

ARDELYX, INC.
Form 10-Q
November 07, 2016
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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 SEPTEMBER 30, 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
(STATE OR OTHER JURISDICTION OF

26-1303944
(I.R.S. EMPLOYER

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 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 November 1, 2016 was 47,301,894.

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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)**

	September 30, 2016 (Unaudited)	December 31, 2015 (1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 160,360	\$ 107,004
Short-term investments	69,726	
Prepaid expenses and other current assets	4,114	5,027
Total current assets	234,200	112,031
Property and equipment, net	6,969	4,711
Other assets	148	104
Restricted cash		100
Total assets	\$ 241,317	\$ 116,946
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 6,298	\$ 2,777
Accrued compensation and benefits	2,227	2,366
Accrued and other liabilities	9,110	2,580
Total current liabilities	17,635	7,723
Other long-term liabilities	789	322
Total liabilities	18,424	8,045
Commitments and contingencies		
Stockholders equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized as of September 30, 2016 and December 31, 2015, respectively; no shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively.		
Common stock, \$0.0001 par value; 300,000,000 shares authorized as of September 30, 2016 and December 31, 2015, respectively; 47,295,834 and	5	3

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25,964,886 shares issued and outstanding as of September 30 2016 and December 31, 2015, respectively.

Additional paid-in capital	405,514	210,386
Accumulated other comprehensive loss	(25)	
Accumulated deficit	(182,601)	(101,488)
Total stockholders' equity	222,893	108,901
Total liabilities and stockholders' equity	\$ 241,317	\$ 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****(in thousands, except share and per share amounts)****(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Licensing revenue	\$	\$	\$	\$ 21,611
Collaborative development revenue				2,415
Total revenue				24,026
Operating expenses:				
Research and development	24,863	14,705	67,951	27,101
General and administrative	4,337	3,374	13,469	9,438
Total operating expenses	29,200	18,079	81,420	36,539
Loss from operations	(29,200)	(18,079)	(81,420)	(12,513)
Other income (expense), net	169	(77)	307	(138)
Loss before provision for income taxes	(29,031)	(18,156)	(81,113)	(12,651)
Provision for income taxes		30		30
Net loss	\$ (29,031)	\$ (18,126)	\$ (81,113)	\$ (12,621)
Net loss per common share, basic and diluted	\$ (0.65)	\$ (0.70)	\$ (2.15)	\$ (0.58)
Shares used in computing basic net loss per share, basic and diluted	44,935,126	25,930,928	37,706,045	21,859,383

See accompanying notes to Condensed Financial Statements.

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ARDELYX, INC.

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	\$ (29,031)	\$ (18,126)	\$ (81,113)	\$ (12,621)
Unrealized loss on available-for-sale securities, net of tax	(25)		(25)	
Comprehensive loss	\$ (29,056)	\$ (18,126)	\$ (81,138)	\$ (12,621)

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ARDELYX, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	\$ (81,113)	\$ (12,621)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	904	540
Amortization of deferred financing costs	289	88
Amortization of deferred compensation for services	148	
Amortization of premium on investment securities	(11)	
Stock-based compensation	3,767	1,877
Loss from disposal of fixed assets		64
Changes in operating assets and liabilities:		
Accounts receivable		2,584
Prepaid expenses and other assets	719	(3,107)
Accounts payable	2,678	(281)
Accrued compensation and benefits	(139)	48
Accrued and other liabilities	6,785	7,624
Deferred revenue		(47,053)
Net cash used in operating activities	(65,973)	(50,237)
Investing activities		
Purchases of short-term investments	(69,740)	
Purchases of property and equipment	(2,108)	(3,000)
Net cash used in investing activities	(71,848)	(3,000)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	190,574	74,322
Proceeds from issuance of common stock under stock plans	603	646
Other		30
Net cash provided by financing activities	191,177	74,998
Net increase in cash and cash equivalents	53,356	21,761
Cash and cash equivalents at beginning of period	107,004	107,286

Cash and cash equivalents at end of period	\$ 160,360	\$ 129,047
Supplemental cash flow disclosure:		
Cash paid during the period for income taxes	\$	\$ 69
Supplemental noncash investing activities:		
Acquisition of property and equipment included in accounts payable and accrued liabilities	\$ 1,054	\$

See accompanying notes to Condensed Financial Statements.

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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 Phase 3 clinical trials in patients with irritable bowel syndrome with constipation, or IBS-C. In a Phase 2b clinical trial, tenapanor demonstrated the ability to lower elevated serum phosphorus levels in patients with end-stage renal disease, or ESRD, on dialysis. The Company has initiated the first of two Phase 3 clinical trials to evaluate efficacy, safety and dosing regimens of tenapanor for the treatment of hyperphosphatemia, or elevated serum phosphorus in ESRD patients on dialysis. The Company is developing another drug candidate, RDX227675, 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, 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, or 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 and nine months ended September 30, 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. Since the issuance of ASU 2014-09, the FASB has issued several amendments which clarify certain points in the new Topic 606 - *Revenue from Contracts with Customers*, including ASU 2016-08 (*Principal versus Agent Considerations Reporting Revenue Gross versus Net*), ASU 2016-10 (*Identifying Performance Obligations and Licensing*), ASU 2016-11 (*Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting*) and ASU 2016-12 (*Narrow-Scope Improvements and Practical Expedients*). The Company plans to adopt all these standards on January 1, 2018. The Company plans to modify its accounting policies to reflect the requirements of these standards and plans to select a retrospective transition method. The Company did not recognize revenue for the three- or nine-months ended September 30, 2016, and therefore, the planned adoption of this standard will not affect the Company's condensed financial statements and related disclosures for these periods or future periods until the Company reports revenues.

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 adoption of ASU 2014-15 is not expected to have a material effect on the Company's 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 the Company's 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 adoption of ASU 2016-09 is not expected to have a material effect on the Company's condensed financial statements.

In August 2016, the FASB issued Accounting Standards Update (ASU) 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which provides additional guidance on the presentation and classification of certain items in the statement of cash flows. Early adoption is permitted and the standard shall be applied retrospectively. The adoption of ASU 2016-15 is not expected to have a material effect on the Company's condensed financial statements.

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.

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Securities classified as cash and cash equivalents and short-term investments as of September 30, 2016 and December 31, 2015 are summarized below (in thousands). Estimated fair value is based on quoted market prices for these investments.

	September 30, 2016			
	Amortized	Gross Unrealized		Fair Value
	Cost	Gains	Losses	
Cash and cash equivalents:				
Cash	\$ 3,782	\$	\$	\$ 3,782
Money market funds	137,412			137,412
Corporate bonds	6,166			6,166
Commercial paper	13,000			13,000
Total cash and cash equivalents	\$ 160,360	\$	\$	\$ 160,360
Short-term investments				
Corporate bonds	30,565		(20)	\$ 30,545
Commercial paper	39,186	9	(14)	39,181