BIOCRYST PHARMACEUTICALS INC
Form 10-Q
November 08, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 10-Q

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Quarterly Report Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 2016

Commission File Number 000-23186

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BIOCRYST PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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DELAWARE	**62-1413174**
(State of other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

4505 Emperor Blvd., Suite 200
Durham, North Carolina 27703
(Address of principal executive offices) (Zip Code)

(919) 859-1302

(Registrant's telephone number, including area code)

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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 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, or 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 shares of Common Stock, par value $0.01, of the Registrant outstanding as of October 31, 2016 was 73,758,320.

BIOCRYST PHARMACEUTICALS, INC.

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

September 30, 2016 and December 31, 2015

(In thousands, except per share data)

	2016 (Unaudited)	2015 (Note 1)
Assets		
Cash and cash equivalents	$35,387	$28,899
Restricted cash	1,506	1,612
Investments	17,434	22,664
Receivables from collaborations	5,968	6,243
Inventory	2,232	1,612
Prepaid expenses and other current assets	2,007	2,674
Deferred collaboration expense	98	90
Total current assets	64,632	63,794
Investments	14,371	47,683
Property and equipment, net	10,095	5,149
Deferred collaboration expense	214	265
Other assets	2,190	5,468
Total assets	$91,502	$122,359
Liabilities and Stockholders' Equity		
Accounts payable	$2,760	$9,307
Accrued expenses	10,782	16,237
Interest payable	7,563	6,746
Deferred collaboration revenue	2,282	2,163
Non-recourse notes payable	28,133	27,804
Total current liabilities	51,520	62,257
Deferred collaboration revenue	8,480	9,674
Deferred rent	265	329
Foreign currency derivative	1,904	—
Lease financing obligation	2,675	2,375
Senior credit facility	22,665	—

Stockholders' equity:		
Preferred stock, $0.001 par value; shares authorized — 5,000; no shares issued and outstanding	—	—
Common stock, $0.01 par value: shares authorized — 200,000; shares issued and outstanding 73,758 in 2016 and 73,355 in 2015	738	734
Additional paid-in capital	564,791	558,113
Accumulated other comprehensive income (loss)	22	(206)
Accumulated deficit	(561,558)	(510,917)
Total stockholders' equity	3,993	47,724
Total liabilities and stockholders' equity	$91,502	$122,359

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Three and Nine Months Ended September 30, 2016 and 2015

(In thousands, except per share data-Unaudited)

	Three Months		Nine Months	
	2016	2015	2016	2015
Revenues				
Product sales, net	$—	$5,699	$—	$6,236
Royalty revenue	3,501	126	6,020	1,776
Collaborative and other research and development	4,262	5,162	11,350	35,643
Total revenues	7,763	10,987	17,370	43,655
Expenses				
Cost of products sold	—	1,346	—	1,361
Research and development	14,105	20,067	48,850	53,711
General and administrative	2,756	2,731	8,692	10,326
Royalty	143	5	247	507
Total operating expenses	17,004	24,149	57,789	65,905
Loss from operations	(9,241)	(13,162)	(40,419)	(22,250)
Interest and other income	109	134	695	367
Interest expense	(1,465)	(1,241)	(4,356)	(3,862)
(Loss) gain on foreign currency derivative	(931)	(352)	(6,561)	861
Net loss	$(11,528)	$(14,621)	$(50,641)	$(24,884)
Basic and diluted net loss per common share	$(0.16)	$(0.20)	$(0.69)	$(0.34)
Weighted average shares outstanding	73,734	73,262	73,677	72,752
Unrealized (loss) gain on available for sale investments	(24)	91	228	129
Comprehensive loss	$(11,552)	$(14,530)	$(50,413)	$(24,755)

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Nine Months Ended September 30, 2016 and 2015

(In thousands-Unaudited)

	2016	2015
Operating activities		
Net loss	$(50,641)	$(24,884)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	311	137
Loss on disposal of property and equipment	21	—
Stock-based compensation expense	6,478	7,773
Amortization of debt issuance costs	335	329
Amortization of premium/discount on investments	499	459
Change in fair value of foreign currency derivative	7,372	793
Changes in operating assets and liabilities:		
Receivables	275	1,995
Inventory	(620)	683
Prepaid expenses and other assets	667	872
Deferred collaboration expense	43	(117)
Accounts payable and accrued expenses	(12,066)	12,582
Interest payable	817	(512)
Deferred revenue	(1,075)	1,602
Net cash (used in) provided by operating activities	(47,584)	1,712
Investing activities		
Acquisitions of property and equipment	(5,278)	(1,076)
Change in restricted cash	106	(1,472)
Purchases of investments	—	(48,343)
Sales and maturities of investments	38,272	35,874
Net cash provided by (used in) investing activities	33,100	(15,017)
Financing activities		
Sale of common stock, net	—	1,175
Net proceeds from common stock issued under stock-based compensation plans	204	4,217
Proceeds from senior credit facility	22,658	—
Payment of foreign currency derivative collateral	(2,190)	—
Increase in lease financing obligation	300	—
Net cash provided by financing activities	20,972	5,392
Increase (decrease) in cash and cash equivalents	6,488	(7,913)
Cash and cash equivalents at beginning of period	28,899	54,540

