses and other current assets	4,019	5,027
Total current assets	175,697	112,031
Property and equipment, net	4,597	4,711
Other assets	104	104
Restricted cash	100	100
Total assets	$ 180,498	$ 116,946
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 4,875	$ 2,777
Accrued compensation and benefits	1,318	2,366
Accrued and other liabilities	6,265	2,580
Total current liabilities	12,458	7,723
Other long-term liabilities	292	322
Total liabilities	12,750	8,045
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized as of March 31, 2016 and December 31, 2015, respectively; no shares issued and outstanding as of March 31, 2016 and December 31, 2015, respectively.		
Common stock, $0.0001 par value; 300,000,000 shares authorized as of March 31, 2016 and December 31, 2015, respectively; 34,630,148 and 25,964,886 shares issued and outstanding as of March 31, 2016 and December 31, 2015, respectively.	4	3

Additional paid-in capital	292,699	210,386
Accumulated deficit	(124,955)	(101,488)
Total stockholders equity	167,748	108,901
Total liabilities and stockholders equity	$ 180,498	$ 116,946

(1) Derived from the audited financial statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2015.

See accompanying notes to Condensed Financial Statements.

Table of Contents

ARDELYX, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2016 (Unaudited)	**2015 (Unaudited)**
Revenue:		
Licensing revenue	$	$ 3,884
Collaborative development revenue		1,999
Total revenue		5,883
Operating expenses:		
Research and development	19,250	6,198
General and administrative	4,279	3,175
Total operating expenses	23,529	9,373
Loss from operations	(23,529)	(3,490)
Other income (expense), net	62	(12)
Loss before provision for income taxes	(23,467)	(3,502)
Provision for income taxes		
Net loss and comprehensive loss	$ (23,467)	$ (3,502)
Net loss per common share, basic and diluted	$ (0.70)	$ (0.19)
Shares used to compute net loss per common share, basic and diluted	33,466,955	18,606,760

See accompanying notes to Condensed Financial Statements.

Table of Contents

ARDELYX, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

	Three Months Ended March 31,	
	2016 (Unaudited)	**2015 (Unaudited)**
Operating activities		
Net loss	$ (23,467)	$ (3,502)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	310	119
Amortization of deferred financing costs	80	
Amortization of deferred compensation for services	47	
Stock-based compensation	1,191	524
Loss from disposal of fixed assets		11
Changes in operating assets and liabilities:		
Accounts receivable		541
Prepaid expenses and other assets	881	(336)
Accounts payable	2,102	(819)
Accrued compensation and benefits	(1,047)	(703)
Accrued and other liabilities	3,656	(134)
Deferred revenue		(3,910)
Net cash used in operating activities	(16,247)	(8,209)
Investing activities		
Purchases of property and equipment	(200)	(1,055)
Net cash used in investing activities	(200)	(1,055)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	80,837	
Proceeds from exercise of stock options	284	296
Net cash provided by financing activities	81,121	296
Net increase (decrease) in cash and cash equivalents	64,674	(8,968)
Cash and cash equivalents at beginning of period	107,004	107,286
Cash and cash equivalents at end of period	$ 171,678	$ 98,318
Supplemental cash flow disclosure:		
Cash paid during the period for income taxes	$	$ 236

Supplemental noncash financing activities:		
Acquisition of property and equipment included in accounts payable and accrued liabilities	$ 16	$ 234

See accompanying notes to Condensed Financial Statements.

Table of Contents

ARDELYX, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

NOTE 1. ORGANIZATION AND BASIS OF PRESENTATION

Ardelyx, Inc., or 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 is currently being evaluated in two pivotal Phase 3 clinical studies in patients with constipation-predominant irritable bowel syndrome, or IBS-C. In a Phase 2b clinical study, tenapanor demonstrated the ability to lower elevated serum phosphorus levels in patients with end-stage renal disease, or ESRD. The Company has initiated an additional Phase 2b clinical trial to evaluate dosing regimens of tenapanor for the treatment of hyperphosphatemia, or elevated serum phosphorus in ESRD patients. The Company is developing another drug candidate, RDX227675, the lead product candidate from its RDX022 program, for the treatment of hyperkalemia, or elevated serum potassium. The Company is pursuing a 505(b)(2) regulatory pathway for RDX227675. The Company has additional drug candidates in earlier research and development programs focused in GI and cardio-renal diseases, including RDX98940, the lead development compound from its RDX009 program focused on secretagogues of glucagon-like peptide-1, or GLP-1, and glucagon-like peptide-2, or GLP-2, and RDX013 program compounds focused on potassium secretagogues.

