BIOCRYST PHARMACEUTICALS INC
Form 10-Q
November 08, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

Quarterly Report Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 2018

Commission File Number 000-23186

BIOCRYST PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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)

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2018 was 109,641,044.

BIOCRYST PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

September 30, 2018 and December 31, 2017

(In thousands, except per share data)

	2018	2017
	(Unaudited)	(Note 1)
Assets		
Cash and cash equivalents	$ 52,584	$ 50,282
Restricted cash	1,506	3,286
Investments	67,737	64,115
Receivables from collaborations	3,394	6,117
Inventory	821	—
Prepaid expenses and other current assets	2,445	1,381
Deferred collaboration expense	8	210
Total current assets	128,495	125,391
Investments	29,157	41,295
Property and equipment, net	9,236	9,546
Other assets	1,420	2,027
Total assets	$ 168,308	$ 178,259
Liabilities and Stockholders' Equity		
Accounts payable	$ 7,911	$ 6,337
Accrued expenses	15,120	12,699
Interest payable	10,427	12,095
Deferred collaboration revenue	200	8,484
Lease financing obligation	66	75
Senior credit facility	1,621	6,464
Non-recourse notes payable	29,012	28,682
Total current liabilities	64,357	74,836
Deferred rent	81	155
Lease financing obligation	2,704	2,751
Senior credit facility	28,293	16,750

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 109,625 in 2018 and 98,411 in 2017	1,096	984
Additional paid-in capital	776,724	714,869
Accumulated other comprehensive loss	(410)	(243)
Accumulated deficit	(704,537)	(631,843)
Total stockholders' equity	72,873	83,767
Total liabilities and stockholders' equity	$168,308	$178,259

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

Three and Nine Months Ended September 30, 2018 and 2017

(In thousands, except per share data-Unaudited)

	Three Months		Nine Months	
	2018	2017	2018	2017
Revenues				
Product sales	$—	$1,501	$—	$1,501
Royalty revenue	523	442	4,326	7,252
Collaborative and other research and development	931	6,817	13,598	12,543
Total revenues	1,454	8,760	17,924	21,296
Expenses				
Cost of products sold	—	1,142	—	1,142
Research and development	22,006	17,509	61,457	50,038
General and administrative	7,923	3,343	25,024	9,235
Royalty	18	115	401	431
Total operating expenses	29,947	22,109	86,882	60,846
Loss from operations	(28,493)	(13,349)	(68,958)	(39,550)
Interest and other income	611	225	1,566	537
Interest expense	(2,346)	(2,140)	(6,762)	(6,334)
Gain (loss) on foreign currency derivative	631	130	334	(892)
Net loss	$(29,597)	$(15,134)	$(73,820)	$(46,239)
Basic and diluted net loss per common share	$(0.28)	$(0.18)	$(0.73)	$(0.58)
Weighted average shares outstanding	105,410	83,570	100,955	79,749
Unrealized gain (loss) on available for sale investments	42	(2)	(167)	(5)
Comprehensive loss	$(29,555)	$(15,136)	$(73,987)	$(46,244)

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

Nine Months Ended September 30, 2018 and 2017

(In thousands-Unaudited)

	2018	2017
Operating activities		
Net loss	$(73,820)	$(46,239)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	572	522
Stock-based compensation expense	7,072	10,307
Amortization of debt issuance costs	676	658
Amortization of premium/discount on investments	152	125
Change in fair value of foreign currency derivative	606	1,858
Changes in operating assets and liabilities:		
Receivables	2,723	(217)
Inventory	(821)	500
Prepaid expenses and other assets	(1,063)	17
Deferred collaboration expense	144	51
Accounts payable and accrued expenses	3,947	1,303
Interest payable	(1,668)	1,715
Deferred revenue	(7,100)	(1,224)
Net cash used in operating activities	(68,580)	(30,624)
Investing activities		
Acquisitions of property and equipment	(262)	(213)
Purchases of investments	(43,158)	(39,572)
Sales and maturities of investments	51,355	32,527
Net cash provided by (used in) investing activities	7,935	(7,258)
Financing activities		
Sale of common stock, net	53,400	133,500
Proceeds from senior credit facility	10,353	—
Payment of senior credit facility	(4,025)	—
Net proceeds from common stock issued under stock-based compensation plans	1,495	1,491
(Decrease) increase in lease financing obligation	(56)	139
Net cash provided by financing activities	61,167	135,130
Increase in cash, cash equivalents and restricted cash	522	97,248
Cash, cash equivalents and restricted cash at beginning of period	53,568	23,650
Cash, cash equivalents and restricted cash at end of period	$54,090	$120,898

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

(In thousands, except per share amounts)

Note 1 — Significant Accounting Policies

Agreement and Plan of Merger Termination

On January 21, 2018, BioCryst Pharmaceuticals, Inc. (the "Company" or "BioCryst"), Idera Pharmaceuticals, Inc. ("Idera"), a Delaware corporation, Nautilus Holdco, Inc., a Delaware corporation and a direct, wholly owned subsidiary of BioCryst ("Holdco"), Island Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Holdco, and Boat Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Holdco, entered into an Agreement and Plan of Merger (the "Merger Agreement").