Cash and cash equivalents at end of period	$35,387	$46,627

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

(In thousands, except per share amounts)

Note 1 — Significant Accounting Policies

The Company

BioCryst Pharmaceuticals, Inc. (the "Company") is a biotechnology company that designs, optimizes and develops novel small molecule drugs that block key enzymes involved in the pathogenesis of diseases. The Company focuses on the treatment of rare diseases in which significant unmet medical needs exist and align with its capabilities and expertise. The Company was incorporated in Delaware in 1986 and its headquarters is located in Durham, North Carolina. The Company integrates the disciplines of biology, crystallography, medicinal chemistry and computer modeling to discover and develop small molecule pharmaceuticals through the process known as structure-guided drug design. BioCryst has incurred losses and negative cash flows from operations since inception.

Based on its current operating plans, the Company expects it has sufficient liquidity, with its existing cash, restricted cash and investments of $68,698, to continue its planned operations into 2018. The Company's liquidity needs, and ability to address those needs, will largely be determined by the success of its product candidates and key development and regulatory events in the future. In order to continue its operations substantially beyond 2017 it will need to: (1) successfully secure or increase U.S. Government funding of its programs, including procurement contracts; (2) out-license rights to certain of its products or product candidates, pursuant to which the Company would receive cash milestones; (3) raise additional capital through equity or debt financings or from other sources; (4) obtain additional product candidate regulatory approvals, which would generate revenue and cash flow; (5) reduce spending on one or more research and development programs; and/or (6) restructure operations. The Company may issue securities, including common stock, preferred stock, depositary shares, stock purchase contracts, warrants and units, through private placement transactions or registered public offerings pursuant to its registration statement on Form S-3 initially filed with the Securities and Exchange Commission ("SEC") on March 3, 2015. The Company will continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations.

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, JPR Royalty Sub LLC ("Royalty Sub") and MDCP, LLC ("MDCP"). Both subsidiaries were formed to facilitate financing

transactions for the Company. Royalty Sub was formed in connection with a $30,000 financing transaction the Company completed on March 9, 2011. See Note 4, Royalty Monetization, for a further description of this transaction. MDCP was formed in connection with a $23,000 Senior Credit Facility the Company closed on September 23, 2016. See Note 5, Senior Credit Facility, for a further description of this transaction. All intercompany transactions and balances have been eliminated.

The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial reporting and the instructions to Form 10-Q and do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Such financial statements reflect all adjustments that are, in management's opinion, necessary to present fairly, in all material respects, the Company's consolidated financial position, results of operations, and cash flows. There were no adjustments other than normal recurring adjustments.

These financial statements should be read in conjunction with the financial statements for the year ended December 31, 2015 and the notes thereto included in the Company's 2015 Annual Report on Form 10-K. Interim operating results are not necessarily indicative of operating results for the full year. The balance sheet as of December 31, 2015 has been derived from the audited consolidated financial statements included in the Company's most recent Annual Report on Form 10-K.

Reclassifications

During the first quarter of 2016, the Company adopted Accounting Standards Update No. 2015-03, *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. Accordingly, debt issuance costs of $2,196 classified as other current assets as of December 31, 2015 have been reclassified and netted against non-recourse notes payable to conform to the 2016 presentation.

Cash and Cash Equivalents

The Company generally considers cash equivalents to be all cash held in commercial checking accounts, certificates of deposit, money market accounts or investments in debt instruments with maturities of three months or less at the time of purchase. The carrying value of cash and cash equivalents approximates fair value due to the short-term nature of these items.

Restricted Cash

Restricted cash as of September 30, 2016 reflects $101 in royalty revenue paid by Shionogi & Co., Ltd. (“Shionogi”) designated for interest on the PhaRMA Notes (defined in Note 4) and $1,405 the Company is required to maintain as collateral for a letter of credit associated with the lease execution and build-out of its new Birmingham research facilities.