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, or 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 (U.S. GAAP) 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 quarter ended March 31, 2016 are not necessarily indicative of results to be expected for the entire year ending December 31, 2016 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, 2015, included in the Company s Annual Report on Form 10-K filed with the SEC (the 2015 Form 10-K). The balance sheet at December 31, 2015 has been derived from the audited financial statements at that date, as filed with the 2015 Form 10-K.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP 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.

Clinical Trial Accruals

Clinical trial costs are a component of research and development expenses. The Company accrues and expenses clinical trial activities performed by third parties based upon actual work completed in accordance with agreements established with clinical research organizations and clinical sites. The Company determines estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services.

Nonrefundable advance payments for goods and services that will be used or rendered in future research and development activities, are deferred and recognized as expense in the period that the related goods are delivered or services are performed.

Table of Contents

Recent Accounting Pronouncements

In May, 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern: Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern* (ASU 2014-15). ASU 2014-15 is intended to define management s responsibility to evaluate whether there is substantial doubt about an organization s ability to continue as a going concern and to provide related footnote disclosures, if required. ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016, and applies to annual and interim periods thereafter. The Company is evaluating the impact that the adoption of ASU 2014-15 will have on its condensed financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. Under the new guidance, lessees will be required to recognize a lease liability and a right-of-use asset for all leases (with the exception of short term leases) at the commencement date. Lessor accounting under ASU 2016-02 is largely unchanged. ASU 2016-02 is effective for annual and interim periods beginning on or after December 15, 2018 and early adoption is permitted. Under ASU 2016-02, lessees (for capital and operating leases) and lessors (for sales-type, direct financing, and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. Lessees and lessors may not apply a full retrospective transition approach. The Company has not yet selected an implementation date nor has it determined the effect of the standard on its ongoing financial reporting.

In March 2016, the FASB issued Accounting Standards 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which amends ASC Topic 718, Stock Compensation. The objective of this amendment is part of the FASB s Simplification Initiative as it applies to several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This pronouncement is effective for the Company on July 1, 2017, and allows for prospective, retrospective or modified retrospective adoption, depending on the area covered in the update, with early adoption permitted. The Company is currently evaluating the impact on our condensed financial statements and the timing of adoption.

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):

	March 31, 2016			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 170,635	$ 170,635	$	$
Certificates of deposit	100		100	
Total	$ 170,735	$ 170,635	$ 100	$

	December 31, 2015			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 105,819	$ 105,819	$	$
Certificates of deposit	100		100	
Total	$ 105,919	$ 105,819	$ 100	$

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 equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values at March 31, 2016 and December 31, 2015, 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, or the AstraZeneca Agreement, the Company received $75.0 million in up-front license fees and milestone payments which was 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, 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. AstraZeneca was obligated to supply the Company with clinical trial materials, drug substance and drug product. The maximum amount that the Company is obligated to pay for such materials was set at $10.0 million in the Termination Agreement, which maximum amount was subsequently reduced to $8.0 million pursuant to an amendment to the Termination Agreement (Amendment Number One). The Company paid AstraZeneca $6.0 million for tenapanor clinical trial material in 2015. The Company recognized $7.3 and $0.7 million of expense for tenapanor clinical trial material for 2015 and for the three months ended March 31, 2016, respectively. The Company paid AstraZeneca $6.0 million for tenapanor clinical trial material in 2015 and have recorded a $2.0 million accrual as of March 31, 2016.

Table of Contents

NOTE 5. STOCK-BASED COMPENSATION

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

	Three Months Ended March 31,	
	2016	2015
Research and development	$ 626	$ 286
General and administrative	565	238
Total	$ 1,191	$ 524

At March 31, 2016, the Company had $12.7 million, $1.0 million and $0.1 million of total unrecognized compensation expense, net of estimated forfeitures, related to stock option grants, restricted stock units and purchase rights, respectively, that will be recognized over an average vesting period of 3.4 years, 3.6 years and 0.4 years, respectively.

NOTE 6. NET LOSS PER SHARE

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per common share is computed giving effect to all potential dilutive common shares, including common stock issuable upon exercise of stock options, and unvested restricted common stock and stock units. As the Company had net losses for the three months ended March 31, 2016 and 2015, all potential common stock equivalents were determined to be anti-dilutive. Basic and diluted earnings per common share are calculated as follows (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2016	2015
Numerator:		
Net loss	$ (23,467)	$ (3,502)
Denominator:		
Weighted average common shares outstanding basic and diluted	33,466,955	18,606,760
Net loss per share basic and diluted	$ (0.70)	$ (0.19)

For the three months ended March 31, 2016 and 2015, the total number of anti-dilutive outstanding common stock equivalents excluded from the net loss per common share computation was 4.5 million and 1.2 million, respectively.

NOTE 7. ACCRUED AND OTHER LIABILITIES

Accrued liabilities and