Following the BioCryst stockholders' failure to approve the adoption of the Merger Agreement at the BioCryst special meeting of stockholders held on July 10, 2018, the Merger Agreement was terminated. Pursuant to the terms of the Merger Agreement, BioCryst reimbursed Idera for transaction-related expenses of $6,000 in July 2018.

The Company

BioCryst is a biotechnology company that discovers novel small molecule drugs that block key enzymes involved in the pathogenesis of diseases. The Company focuses on oral treatments for rare diseases in which significant unmet medical needs exist and an enzyme plays the key role in the biological pathway of the disease. 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.

With the funds available at September 30, 2018, the Company believes its resources will be sufficient to fund its operations into 2020. The Company has sustained operating losses for the majority of its corporate history and expects that its 2018 expenses will exceed its 2018 revenues. The Company expects to continue to incur operating losses and negative cash flows until revenues reach a level sufficient to support ongoing operations. Accordingly, its planned operations raise doubt about its ability to continue as a going concern through 2020. The Company's liquidity needs will be largely determined by the success of operations in regards to the progression of its product candidates in the future. The Company also may consider other plans to fund operations through 2020 including: (1) securing or increasing U.S. Government funding of its programs, including obtaining procurement contracts; (2) out-licensing rights to certain of its products or product candidates, pursuant to which the Company would receive cash milestones; (3) raising additional capital through equity or debt financings or from other sources; (4) obtaining additional product candidate regulatory approvals, which would generate revenue, milestones and cash flow; (5) reducing spending on one or more research and development programs, including by discontinuing development; and/or (6) restructuring operations to change its overhead structure. 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 in the future. The Company's future 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 and its decisions in the future.

Basis of Presentation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, JPR Royalty Sub LLC ("Royalty Sub") and MDCP, LLC ("MDCP"). All 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 that 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, 2017 and the notes thereto included in the Company's 2017 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, 2017 has been derived from the audited consolidated financial statements included in the Company's most recent Annual Report on Form 10-K.

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, 2018 reflects $93 in royalty revenue paid by Shionogi & Co., Ltd. ("Shionogi") designated for interest on the PhaRMA Notes (defined in Note 4) and $1,413 the Company is required to maintain as collateral for a letter of credit associated with the lease execution and build-out of its 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, 2018, 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, 2018				
	Amortized Cost	**Accrued Interest**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Estimated Fair Value**
Obligations of the U.S. Government and its agencies	$51,436	$ 170	$ —	$ (188)	$ 51,418
Corporate debt securities	40,893	244	—	(207)	40,930
Certificates of deposit	4,543	18	—	(15)	4,546
Total investments	$96,872	$ 432	$ —	$ (410)	$ 96,894

	December 31, 2017				
	Amortized Cost	**Accrued Interest**	**Gross Unrealized Gains**	**Gross Unrealized Losses**	**Estimated Fair Value**
Obligations of the U.S. Government and its agencies	$60,121	$ 177	$ —	$ (122)	$ 60,176
Corporate debt securities	34,021	203	—	(108)	34,116
Certificates of deposit	11,099	32	1	(14)	11,118
Total investments	$105,241	$ 412	$ 1	$ (244)	$ 105,410

The following table summarizes the scheduled maturity for the Company's investments at September 30, 2018 and December 31, 2017.

	2018	2017
Maturing in one year or less	$67,737	$64,115
Maturing after one year through two years	29,157	34,257
Maturing after two years	—	7,038
Total investments	$96,894	$105,410

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"), Mundipharma International Holdings Limited ("Mundipharma") 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, 2018 and December 31, 2017, the Company had the following receivables.

	September 30, 2018		
	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$403	$1,289	$1,692
Shionogi & Co. Ltd.	35	—	35
Green Cross Corporation	313	27	340
Mundipharma International Holdings Limited	75	—	75
Seqirus UK Limited	1,252	—	1,252
Total receivables	$2,078	$1,316	$3,394

	December 31, 2017		
	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$42	$2,020	$2,062
Shionogi & Co. Ltd.	1,600	—	1,600
Green Cross Corporation	1,388	28	1,416
Mundipharma International Holdings Limited	47	—	47
Seqirus UK Limited	825	167	992
Total receivables	$3,902	$2,215	