Investments

The Company invests in high credit quality investments in accordance with its investment policy, which is designed to minimize the possibility of loss. The objective of the Company’s investment policy is to ensure the safety and preservation of invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. The Company places its excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of its credit exposure. In accordance with its policy, the Company is able to invest in marketable debt securities that may consist of U.S. Government and government agency securities, money market and mutual fund investments, municipal and corporate notes and bonds, commercial paper and asset or mortgage-backed securities, among others. The Company’s investment policy requires it to purchase high-quality marketable securities with a maximum individual maturity of three years and requires an average portfolio maturity of no more than 18 months. Some of the securities the Company invests in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. To minimize this risk, the Company schedules its investments with maturities that coincide with expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, the Company does not believe it has a material exposure to interest rate risk arising from its investments. Generally, the Company’s investments are not collateralized. The Company has not realized any significant losses from its investments.

The Company classifies all of its investments as available-for-sale. Unrealized gains and losses on investments are recognized in comprehensive loss, unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are reflected in interest and other income in the Consolidated Statements of Comprehensive Loss and are determined using the specific identification method with transactions recorded on a settlement date basis. Investments with original maturities at date of purchase beyond three months and which mature at or less than 12 months from the balance sheet date are classified as current. Investments with a maturity beyond 12 months from the balance sheet date are classified as long-term. At September 30, 2016, the Company believes that the cost of its investments is recoverable in all material respects.

The following tables summarize the fair value of the Company's investments by type. The estimated fair values of the Company's fixed income investments are classified as Level 2 in the fair value hierarchy as defined in U.S. GAAP. These valuations are based on observable direct and indirect inputs, primarily quoted prices of similar, but not identical, instruments in active markets or quoted prices for identical or similar instruments in markets that are not active. These fair values are obtained from independent pricing services which utilize Level 2 inputs.

	September 30, 2016				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Obligations of the U.S. Government and its agencies	$6,186	$ 15	$ 3	$ —	$ 6,204
Corporate debt securities	7,187	24	5	(1)	7,215
Certificates of deposit	18,342	29	19	(4)	18,386
Total investments	$31,715	$ 68	$ 27	$ (5)	$ 31,805

	December 31, 2015				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Obligations of the U.S. Government and its agencies	$26,557	$ 88	$ —	$ (99)	$ 26,546
Corporate debt securities	21,820	184	—	(41)	21,963
Certificates of deposit	21,884	21	5	(72)	21,838
Total investments	$70,261	$ 293	$ 5	$ (212)	$ 70,347

The following table summarizes the scheduled maturity for the Company's investments at September 30, 2016 and December 31, 2015.

	2016	2015
Maturing in one year or less	$17,434	$22,664
Maturing after one year through two years	14,371	28,395
Maturing after two years	—	19,288
Total investments	$31,805	$70,347

Receivables from Collaborations

Receivables from collaborations are recorded for amounts due to the Company related to reimbursable research and development costs from the U.S. Department of Health and Human Services, royalty receivables from Shionogi, Green Cross Corporation ("Green Cross") and Seqirus UK Limited ("SUL"), and product sales to SUL. These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date. At September 30, 2016 and December 31, 2015, the Company had the following receivables.

	September 30, 2016		
	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$83	$1,746	$1,829
Shionogi & Co. Ltd.	3,902	—	3,902
Green Cross Corporation	9	—	9
Seqirus UK Limited	—	228	228
Total receivables	$3,994	$1,974	$5,968

	December 31, 2015		
	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$—	$5,536	$5,536

Shionogi & Co. Ltd.	469	—	469
Seqirus UK Limited	210	28	238
Total receivables	$679	$5,564	$6,243

Monthly invoices are submitted to the U.S. Department of Health and Human Services related to reimbursable research and development costs. The Company is also entitled to monthly reimbursement of indirect costs based on rates stipulated in the underlying contract. The Company's calculations of its indirect cost rates are subject to audit by the U.S. Government.

Receivables from Product Sales

Receivables from product sales are recorded for amounts due to the Company related to sales of RAPIVAB. These receivables are evaluated to determine if any reserve or allowance should be established at each reporting date.

Inventory

At September 30, 2016 and December 31, 2015, the Company's inventory consisted primarily of RAPIVAB work in process. Inventory is stated at the lower of cost, determined under the first-in, first-out ("FIFO") method, or market. The Company expenses costs related to the production of inventories as research and development expenses in the period incurred until such time it is believed that future economic benefit is expected to be recognized, which generally is reliant upon receipt of regulatory approval. Upon regulatory approval, the Company will capitalize subsequent costs related to the production of inventories.

During 2014, in connection with the U.S. Food and Drug Administration ("FDA") approval of RAPIVAB, the Company began capitalizing costs associated with the production of RAPIVAB inventories.

The Company's inventory consisted of the following at September 30, 2016 and December 31, 2015: