BIOCRYST PHARMACEUTICALS INC
Form 10-Q
August 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 June 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 July 31, 2016 was 73,700,542.

BIOCRYST PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BIOCRYST PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

June 30, 2016 and December 31, 2015

(In thousands, except per share data)

	2016 (Unaudited)	2015 (Note 1)
Assets		
Cash and cash equivalents	$8,661	$28,899
Restricted cash	4,426	1,612
Investments	27,079	22,664
Receivables from collaborations	2,234	6,243
Inventory	1,949	1,612
Prepaid expenses and other current assets	1,674	2,674
Deferred collaboration expense	89	90
Total current assets	46,112	63,794
Investments	24,154	47,683
Property and equipment, net	10,112	5,149
Deferred collaboration expense	229	265
Other assets	1,610	5,468
Total assets	$82,217	$122,359
Liabilities and Stockholders' Equity		
Accounts payable	$5,051	$9,307
Accrued expenses	11,783	16,237
Interest payable	9,203	6,746
Deferred collaboration revenue	2,134	2,163
Non-recourse notes payable	28,023	27,804
Total current liabilities	56,194	62,257
Deferred collaboration revenue	8,776	9,674
Deferred rent	297	329
Foreign currency derivative	974	—
Lease financing obligation	2,589	2,375

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 73,701 in 2016 and 73,355 in 2015	737	734
Additional paid-in capital	562,634	558,113
Accumulated other comprehensive income (loss)	46	(206)
Accumulated deficit	(550,030)	(510,917)
Total stockholders' equity	13,387	47,724
Total liabilities and stockholders' equity	$82,217	$122,359

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

Three and Six Months Ended June 30, 2016 and 2015

(In thousands, except per share data-Unaudited)

	Three Months		Six Months	
	2016	2015	2016	2015
Revenues				
Product sales, net	$—	$—	$—	$537
Royalty revenue	629	132	2,519	1,650
Collaborative and other research and development	4,158	25,710	7,088	30,481
Total revenues	4,787	25,842	9,607	32,668
Expenses				
Cost of products sold	—	—	—	15
Research and development	14,166	16,524	34,745	33,644
General and administrative	2,724	3,534	5,936	7,595
Royalty	27	442	104	502
Total operating expenses	16,917	20,500	40,785	41,756
(Loss) income from operations	(12,130)	5,342	(31,178)	(9,088)
Interest and other income	147	116	586	233
Interest expense	(1,421)	(1,306)	(2,891)	(2,621)
(Loss) gain on foreign currency derivative	(2,877)	749	(5,630)	1,213
Net (loss) income	$(16,281)	$4,901	$(39,113)	$(10,263)
Basic net (loss) income per common share	$(0.22)	$0.07	$(0.53)	$(0.14)
Diluted net (loss) income per common share	$(0.22)	$0.06	$(0.53)	$(0.14)
Weighted average shares outstanding, basic	73,695	72,642	73,648	72,492
Weighted average shares outstanding, diluted	73,695	76,760	73,648	72,492
Unrealized (loss) gain on available for sale investments	(2)	(102)	252	38
Comprehensive (loss) income	$(16,283)	$4,799	$(38,861)	$(10,225)

See accompanying notes to consolidated financial statements.

BIOCRYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Six Months Ended June 30, 2016 and 2015

(In thousands-Unaudited)

	2016	2015
Operating activities		
Net loss	$(39,113)	$(10,263)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	136	94
Stock-based compensation expense	4,491	5,934
Amortization of debt issuance costs	220	220
Amortization of premium/discount on investments	302	266
Change in fair value of foreign currency derivative	6,441	332
Changes in operating assets and liabilities:		
Receivables	4,009	5,194
Inventory	(337)	(625)
Prepaid expenses and other assets	1,000	503
Deferred collaboration expense	37	(136)
Accounts payable and accrued expenses	(8,742)	8,612
Interest payable	2,457	(1,579)
Deferred revenue	(927)	5,820
Net cash (used in) provided by operating activities	(30,026)	14,372
Investing activities		
Acquisitions of property and equipment	(5,099)	(934)
Change in restricted cash	(2,814)	(1,419)
Purchases of investments	—	(19,407)
Sales and maturities of investments	19,064	24,884
Net cash provided by investing activities	11,151	3,124
Financing activities		
Sale of common stock, net	—	1,175
Net proceeds from common stock issued under stock-based compensation plans	33	3,570
Payment of foreign currency derivative collateral	(1,610)	—
Increase in lease financing obligation	214	—
Net cash (used in) provided by financing activities	(1,363)	4,745
(Decrease) increase in cash and cash equivalents	(20,238)	22,241
Cash and cash equivalents at beginning of period	28,899	54,540

Cash and cash equivalents at end of period	$8,661	$76,781

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 $64,320, to continue its planned operations through mid-2017. 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 mid-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 statements on Form S-3 initially filed with the Securities and Exchange Commission ("SEC") on March 3, 2015 and November 6, 2013. 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 subsidiary, JPR Royalty Sub LLC ("Royalty Sub"). 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. 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 June 30, 2016 reflects $3,022 in royalty revenue paid by Shionogi & Co., Ltd. (“Shionogi”) designated for interest on the PhaRMA Notes (defined in Note 4) and $1,404 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 June 30, 2016, the Company believes that the costs of its investments are recoverable in all material respects.

The following tables summarize the fair value of the Company’s investments by type. The estimated fair value 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.

	June 30, 2016				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Obligations of the U.S. Government and its agencies	$14,081	$ 38	$ 8	$ —	$ 14,127
Corporate debt securities	16,641	147	23	(1)	16,810
Certificates of deposit	20,258	22	23	(7)	20,296
Total investments	$50,980	$ 207	$ 54	$ (8)	$ 51,233

	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 June 30, 2016 and December 31, 2015.

	2016	2015
Maturing in one year or less	$27,079	$22,664
Maturing after one year through two years	18,164	28,395
Maturing after two years	5,990	19,288
Total investments	$51,233	$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 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 June 30, 2016 and December 31, 2015, the Company had the following receivables.

	June 30, 2016		
	Billed	Unbilled	Total
U.S. Department of Health and Human Services	$723	$1,273	$1,996
Shionogi & Co. Ltd.	145	—	145
Seqirus UK Limited	37	56	93
Total receivables	$905	$1,329	$2,234

	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 June 30, 2016 and December 31, 2015, the Company's inventory consisted 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 June 30, 2016 and December 31, 2015:

	2016	2015
Work in process	$1,949	$1,612
Inventories	$1,949	$1,612

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Computer equipment is depreciated over a life of three years. Laboratory equipment, office equipment, and software are depreciated over a life of five years. Furniture and fixtures are depreciated over a life of seven years. Leasehold improvements are amortized over their estimated useful lives or the expected lease term, whichever is less. Property consists of a leased building which did not meet the sale-leaseback criteria and is recorded at its fair value, less depreciation. The building is being depreciated over a period equal to the expected term of the related lease.

In accordance with U.S. GAAP, the Company periodically reviews its property and equipment for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Property and equipment to be disposed of are reported at the lower of carrying amount or fair value less cost to sell.

Patents and Licenses

The Company seeks patent protection on all internally developed processes and products. All patent related costs are expensed to selling, general and administrative expenses when incurred as recoverability of such expenditures is uncertain.

Accrued Expenses

The Company generally enters into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. The Company records

liabilities under these contractual commitments when it determines an obligation has been incurred, regardless of the timing of the invoice. This process involves reviewing open contracts and purchase orders, communicating with applicable Company personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. The majority of service providers invoice the Company monthly in arrears for services performed. The Company makes estimates of accrued expenses as of each balance sheet date in its financial statements based on the facts and circumstances. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. Examples of estimated accrued expenses include:

- fees paid to Clinical Research Organizations ("CROs") in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of our raw materials, drug substance and drug products; and
- professional fees.

The Company bases its expenses related to clinical trials on its estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on the Company's behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. As of June 30, 2016 and December 31, 2015, the carrying value of accrued expenses approximates their fair value due to their short-term settlement.

Income Taxes

The liability method is used in the Company's accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse.

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) is comprised of unrealized gains and losses on available-for-sale investments and is disclosed as a separate component of stockholders' equity. Amounts reclassified from accumulated other comprehensive income (loss) are recorded as interest and other income on the Consolidated Statements of Comprehensive Loss. During the six months ended June 30, 2016, realized gains of $10 were reclassified out of accumulated other comprehensive income (loss). During the six months ended June 30, 2015, realized gains of $12 were reclassified out of accumulated other comprehensive income (loss).

Revenue Recognition

The Company recognizes revenues from collaborative and other research and development arrangements, royalties and product sales when realized or realizable and earned. Revenue is realized or realizable and earned when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

Collaborative and Other Research and Development Arrangements and Royalties

Revenue from license fees, royalty payments, event payments, and research and development fees are recognized as revenue when the earnings process is complete and the Company has no further continuing performance obligations or the Company has completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized over an estimated period determined by management based on the terms of the agreement and the products licensed. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

Under certain of the Company's license agreements, the Company receives royalty payments based upon its licensees' net sales of covered products. The Company recognizes royalty revenues when it can reliably estimate such amounts and collectability is reasonably assured.

For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price ("TPE") and (iii) best estimate of selling price ("BESP"). The BESP

reflects our best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis. In most cases the Company expects to use TPE or BESP for allocating consideration to each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

In June 2015, the Company entered into a License Agreement (the "SUL Agreement") granting SUL and its affiliates worldwide rights, excluding Israel, Japan, Korea and Taiwan, to develop, manufacture and commercialize RAPIVAB. The SUL Agreement provides for various types of payments, including a non-refundable upfront fee, milestone payments, and future royalties. Analysis of the SUL Agreement identified three deliverables: (i) license rights, (ii) inventory and (iii) regulatory support to obtain Canadian and European Union ("EU") marketing approvals. The Company received an upfront payment of $33,740 from SUL, of which $7,000 was determined to be contingent upon EU marketing approval and will be deferred until that time. Approximately $21,777 of the upfront payment was allocated to the license rights and recognized as revenue in the second quarter. Approximately $3,740 of the upfront payment was allocated to the pending sale of inventory and was recognized during the third quarter, when the inventory transfer was completed. Approximately $1,223 of the revenue from the SUL Agreement will be recognized over the expected period of involvement in these regulatory support activities.

Milestone payments are recognized as licensing revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement; and (ii) the fees are non-refundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

Under the terms of the SUL Agreement, the Company may receive up to $12,000 in additional payments related to the successful achievement of regulatory milestones, including marketing approval (i) by the FDA for a pediatric indication, (ii) by the EMA for an adult indication in the EU and (iii) by Health Products and Food Branch of Health Canada ("Health Canada") for an adult indication in Canada. The Company evaluated each event based payment under the provisions of ASU 2010-17, *Milestone Method of Revenue Recognition*, and determined that each event based payment met the criteria to be considered substantive and represents a milestone under the milestone method of accounting. No event based payments were achieved during the periods presented.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the Consolidated Statements of Comprehensive Loss rather than as a reduction in expenses. Under the Company's contracts with the Biomedical Advanced Research and Development Authority within the United States Department of Health and Human Services ("BARDA/HHS") and the National Institute of Allergy and Infectious Diseases ("NIAID/HHS"), revenue is recognized as reimbursable direct and indirect costs are incurred.

Product Sales

The Company recognizes revenue for sales of RAPIVAB when title and substantially all the risks and rewards of ownership have transferred to the customer, which generally occurs on the date of shipment from our specialty distributors, utilizing the Sell-Through revenue recognition methodology. Product sales are recognized when there is persuasive evidence that an arrangement exists, title has passed, the price is fixed and determinable, and collectability is reasonably assured. Product sales are recognized net of estimated allowances, discounts, sales returns, chargebacks and rebates. In the United States, and prior to the SUL Agreement, the Company sold RAPIVAB to specialty distributors, who in turn, sell to physician offices, hospitals and federal, state and commercial health care organizations. With the completion of the SUL worldwide license of RAPIVAB, SUL will be responsible for sales of RAPIVAB, other than U.S. Government stockpiling sales. With the completion of the SUL collaboration, all peramivir sales (i.e., RAPIVAB, RAPIACTA, and PERAMIFLU) will be made by the Company's partners, except for U.S. Government stockpiling sales, and the Company will be reliant on these partners to generate sales.

Sales deductions consist of statutory rebates to state Medicaid, Medicare and other government agencies and sales discounts (including trade discounts and distribution service fees). These deductions are recorded as reductions from revenue from RAPIVAB in the same period as the related sales with estimates of future utilization derived from historical experience adjusted to reflect known changes in the factors that impact such reserves.

The Company utilizes data from external sources to help it estimate gross-to-net sales adjustments as they relate to the recognition of revenue for RAPIVAB sold. Externally sourced data includes, but is not limited to, information obtained from specialty distributors with respect to their inventory levels and their sell-through to customers, as well as information from third-party suppliers of market research data to the pharmaceutical industry.

The Company accounts for these sales deductions in accordance with authoritative guidance on revenue recognition when consideration is given by a vendor to a customer.

The Company has categorized and described more fully the following significant sales deductions, all of which involve estimates and judgments, which the Company considers to be critical accounting estimates, and require it to use information from external sources.

Rebates and Chargebacks

Statutory rebates to state Medicaid agencies and Medicare are based on statutory discounts to RAPIVAB's selling price. As it can take up to nine months or more for information to be received on actual usage of RAPIVAB in Medicaid and other governmental programs, the Company maintains reserves for amounts payable under these programs relating to RAPIVAB sales.

Chargebacks claimed by specialty distributors are based on the differentials between product acquisition prices paid by the specialty distributors and lower government contract pricing paid by eligible customers covered under federally qualified programs.

The amount of the reserve for rebates and chargebacks is based on multiple qualitative and quantitative factors, including the historical and projected utilization levels, historical payment experience, changes in statutory laws and interpretations as well as contractual terms, product pricing (both normal selling prices and statutory or negotiated prices), changes in prescription demand patterns and utilization of the Company's product through public benefit plans, and the levels of RAPIVAB inventory in the distribution channel. The Company acquires prescription utilization data from third-party suppliers of market research data to the pharmaceutical industry. The Company updates its estimates and assumptions each period and records any necessary adjustments to its reserves. Settlements of rebates and chargebacks typically occur within nine months from point of sale. To the extent actual rebates and chargebacks differ from the Company's estimates, additional reserves may be required or reserves may need to be reversed, either of which would impact current period product revenue.

Discounts and Sales Incentives

Discounts and other sales incentives primarily consist of Inventory Management Agreement ("IMA") Fees. Per contractual agreements with the Company's specialty distributors, the Company provides an IMA fee based on a percentage of their purchases of RAPIVAB. The IMA fee rates are set forth in individual contracts. The Company tracks sales to these distributors each period and accrues a liability relating to the unpaid portion of these fees by applying the contractual rates to such product sales. With the completion of the SUL collaboration, all peramivir sales (i.e., RAPIVAB, RAPIACTA, and PERAMIFLU) will be made by the Company's partners, except for U.S. Government stockpiling sales, and the Company will be reliant on these partners to generate sales and to provide for discounts and sales incentives.

Product Returns

The Company does not record a product return allowance as it does not offer the ability to return goods once a bonafide shipment has been accepted by a specialty distributor.

The Company recorded the following revenues for the three and six months ended June 30, 2016 and 2015:

	Three Months		Six Months	
	2016	2015	2016	2015
Product sales, net	$—	$—	$—	$537
Royalty revenue	629	132	2,519	1,650
Collaborative and other research and development revenues:				
U.S. Department of Health and Human Services	3,709	3,731	6,033	8,206
Shionogi (Japan)	296	296	592	592
Seqirus UK Limited	153	21,683	463	21,683
Total collaborative and other research and development revenues	4,158	25,710	7,088	30,481
Total revenues	$4,787	$25,842	$9,607	$32,668

Advertising

The Company engages in very limited distribution and direct-response advertising when promoting RAPIVAB. Advertising and promotional costs are expensed as the costs are incurred.

Research and Development Expenses

The Company's research and development costs are charged to expense when incurred. Research and development expenses include all direct and indirect development costs related to the development of the Company's portfolio of product candidates. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as expense when the related goods are delivered or the related services are performed. Research and development expenses include, among other items, personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by CROs, materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Most of the Company's manufacturing and clinical and preclinical studies are performed by third-party CROs. Costs for studies performed by CROs are accrued by the Company over the service periods specified in the contracts and estimates are adjusted, if required, based upon the Company's on-going review of the level of services actually performed.

Additionally, the Company has license agreements with third parties, such as Albert Einstein College of Medicine of Yeshiva University ("AECOM"), Industrial Research, Ltd. ("IRL"), and the University of Alabama at Birmingham ("UAB"), which require fees related to sublicense agreements or maintenance fees. The Company expenses sublicense payments as incurred unless they are related to revenues that have been deferred, in which case the expenses are deferred and recognized over the related revenue recognition period. The Company expenses maintenance payments as incurred.

Deferred collaboration expenses represent sub-license payments, paid to the Company's academic partners upon receipt of consideration from various commercial partners, and other consideration paid to our academic partners for modification to existing license agreements. These deferred expenses would not have been incurred without receipt of such payments or modifications from the Company's commercial partners and are being expensed in proportion to the related revenue being recognized. The Company believes that this accounting treatment appropriately matches expenses with the associated revenue.

Stock-Based Compensation

All share-based payments, including grants of stock option awards and restricted stock unit awards, are recognized in the Company's Consolidated Statements of Comprehensive Loss based on their fair values. The fair value of stock option awards is estimated using the Black-Scholes option pricing model. The fair value of restricted stock unit awards is based on the grant date closing price of the common stock. Stock-based compensation cost is recognized as expense on a straight-line basis over the requisite service period of the award. In addition, we have outstanding performance-based stock options for which no compensation expense is recognized until "performance" is deemed to have occurred.

Interest Expense and Deferred Financing Costs

Interest expense for the three months ended June 30, 2016 and 2015 was $1,338 and $1,306, respectively, and for the six months ended June 30, 2016 and 2015 was $2,677 and $2,621, respectively, and relates to the issuance of the PhaRMA Notes (defined in Note 4). Costs directly associated with the issuance of the PhaRMA Notes have been capitalized and are netted against the non-recourse notes payable on the Consolidated Balance Sheets. These costs are being amortized to interest expense over the term of the PhaRMA Notes using the effective interest rate method. Amortization of deferred financing costs included in interest expense was $110 for each of the three months ended June 30, 2016 and 2015, and $220 for each of the six months ended June 30, 2016 and 2015.

Lease Financing Obligation

Based on the terms of the lease agreement for the new research facility in Birmingham, Alabama, the Company had construction period risks during the construction period and the Company was deemed the owner of the building (for accounting purposes only) during the construction period. Accordingly, the Company recorded an asset of $1,589, representing the Company's leased portion of the building and recorded a corresponding liability. Upon completion of leasehold improvement construction, the Company did not meet the sale-leaseback criteria for de-recognition of the building asset and liability. Therefore, the lease is accounted for as a financing obligation. The asset will be depreciated over the expected duration of the lease of 20.5 years, and rental payments will be treated as principal and interest payments on the lease financing obligation liability. The underlying accounting for this transaction has no impact on cash flows associated with the underlying lease or construction in process. Interest expense for the three and six months ended June 30, 2016 includes $83 and $214, respectively, related to the lease financing obligation.

At June 30, 2016, the lease financing obligation balance was $2,589 and was recorded as a long term liability on the consolidated balance sheets. The remaining future minimum payments under the lease financing obligation are $4,839.

Currency Hedge Agreement

In connection with the issuance by Royalty Sub of the PhaRMA Notes, the Company entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. The Currency Hedge Agreement does not qualify for hedge accounting treatment; therefore, mark-to-market adjustments are recognized in the Company's Consolidated Statements of Comprehensive Loss. Cumulative mark-to-market adjustments for the six months ended June 30, 2016 and 2015 resulted in losses of $6,441 and $332, respectively. Mark-to-market adjustments are determined by a third party pricing model that uses quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing Level 2 in the fair value hierarchy as defined by U.S. GAAP. The Company is also required to post collateral in connection with the mark-to-market adjustments based on thresholds defined in the Currency Hedge Agreement. In addition, the Company realized currency exchange gains of $811 and $1,545 during the first six months of 2016 and 2015, respectively, associated with the exercise of a U.S. dollar/Japanese yen currency option under the Currency Hedge Agreement. As of June 30, 2016, $1,610 of hedge collateral was posted under the agreement. No hedge collateral was posted as of December 31, 2015.

Net Loss Per Share

Net loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted loss per share is equivalent to basic net loss per share for all periods presented herein, except for the three months ended June 30, 2015 for which diluted income per share is $0.06 and basic income per share is $0.07 per share, because common equivalent shares from unexercised stock options and common shares expected to be issued under the Company's employee stock purchase plan were anti-dilutive. The calculation of diluted earnings per share for the three months ended June 30, 2016 does not include 885 of such potential common shares, as their impact would be anti-dilutive. The calculation of diluted earnings per share for the six months ended June 30, 2016 and 2015 does not include 1,091 and 4,038, respectively, of such potential common shares, as their impact would be anti-dilutive.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates.

Significant Customers and Other Risks

Significant Customers

Prior to the SUL Agreement, the Company relied primarily on three specialty distributors to purchase and supply the majority of RAPIVAB. These three pharmaceutical specialty distributors accounted for greater than 90% of all RAPIVAB product sales to date and accounted for predominantly all of the Company's outstanding receivables from product sales. The loss of one or more of these specialty distributors as a customer could negatively impact the commercialization of RAPIVAB. However, the Company will utilize these specialty distributors on a limited basis subsequent to the SUL collaboration as SUL, and other peramivir collaboration partners, will be responsible for commercial sales on a worldwide basis. In addition, in connection with the SUL collaboration, all peramivir sales (i.e., RAPIVAB, RAPIACTA, and PERAMIFLU) will be made by the Company's partners and the Company will be reliant on these partners to generate sales and remit cash to satisfy receivables.

The Company's primary source of revenue that has an underlying cash flow stream is the reimbursement of RAPIVAB and BCX4430 development expenses earned under cost-plus-fixed-fee contracts with BARDA/HHS and NIAID/HHS. The Company relies on BARDA/HHS and NIAID/HHS to reimburse predominantly all of the development costs for its RAPIVAB and BCX4430 programs. Accordingly, reimbursement of these expenses represents a significant portion of the Company's collaborative and other research and development revenues. The completion (as with the June 30, 2014 BARDA/HHS peramivir development contract) or termination of the NIAID/HHS and BARDA/HHS BCX4430 contracts could negatively impact the Company's future Consolidated Statements of Comprehensive Loss and Cash Flows. In addition, the Company also recognizes royalty revenue from the net sales of RAPIACTA by Shionogi; however, the underlying cash flow from these royalty payments goes directly to pay the interest, and then the principal, on the Company's non-recourse notes payable. Payment of the interest and the ultimate repayment of principal of these notes will be entirely funded by future royalty payments derived from net sales of RAPIACTA. Further, the Company's drug development activities are performed by a limited group of third party vendors. If any of these vendors were unable to perform their services, this could significantly impact the Company's ability to complete its drug development activities.

Risks from Third Party Manufacturing and Distribution Concentration

The Company relies on single source manufacturers for active pharmaceutical ingredient and finished drug product manufacturing of RAPIVAB, as well as for its other product candidates in development. Delays in the manufacture or distribution of any product could adversely impact the commercial revenue and future procurement stockpiling of RAPIVAB or the Company's product candidates in development.

Credit Risk

Cash equivalents and investments are financial instruments which potentially subject the Company to concentration of risk to the extent recorded on the Consolidated Balance Sheets. The Company deposits excess cash with major financial institutions in the United States. Balances may exceed the amount of insurance provided on such deposits. The Company believes it has established guidelines for investment of its excess cash relative to diversification and maturities that maintain safety and liquidity. To minimize the exposure due to adverse shifts in interest rates, the Company maintains a portfolio of investments with an average maturity of approximately 18 months or less. Other than product sale and collaborative partner receivables discussed above, the majority of the Company's receivables from collaborations are due from the U.S. Government, for which there is no assumed credit risk.

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2016-09: *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). The amendments in this update simplify several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 will be effective for the Company in fiscal year 2017, but early adoption is permitted. The Company is currently evaluating the impact of this update on its consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02: *Leases (Topic 842)* ("ASU 2016-02"). The amendments in this update require lessees, among other things, to recognize lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous authoritative guidance. This update also introduces new disclosure requirements for leasing arrangements. ASU 2016-02 will be effective for the Company in fiscal year 2019, but early adoption is permitted. The Company is currently evaluating the impact of this update on its consolidated financial statements.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01: *Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). The amendments in this update address certain aspects of recognition, measurement, presentation and disclosure of financial instruments. In particular, the amendments in this update supersede, for public business entities, the requirement to disclose the methods and significant assumptions used in calculating the fair value of financial instruments required to be disclosed for financial instruments measured at amortized cost on the balance sheet. ASU 2016-01 will be effective for the Company in fiscal year 2018, but early adoption is permitted. The Company does not expect this standard to have a material impact on its consolidated financial statements.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17, *Balance Sheet Classification of Deferred Taxes*, requiring all deferred tax assets and liabilities, and any related valuation allowance, to be classified as noncurrent on the balance sheet. The classification change for all deferred taxes as noncurrent simplifies entities' processes as it eliminates the need to separately identify the net current and net noncurrent deferred tax asset or liability in each jurisdiction and allocate valuation allowances. We elected to prospectively adopt the accounting standard in the beginning of our fourth quarter of fiscal 2015. Adoption of this standard had no impact on the Company's consolidated financial statements.

In July 2015, the FASB issued Accounting Standards Update No. 2015-11: *Inventory (Topic 330): Simplifying the Measurement of Inventory* ("ASU 2015-11"), which changes the measurement principle for inventory from the lower of cost or market to the lower of cost and net realizable value. ASU 2015-11 defines net realizable value as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The update does not apply to inventory that is measured using last-in, first-out or the retail inventory method. The update applies to all other inventory, which includes inventory that is measured using first-in, first-out or average cost methods. The amendments in ASU 2015-11 will be effective for the Company for fiscal years, and the interim periods within those years, beginning after December 15, 2016. The amendments must be applied prospectively and early adoption is permitted. The Company does not expect this standard to have a material impact on its consolidated financial statements.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03: *Interest – Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"). This standard amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability instead of a deferred charge. It is effective for annual reporting periods beginning after December 15, 2015 and requires retrospective application for all periods presented. The Company adopted ASU 2015-03 in the first quarter of 2016. Adoption did not have a material impact on its consolidated financial statements.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15: *Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15") , which defines management's responsibility to evaluate, at each annual and interim reporting period, whether there are conditions or events that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management must assess if there is substantial doubt about the company's ability to continue as a going concern within one year after the issuance date. Disclosures are required if conditions give rise to substantial doubt. ASU 2014-15 is effective for all companies in the first annual period ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the impact this standard will have on its financial statements and disclosures.

In May 2014, the FASB issued Standards Update No. 2014-09: *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which provides a single, comprehensive revenue recognition model for all contracts with customers. The core principal of this ASU is that an entity should recognize revenue when it transfers promised goods or services

to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB finalized a one year delay in the effective date of this standard, which will now be effective January 1, 2018; however, early adoption is permitted any time after the original effective date, January 1, 2017. Companies can transition to the new standard under the full retrospective method or the modified retrospective method. The Company is currently evaluating the impact this standard will have on its consolidated financial statements.

Note 2 — Stock-Based Compensation

As of June 30, 2016, the Company had two stock-based employee compensation plans, the Stock Incentive Plan ("Incentive Plan") and the Employee Stock Purchase Plan ("ESPP"). The Incentive Plan was amended and restated in April 2016 and approved by the Company's stockholders in May 2016. The ESPP was amended and restated in March 2014 and approved by the Company's stockholders in May 2014. Stock-based compensation expense of $4,491 ($4,402 of expense related to the Incentive Plan and $89 of expense related to the ESPP) was recognized during the first six months of 2016, while $5,934 ($5,840 of expense related to the Incentive Plan and $94 of expense related to the ESPP) was recognized during the first six months of 2015.

There was approximately $18,417 of total unrecognized compensation cost related to non-vested stock option awards and restricted stock unit awards granted by the Company as of June 30, 2016. That cost is expected to be recognized as follows: $3,782 during the remainder of 2016, $6,966 in 2017, $4,703 in 2018, $2,586 in 2019 and $380 in 2020. In addition, the Company has outstanding performance-based stock options for which no compensation expense is recognized until "performance" has occurred and the award vests. At the time of vesting, compensation expense will be recognized.

Stock Incentive Plan

The Company grants stock option awards and restricted stock unit awards to its employees, directors, and consultants under the Incentive Plan. Under the Incentive Plan, stock option awards are granted with an exercise price equal to the market price of the Company's stock at the date of grant. Since March 1, 2011, stock option awards granted to employees generally vest 25% each year until fully vested after four years. In January 2013, the Company made retention grants of stock option awards and restricted stock units. These awards vest 50% each year until fully vested after two years. In August 2013 and December 2014, the Company issued 1,032 and 1,250 performance-based stock options, respectively. These awards vest upon successful completion of specific development milestones. As of June 30, 2016, 75% of the August 2013 grants have vested based upon achievement of three milestones: (1) successful completion of the OPuS-1 clinical trial, for which vesting occurred in the second quarter of 2014, (2) FDA approval of RAPIVAB for which vesting occurred in the fourth quarter of 2014, and (3) initiation of a Phase 1 clinical trial to evaluate the safety, pharmacokinetics and pharmacodynamics of orally-administered BCX7353 in healthy volunteers, for which vesting occurred in the second quarter of 2015. Thus, as of June 30, 2016, 25% of the August 2013 performance-based grants and 100% of the December 2014 performance-based grants remain unvested and no compensation expense has been recognized for these portions of the previously issued performance-based grants. Stock option awards granted to non-employee directors of the Company generally vest monthly over one year. All stock option awards have contractual terms of 5 to 10 years. The vesting exercise provisions of all awards granted under the Incentive Plan are subject to acceleration in the event of certain stockholder-approved transactions, or upon the occurrence of a change in control as defined in the Incentive Plan.

Related activity under the Incentive Plan is as follows:

	Awards Available	Options Outstanding	Weighted Average Exercise Price
Balance December 31, 2015	16	10,671	$ 7.50
Plan amendment	3,800	—	—
Restricted stock unit awards granted	(21)	—	—
Restricted stock unit awards cancelled	15	—	—
Stock option awards granted	(2,120)	2,120	3.21
Stock option awards exercised	—	(79)	2.32
Stock option awards cancelled	499	(499)	11.24
Balance June 30, 2016	2,189	12,213	$ 6.63

For stock option awards granted under the Incentive Plan during the first six months of 2016 and 2015, the fair value was estimated on the date of grant using a Black-Scholes option pricing model and the assumptions noted in the table below. The weighted average grant date fair value per share of the awards granted during the first six months of 2016 and 2015 was $2.18 and $8.21, respectively. The fair value of the stock option awards is amortized to expense over the vesting periods using a straight-line expense attribution method. The following table summarizes the key assumptions used by the Company to value the stock option awards granted during the first six months of 2016 and

2015. The expected life is based on the average of the assumption that all outstanding stock option awards will be exercised at full vesting and the assumption that all outstanding stock option awards will be exercised at the midpoint of the current date (if already vested) or at full vesting (if not yet vested) and the full contractual term. The expected volatility represents the historical volatility on the Company's publicly traded common stock. The Company has assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. The weighted average risk-free interest rate is the implied yield currently available on zero-coupon government issues with a remaining term equal to the expected term.

Weighted Average Assumptions for Stock Option Awards Granted to

Employees and Directors under the Incentive Plan

	2016	2015
Expected Life in Years	5.6	5.5
Expected Volatility	82 %	83 %
Expected Dividend Yield	0.0%	0.0%
Risk-Free Interest Rate	1.4%	1.5%

Employee Stock Purchase Plan

The Company has reserved a total of 1,475 shares of common stock to be purchased under the ESPP, of which 463 shares remain available for purchase at June 30, 2016. Eligible employees may authorize up to 15% of their salary to purchase common stock at the lower of 85% of the beginning or 85% of the ending price during six-month purchase intervals. No more than 3 shares may be purchased by any one employee at the six-month purchase dates and no employee may purchase stock having a fair market value at the commencement date of $25 or more in any one calendar year. The Company issued 34 shares during the first six months of 2016 under the ESPP. Compensation expense for shares purchased under the ESPP related to the purchase discount and the "look-back" option were determined using a Black-Scholes option pricing model.

Note 3 — Collaborative and Other Research and Development Contracts

U.S. Department of Health and Human Services ("BARDA/HHS"). On March 31, 2015, the Company announced that BARDA/HHS had awarded the Company a contract for the continued development of BCX4430 as a potential treatment for diseases caused by RNA pathogens, including filoviruses. This BARDA/HHS contract includes a base contract of $16,265 to support BCX4430 drug manufacturing, as well as $22,855 in additional development options that can be exercised by the government, bringing the potential value of the contract to $39,120. As of June 30, 2016, a total of $20,574 has been awarded under exercised options within this contract.

National Institute of Allergy and Infectious Diseases ("NIAID/HHS"). In September 2013, NIAID/HHS contracted with the Company for the development of BCX4430 as a treatment for Marburg virus disease. NIAID/HHS, part of the National Institutes of Health, made an initial award of $5,000 to the Company. The goals of this contract, including amendments, are to file IND applications for intravenous ("i.v.") and intramuscular ("i.m.") BCX4430 for the treatment of Marburg virus disease and other hemorrhagic fever virus diseases, to study BCX4430 as a treatment for Ebola virus disease and to conduct an initial Phase 1 human clinical trial. BCX4430 is the lead compound in the Company's BSAV research program. On June 30, 2016, NIAID/HHS granted an additional $5,475 to BioCryst for the development of BCX4430 as a treatment for hemorrhagic fever viruses. As of June 30, 2016, the total NIAID/HHS contract amount to advance the program through the completion of the Phase I clinical program could be up to $39,477, if all contract options are exercised. As of June 30, 2016, a total of $35,350 has been awarded under the exercised options within this contract.

The contracts with BARDA/HHS and NIAID/HHS are cost-plus-fixed-fee contracts. That is, the Company is entitled to receive reimbursement for all costs incurred in accordance with the contract provisions that are related to the development of BCX4430 plus a fixed fee, or profit. BARDA/HHS and NIAID/HHS will make periodic assessments of progress and the continuation of the contract is based on the Company's performance, the timeliness and quality of deliverables, and other factors. The government has rights under certain contract clauses to terminate these contracts. These contracts are terminable by the government at any time for breach or without cause.

Seqirus UK Limited ("SUL"). On June 16, 2015, the Company and Seqirus UK Limited ("SUL"), a limited company organized under the laws of the United Kingdom and a subsidiary of CSL Limited, a company organized under the laws of Australia, entered into a License Agreement (the "SUL Agreement") granting SUL and its affiliates worldwide rights to develop, manufacture and commercialize RAPIVAB (peramivir injection) for the treatment of influenza except for the rights to conduct such activities in Israel, Japan, Korea and Taiwan (the permitted geographies together constituting the "Territory"). RAPIVAB is an intravenous treatment for acute uncomplicated influenza and is currently licensed for use in the United States, Japan and Korea. RAPIVAB is the first and only intravenous influenza treatment in the world and was approved by the FDA in December 2014 for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days. The Company retains all rights and associated economics to procure pandemic stockpiling orders for RAPIVAB from the U.S. Government, while SUL has the right to pursue government stockpiling outside the U.S.

Pursuant to the SUL Agreement, RAPIVAB will be commercialized by CSL's subsidiary, SUL, which specializes in influenza prevention through the supply of seasonal and pandemic vaccine to global markets. SUL will manufacture, commercialize and exercise decision-making authority with respect to the development and commercialization of RAPIVAB within the Territory and be responsible for all related costs, including sales and promotion.

In December 2013, the Company submitted an NDA for RAPIVAB to the FDA. Under the terms of the SUL Agreement, the Company is responsible for fulfilling all post-marketing approval commitments in connection with the FDA's approval of the NDA, and upon fulfillment will transfer ownership of and financial responsibility for the NDA to SUL. Pursuant to potential rights to sell RAPIVAB in Canada and the EU, the Company is also responsible for regulatory filings and interactions with the Health Canada and the European Medicines Agency ("EMA") until marketing approval for RAPIVAB is obtained and assigned to SUL. In January 2016, the Company submitted a New Drug Submission (“NDS”) for RAPIVAB in Canada, seeking approval for treatment of acute uncomplicated influenza in adult patients. In accordance with the SUL Agreement, the Company and SUL formed a joint steering committee, composed of an equal number of representatives from each party, to oversee, review and coordinate the conduct and progress of the commercialization of RAPIVAB in the Territory and any additional development.

Under the terms of the SUL Agreement, the Company received an upfront payment of $33,740, and may receive up to $12,000 in additional milestone payments related to the successful achievement of regulatory milestones, including marketing approval (i) by the FDA for a pediatric indication, (ii) by the EMA for an adult indication in the EU and (iii) by Health Canada for an adult indication in Canada. The Company is also entitled under the SUL Agreement to receive tiered royalties at a percentage rate beginning in the mid-teens contingent upon meeting minimum thresholds of net sales, as well as a low-thirties percentage of the gross profit from government stockpiling purchases made outside the U.S. Specifically, the Company receives tiered royalties at a percentage rate in the mid-teens to low-forties on net sales in the U.S. during a Contract Year (defined as July 1 - June 30) and tiered royalties at a percentage rate in the mid-teens to mid-twenties on net sales in the Territory, other than in the U.S., during a Calendar Year, each subject to certain downward adjustments for circumstance or events impacting the overall market opportunity. SUL's royalty payment obligations commence on the date of the SUL Agreement and expire, on a country-by-country basis, upon the later of (i) the expiration of legal exclusivity in such country and (ii) ten years from the date of the SUL Agreement. The Company developed RAPIVAB under a license from UAB and will owe sublicense payments to them on any future milestone payments and/or royalties received by the Company from SUL.

Shionogi & Co., Ltd. ("Shionogi"). In February 2007, the Company entered into an exclusive license agreement with Shionogi to develop and commercialize peramivir in Japan for the treatment of seasonal and potentially life-threatening human influenza. Under the terms of the agreement, Shionogi obtained rights to injectable formulations of peramivir in Japan. The Company developed peramivir under a license from UAB and will owe sublicense payments to them on any future milestone payments and/or royalties received by the Company from Shionogi. In October 2008, the Company and Shionogi amended the license agreement to expand the territory covered by the agreement to include Taiwan. Shionogi has commercially launched peramivir under the commercial name RAPIACTA in Japan. Shionogi submitted an NDA to the Taiwan FDA in late 2013.

Green Cross Corporation ("Green Cross"). In June 2006, the Company entered into an agreement with Green Cross to develop and commercialize peramivir in Korea. Under the terms of the agreement, Green Cross will be responsible for all development, regulatory, and commercialization costs in Korea. The Company received a one-time license fee of $250. The license also provides that the Company will share in profits resulting from the sale of peramivir in Korea, including the sale of peramivir to the Korean government for stockpiling purposes. Furthermore, Green Cross will pay the Company a premium over its cost to supply peramivir for development and any future marketing of peramivir products in Korea.

Mundipharma International Holdings Limited ("Mundipharma"). In February 2006, the Company entered into an exclusive, royalty bearing right and license agreement with Mundipharma for the development and commercialization of forodesine, a Purine Nucleoside Phosphorylase ("PNP") inhibitor, for use in oncology. Under the terms of the license agreement, as amended, Mundipharma obtained rights to forodesine in markets across Europe, Asia, and Australasia in exchange for a $10,000 up-front payment.

Albert Einstein College of Medicine of Yeshiva University and Industrial Research, Ltd. ("AECOM" and "IRL" respectively). In June 2000, the Company licensed a series of potent inhibitors of PNP from AECOM and IRL, (collectively, the "Licensors"). The lead product candidates from this collaboration are forodesine and ulodesine. The Company has obtained worldwide exclusive rights to develop and ultimately distribute these, or any other, product candidates that might arise from research on these inhibitors. The Company has the option to expand the Agreement to include other inventions in the field made by the investigators or employees of the Licensors. The Company agreed to use commercially reasonable efforts to develop these drugs. In addition, the Company has agreed to pay certain milestone payments for each licensed product (which range in the aggregate from $1,400 to almost $4,000 per indication) for future development of these inhibitors, single digit royalties on net sales of any resulting product made by the Company, and to share approximately one quarter of future payments received from other third-party partners, if any. In addition, the Company has agreed to pay annual license fees, which can range from $150 to $500, that are creditable against actual royalties and other payments due to the Licensors. This agreement may be terminated by the Company at any time by giving 60 days advance notice or in the event of material uncured breach by the Licensors.

In May 2010, the Company amended the licensee agreement through which the Company obtained worldwide exclusive rights to develop and ultimately distribute any product candidates that might arise from research on a series of PNP inhibitors, including forodesine and ulodesine. Under the terms of the amendment, the Licensors agreed to accept a reduction of one-half in the percentage of future payments received from third-party sub licensees of the licensed PNP inhibitors that must be paid to the Licensors. This reduction does not apply to (i) any milestone

payments the Company may receive in the future under its license agreement dated February 1, 2006 with Mundipharma and (ii) royalties received from its sub licensees in connection with the sale of licensed products, for which the original payment rate will remain in effect. The rate of royalty payments to the Licensors based on net sales of any resulting product made by the Company remains unchanged.

On November 17, 2011, the Company further amended its agreements with the Licensors whereby the Licensors agreed to accept a reduction of one-half in the percentage of Net Proceeds (as defined) received by the Company under its Amended and Restated Agreement with Mundipharma that will be paid to AECOM/IRL.

On June 19, 2012, the Company further amended its agreements with AECOM/IRL whereby the parties clarified the definition of the field with respect to PNP inhibition and AECOM/IRL agreed to exclusive worldwide license of BCX4430 to BioCryst for any antiviral use.

At its sole option and subject to certain agreed upon conditions, any future non-royalty payments due to be paid by the Company to AECOM/IRL under the license agreement may be made either in cash, in shares of the Company’s common stock, or in a combination of cash and shares.

On January 6, 2014, the Carbohydrate Chemistry Research Team from Callaghan Innovation Research Limited, formerly Industrial Research Limited, transferred to Victoria University of Wellington ("VUW") to establish the Ferrier Research Institute. The intellectual property rights relating to this research team, and the contracts relating to that intellectual property were transferred to a wholly owned subsidiary of VUW, including the contracts to which BioCryst is a party. The parties executed novation agreements in order to effectuate the transfer. Except for a substitution of parties, the terms and conditions of the contracts are substantially the same.

The University of Alabama at Birmingham ("UAB"). The Company currently has agreements with UAB for influenza neuraminidase and complement inhibitors. Under the terms of these agreements, UAB performed specific research for the Company in return for research payments and license fees. UAB has granted the Company certain rights to any discoveries in these areas resulting from research developed by UAB or jointly developed with the Company. The Company has agreed to pay single digit royalties on sales of any resulting product and to share in future payments received from other third-party partners. The Company has completed the research under the UAB agreements. These two agreements have initial 25-year terms, are automatically renewable for five-year terms throughout the life of the last patent and are terminable by the Company upon three months' notice and by UAB under certain circumstances. Upon termination both parties shall cease using the other parties' proprietary and confidential information and materials, the parties shall jointly own joint inventions and UAB shall resume full ownership of all UAB licensed products. There is currently no activity between the Company and UAB on these agreements, but when the Company licenses this technology, such as in the case of the Shionogi, Green Cross and SUL agreements, or commercializes products related to these programs, the Company will owe sublicense fees or royalties on amounts it receives.

Note 4 — Royalty Monetization

Overview

On March 9, 2011, the Company completed a $30,000 financing transaction to monetize certain future royalty and milestone payments under the Shionogi Agreement, pursuant to which Shionogi licensed from the Company the rights to market RAPIACTA in Japan and, if approved for commercial sale, Taiwan. The Company received net proceeds of $22,691 from the transaction after transaction costs of $4,309 and the establishment of a $3,000 interest reserve account by Royalty Sub, available to help cover interest shortfalls in the future. All of the interest reserve account has been fully utilized with the September 2012 interest payment.

As part of the transaction, the Company entered into a purchase and sale agreement dated as of March 9, 2011 with Royalty Sub, whereby the Company transferred to Royalty Sub, among other things, (i) its rights to receive certain royalty and milestone payments from Shionogi arising under the Shionogi Agreement, and (ii) the right to receive payments under a Japanese yen/US dollar foreign currency hedge arrangement (as further described below, the "Currency Hedge Agreement") put into place by the Company in connection with the transaction. Royalty payments will be paid by Shionogi in Japanese yen and milestone payments will paid in U.S. dollars. The Company's collaboration with Shionogi was not impacted as a result of this transaction.

Non-Recourse Notes Payable

On March 9, 2011, Royalty Sub completed a private placement to institutional investors of $30,000 in aggregate principal amount of its PhaRMA Senior Secured 14.0% Notes due 2020 (the "PhaRMA Notes"). The PhaRMA Notes were issued by Royalty Sub under an Indenture, dated as of March 9, 2011 (the "Indenture"), by and between Royalty Sub and U.S. Bank National Association, as Trustee. Principal and interest on the PhaRMA Notes issued are payable from, and are secured by, the rights to royalty and milestone payments under the Shionogi Agreement transferred by the Company to Royalty Sub and payments, if any, made to Royalty Sub under the Currency Hedge Agreement. The PhaRMA Notes bear interest at 14% per annum, payable annually in arrears on September 1st of each year. The Company remains entitled to receive any royalties and milestone payments related to sales of peramivir by Shionogi following repayment of the PhaRMA Notes.

Royalty Sub's obligations to pay principal and interest on the PhaRMA Notes are obligations solely of Royalty Sub and are without recourse to any other person, including the Company, except to the extent of the Company's pledge of its equity interests in Royalty Sub in support of the PhaRMA Notes. The Company may, but is not obligated to, make capital contributions to a capital account that may be used to redeem, or on up to one occasion pay any interest shortfall on, the PhaRMA Notes.

On September 1, 2014, Royalty Sub was unable to pay the full amount of interest payable to avoid an event of default. Accordingly, the PhaRMA Notes and related accrued interest have been classified as current liabilities on the balance sheet. As a result of the event of default under the PhaRMA Notes, the holders of the PhaRMA Notes may pursue acceleration of the PhaRMA Notes, may foreclose on the collateral securing the PhaRMA Notes and the equity interest in Royalty Sub and exercise other remedies available to them under the Indenture in respect of the PhaRMA Notes. In such event, the Company may not realize the benefit of future royalty payments that might otherwise accrue to it following repayment of the PhaRMA Notes and it might otherwise be adversely affected. Due to the non-recourse nature of the PhaRMA Notes, in the event of any potential acceleration or foreclosure, the primary impact to the Company would be the loss of future royalty payments from Shionogi and legal costs associated with retiring the PhaRMA Notes. In addition, the Company may incur costs associated with liquidating the related Currency Hedge Agreement, which would no longer be required in the event of foreclosure, or if the PhaRMA Notes cease to be outstanding. As the PhaRMA Notes are the obligation of Royalty Sub and non-recourse to the Company, the event of default of the PhaRMA Notes is not expected to have a significant impact on the Company's future results of operations or cash flows. As of June 30, 2016, the PhaRMA Notes remain in default.

As of June 30, 2016, the aggregate fair value of the PhaRMA Notes was estimated to be approximately 50% of its carrying value of $30,000. The estimated fair value of the PhaRMA Notes is classified as Level 2 in the fair value hierarchy as defined in U.S. GAAP.

The PhaRMA Notes are redeemable at the option of Royalty Sub at any time at a redemption price equal to the outstanding principal balance of the PhaRMA Notes being redeemed plus accrued and unpaid interest through the redemption date on the PhaRMA Notes being redeemed.

Foreign Currency Hedge

In connection with the issuance by Royalty Sub of the PhaRMA Notes, the Company entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, the Company has the right to purchase dollars and sell yen at a rate of 100 yen per dollar for which the Company may be required to pay a premium in each year from 2017 through 2020, provided the Currency Hedge Agreement remains in effect. A payment of $1,950 will be required if, on May 18 of the relevant year, the U.S. dollar is worth 100 yen or less as determined in accordance with the Currency Hedge Agreement.

The Currency Hedge Agreement does not qualify for hedge accounting treatment; therefore, mark-to-market adjustments are recognized in the Company's Consolidated Statement of Comprehensive Loss. Cumulative mark-to-market adjustments for the six months ended June 30, 2016 and 2015 resulted in losses of $6,441 and $332, respectively. The Company is also required to post collateral in connection with the mark-to-market adjustments based on defined thresholds. As of June 30, 2016, $1,610 of hedge collateral was posted under the Currency Hedge Agreement. The Company will not be required to post collateral exceeding the maximum premium payments remaining payable under the Currency Hedge Agreement. As of June 30, 2016, the maximum amount of hedge collateral the Company may be required to post is $7,800.

Note 5 — Stockholders' Equity

On March 3, 2015, the Company filed a $150,000 shelf registration statement on Form S-3 with the SEC. This shelf registration statement, as amended by a post-effective amendment filed on February 26, 2016 and declared effective on April 18, 2016, allows the Company to sell securities, including common stock, preferred stock, depository shares, stock purchase contracts, warrants and units, from time to time at prices and on terms to be determined at the time of sale.

On November 6, 2013, the Company filed a $125,000 shelf registration statement on Form S-3 with the SEC. This shelf registration statement was declared effective in November 2013 and allows the Company to sell securities,

including common stock, preferred stock, depository shares, stock purchase contracts, warrants and units, from time to time at prices and on terms to be determined at the time of sale. The Company has $10,000 remaining under this shelf registration statement.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains statements of a forward-looking nature relating to future events or the future financial performance of BioCryst. Such statements are only predictions and the actual events or results may differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include those discussed below and elsewhere in this report, as well as those discussed in other filings made by the Company with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. See "Information Regarding Forward-Looking Statements."

Cautionary Statement

The discussion herein contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created in Section 21E. Forward looking statements regarding our financial condition and our results of operations that are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted within the United States ("U.S. GAAP"), as well as projections for the future. The preparation of these financial statements requires our management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. Our estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. The results of our estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

We operate in a highly competitive environment that involves a number of risks, some of which are beyond our control. We are subject to risks common to biotechnology and biopharmaceutical companies, including risks inherent in our drug discovery, drug development and commercialization efforts, clinical trials, uncertainty of regulatory actions and marketing approvals, reliance on collaborative partners, enforcement of patent and proprietary rights, the need for future capital, competition associated with products, potential competition associated with our product candidates and retention of key employees. In order for any of our product candidates to be commercialized, it will be necessary for us, or our collaborative partners, to conduct clinical trials, demonstrate efficacy and safety of the product candidate to the satisfaction of regulatory authorities, obtain marketing approval, enter into manufacturing, distribution and marketing arrangements, and obtain market acceptance and adequate reimbursement from government and private insurers. We cannot provide assurance that we will generate significant revenues or achieve and sustain profitability in the future. In addition, we can provide no assurance that we will have sufficient funding to meet our future capital requirements. Statements contained in Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report which are not historical facts are, or may constitute, forward-looking statements. Forward-looking statements involve known and unknown risks that could cause our actual results to differ materially from expected results. The most significant known risks are discussed in the section entitled "Risk Factors." Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We caution you not to place undue reliance on any forward-looking statements.

Our revenues are difficult to predict and depend on numerous factors, including the prevalence and severity of influenza in regions for which peramivir has received regulatory approval, seasonality of influenza, ongoing discussions with government agencies regarding future RAPIVAB and/or BCX4430 development and stockpiling procurement, as well as entering into, or modifying, licensing agreements for our product candidates. Furthermore, revenues related to our collaborative development activities are dependent upon the progress toward and the achievement of developmental milestones by us or our collaborative partners.

Our operating expenses are also difficult to predict and depend on several factors, including research and development expenses (and whether these expenses are reimbursable under government contracts), drug manufacturing, and clinical research activities, the ongoing requirements of our development programs, and the availability of capital and direction from regulatory agencies, which are difficult to predict. Management may be able to control the timing and level of research and development and general and administrative expenses, but many of these expenditures will occur irrespective of our actions due to contractually committed activities and/or payments.

As a result of these factors, we believe that period to period comparisons are not necessarily meaningful and you should not rely on them as an indication of future performance. Due to all of the foregoing factors, it is possible that our operating results will be below the expectations of market analysts and investors. In such event, the prevailing market price of our common stock could be materially adversely affected.

Overview

We are a biotechnology company that designs, optimizes and develops novel small molecule drugs that block key enzymes involved in the pathogenesis of diseases. We focus on the treatment of rare diseases in which significant unmet medical needs exist and align with our capabilities and expertise. We integrate 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.

Critical Accounting Policies and Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. We evaluate our estimates, judgments and the policies underlying these estimates on a periodic basis, as situations change, and regularly discuss financial events, policies, and issues with members of our audit committee and our independent registered public accounting firm. We routinely evaluate our estimates and policies regarding revenue recognition, administration, inventory and manufacturing, taxes, stock-based compensation, research and development, consulting and other expenses and any associated liabilities.

Recent Corporate Highlights

RAPIVAB (peramivir injection)

RAPIVAB was approved by the FDA on December 19, 2014 and on June 16, 2015 we entered into a license agreement granting SUL and its affiliates worldwide rights to develop, manufacture and commercialize RAPIVAB (peramivir injection) for the treatment of influenza on a worldwide basis except in Israel, Japan, Korea and Taiwan. With the approval, commercial availability and out-licensing collaboration of RAPIVAB, we have moved our focus to: (1) obtaining a stockpiling procurement contract with the U.S. Government to realize the strategic value of this program; (2) fulfilling our post-approval development requirements, including conducting a pediatric trial and a trial in elderly/high risk influenza patients; and (3) submitting a Marketing Authorization Application (“MAA”) and New Drug Submission (“NDS”) in the European Union (“EU”) and Canada, respectively, to allow SUL the ability to commercialize the drug in those regions. In January 2016, we submitted a NDS for RAPIVAB in Canada, seeking approval for the treatment of acute uncomplicated influenza in adult patients.

HAE Program

Avoralstat

On December 18, 2014, we announced the dosing of the first patient in OPuS-2 (**O**ral **P**rophylaxi**S-2**), a blinded, randomized, placebo-controlled clinical trial of orally-administered avoralstat in patients with hereditary angioedema ("HAE"). OPuS-2 was a 12-week, three-arm, parallel cohort design trial to evaluate the efficacy and safety of two doses of avoralstat, 300 mg and 500 mg, administered three-times daily compared with placebo. This trial was conducted in the U.S. and select European countries. The primary efficacy endpoint for the trial was the mean angioedema attack rate for each avoralstat dose group compared to placebo. On February 8, 2016, we announced results from OPuS-2. In the OPuS-2 study, HAE patients with a historical attack frequency of greater than 0.45 attacks per week were randomized to treatment with either 500 mg or 300 mg of avoralstat, or placebo, administered three times daily for 12 weeks. Thirty-eight subjects received avoralstat 500 mg, 36 subjects received avoralstat 300 mg, and 36 subjects received placebo. Treatment with 500 mg and 300 mg of avoralstat three times daily failed to demonstrate a statistically significantly lower mean attack rate versus placebo. The mean (standard deviation) attack rates per week were 0.63 (0.57) on avoralstat 500mg and 0.71 (0.66) on avoralstat 300mg, compared to 0.61 (0.41) on placebo. Statistically significant improvements in duration of attacks and in the Angioedema Quality of Life total score were observed comparing the 500 mg three times a day avoralstat arm to placebo. Following the analysis of OPuS-2 results, the decision was made to discontinue further development of the softgel avoralstat formulation in order to focus development efforts on novel dosage forms of avoralstat to achieve meaningfully better drug exposure.

In August 2016, we reported a clinical pharmacology study of several avoralstat dosage formulations was nearing completion. Cohorts of healthy volunteers have received single doses ranging from 200 mg to 2000 mg of avoralstat in tablet or suspension formulations, with no clinically significant adverse events reported. While these dosing formulations have improved total avoralstat exposure (AUC) up to approximately five-fold compared to a 500 mg dose given as soft gel capsules, the plasma concentration-time profile has not met our objectives of twice-daily dosing with drug levels at or above the target range. For that reason, we have decided to stop further development of avoralstat.

BCX7353

In January 2015, we selected BCX7353 to advance into Phase 1 development as a once-daily, oral prophylactic HAE treatment. In October 2015, we successfully completed a Phase 1 clinical trial of BCX7353 in Western and Japanese healthy volunteers. In the Western portion of this trial, we studied BCX7353 single doses of up to 1000mg, once-daily doses of up to 500mg for seven days, and once-daily doses of 350mg for 14 days in healthy Western volunteers. Plasma levels increased in approximate proportion to dose, and drug exposure was not affected by dosing with food. The half-life of BCX7353 was estimated at 50-60 hours. After daily dosing, blood levels met or exceeded a predicted target therapeutic range throughout the 24 hour dosing interval. Inhibition of the target enzyme, plasma kallikrein, was measured in a sensitive and specific bioassay. Daily dosing with BCX7353 strongly inhibited plasma kallikrein at all four dose levels; the degree of inhibition was dose-related ($p < 0.0001$) and inhibition was sustained throughout the 24

hour dosing interval. This pharmacodynamic effect correlated strongly to the achieved drug concentration ($r = 0.91$, $p < 0.0001$).

In the Japanese portion of this trial, we enrolled cohorts of healthy Japanese volunteers and gave single oral doses of BCX7353 of 100mg and 500mg, and daily doses of 250mg of BCX7353 for seven days. Compared to Western subjects administered the same dose level, plasma drug levels in Japanese subjects were moderately higher. Kallikrein inhibition on day seven of daily dosing with 250mg in Japanese subjects was similar to that seen at the 350mg daily and 500mg daily dose levels in Western subjects.

The combined data from all Phase 1 clinical trials completed as of July 2016 indicates that oral BCX7353 has been generally safe and well tolerated in a total of 117 healthy volunteers, 46 receiving single doses of up to 1000 mg, and 71 receiving once-daily doses of up to 500 mg for 7 days and 350 mg for 14 days. In our Phase 1 trials, we have observed an approximate 5% rate of drug-related rash in healthy volunteers administered daily doses of BCX7353 for at least 7 days. This drug-related rash appears within the first 14 days of drug administration and resolves within a few days after discontinuing drug. No serious adverse events have been seen and no dose-limiting toxicity has been identified. There have been no clinically significant laboratory abnormalities, ECG changes, or vital sign changes observed.

The safety, tolerability, drug exposure and on-target plasma kallikrein inhibition results strongly support advancing the development program into a Phase 2 study in HAE patients. A Phase 2 trial (“APeX-1”) to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of BCX7353 for prophylaxis of angioedema attacks in patients with HAE has received regulatory approval in Canada and several European countries, and patient screening has commenced.

APeX-1 is a two-part, Phase 2, randomized, double-blind, placebo-controlled proof of concept and dose ranging trial studying BCX7353 as a preventative treatment to eliminate or reduce the frequency of angioedema attacks in HAE patients. Up to a total of approximately 50 eligible subjects with HAE will be enrolled in the trial.

In part 1 of APeX-1, up to 36 subjects with HAE will be randomized in a 1:1 ratio to receive an oral dose of either 350 mg of BCX7353 once daily or placebo once daily for four weeks. An interim analysis will be conducted after the first 24 subjects have completed treatment through study day 28. If a robust treatment effect is observed at the interim analysis, Part 2 of the study will be initiated. In the event the treatment effect is not well characterized with 24 subjects, a total of up to approximately 36 subjects may be enrolled in part 1 under the existing protocol. The sample size in Part 1 was kept flexible to cover a range of response options. To characterize dose-response in part 2 of APeX-1, 14 additional subjects with HAE will be randomized to 250mg of BCX7353 once daily (n=6), 125mg of BCX7353 once daily (n=6) or placebo (n=2).

The primary efficacy endpoint of APeX-1 is the number of angioedema attacks; attack rate per week, counts of attacks, proportion of subjects with no attacks, and number of attack-free days. Secondary efficacy endpoints include severity and duration of angioedema attacks, and measures of health-related quality of life. Safety will be characterized through evaluation of adverse events and laboratory testing.

In October 2015 the Japanese Ministry of Health Labor & Welfare (“MHLW”) announced that BioCryst’s BCX7353 was one of six products designated under MHLW’s new Sakigake fast track review system. The Sakigake Designation System promotes R&D in Japan and provides for additional interactions with the regulatory agency in Japan from early development through filing, and prioritized development and review, with the aim of introduction of the product as soon as possible to address a serious unmet medical need.

Other 2nd generation kallikrein inhibitors

In addition to BCX7353, we have succeeded in inventing several uniquely different plasma kallikrein inhibitor molecules from distinct structural classes. Accordingly, we have selected additional drug candidates that have suitable pharmacologic properties to advance into preclinical development. Additional disclosure on these compounds will occur as we near IND filings for any of these compounds.

BCX4430

In December 2014, we began dosing subjects in a randomized, placebo-controlled Phase 1 clinical trial to evaluate i.m. administration of BCX4430 in healthy volunteers. The main goals of this first-in-human study are to evaluate the

safety, tolerability and pharmacokinetics of escalating doses of BCX4430 administered via i.m. injection in healthy subjects. In May 2016, we completed the Phase I trial. Single doses of BCX4430 ranging from 0.3 to 10 mg/kg were administered, and daily doses of 2.5 mg/kg to 10 mg/kg were administered for 7 days. Exposure to BCX4430 was dose-proportional. BCX4430 dosing was generally safe and well-tolerated, and there were no grade 3 or 4 adverse events.

On March 7, 2016, results from a preclinical study of our antiviral BCX4430 in interferon-receptor-deficient mice infected with Zika virus were presented at a World Health Organization (WHO) conference in Geneva, Switzerland. The primary goal of the study was to assess the effect of BCX4430 treatment on survival through Day 28 in interferon-receptor-deficient mice infected with the Zika virus. BCX4430 was administered by i.m. injection twice a day beginning four hours prior to virus challenge and continuing for eight days; two dose levels were tested. In the standard dose BCX4430 group, 7 of 8 mice survived through Day 28. In the low dose BCX4430 group (n=8), and in control groups administered vehicle placebo (n=8) or ribavirin at two dose levels (n=16); no animals survived to Day 28. Overall survival for the standard dose level of BCX4430 was superior to both the placebo and the ribavirin treatment control groups ($p < 0.0001$). For both dose levels of BCX4430, median survival was superior to both control groups (>28 days for BCX4430 standard dose and 23 days for low dose) compared to 14 to 17 days for controls.

Additional studies of BCX4430 in the same mouse model were conducted at Utah State University. In one study, surviving mice that were previously treated with the standard dose of BCX4430 after initial Zika virus challenge, were re-challenged with the Zika virus on Day 28, without additional BCX4430 treatment. All the re-challenged mice survived through day 56 with no disease signs observed, indicating the development of effective immune responses. A further experiment using the same AG129 mouse model tested the delayed treatment with BCX4430 after viral challenge. Groups of mice received BCX4430 150 mg/kg twice-daily by i.m. injection starting on days 1, 3, 5, or 7 post infection, or vehicle (control group). All BCX4430 treated groups showed a statistically significant survival benefit compared to vehicle controls.

Results of Operations (three months ended June 30, 2016 compared to the three months ended June 30, 2015)

For the three months ended June 30, 2016, total revenues were $4.8 million as compared to $25.8 million for the three months ended June 30, 2015. The decrease in revenue in the second quarter of 2016, as compared to 2015, resulted primarily from lower collaborative revenue associated with the SUL agreement due to the partial recognition of a one-time large upfront payment recognized in the second quarter of 2015 as well as lower collaborative revenue associated with BCX4430 development in the second quarter of 2016. Revenues in the second quarter of 2016 included $0.6 million of royalty revenue from SUL, Shionogi and Green Cross associated with sales of peramivir in the United States, Japan and Korea, $0.8 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of BCX4430, $2.9 million of reimbursement of collaborative expenses from BARDA/HHS related to the development of RAPIVAB and $0.5 million associated with collaborative revenue amortization from other corporate partnerships. Revenues in the second quarter of 2015 included $21.7 million of collaborative revenue related to recognizing revenue on a portion of the upfront payment from the SUL out-licensing transaction, $0.1 million of royalty revenue from Shionogi and Green Cross associated with sales of peramivir in Japan and Korea, $3.7 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of BCX4430 and $0.3 million associated with collaborative revenue amortization from other corporate partnerships.

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Research and development ("R&D") expenses decreased to $14.2 million for the second quarter of 2016 from $16.5 million in 2015. The decrease in 2016 R&D expenses, as compared to 2015, was primarily due to lower development costs associated with our BCX4430 program.

General and administrative ("G&A") expenses decreased to $2.7 million for the second quarter of 2016 as compared to $3.5 million in 2015. The decrease reflects a general reduction of administrative expenses throughout the Company in the second quarter of 2016, as compared to the second quarter of 2015. With the completion of the SUL transaction we do not anticipate incurring substantial commercial expenses to promote RAPIVAB in the future.

Interest expense, which is primarily related to the non-recourse notes issued in conjunction with the non-dilutive RAPIACTA royalty monetization transaction in March 2011, was $1.4 million in the second quarter of 2016, compared to $1.3 million in the second quarter of 2015.

A mark-to-market loss of $3.7 million was also recognized in the second quarter of 2016 related to our foreign currency hedge, compared to a mark-to-market loss of $0.8 million in the same quarter in the prior year, both resulting from changes in the U.S. dollar/Japanese yen exchange rate in the related time periods. In addition, we realized a currency exchange gain of $0.8 million and $1.5 million, respectively, in the second quarter of 2016 and 2015 related to the exercise of a U.S. dollar/Japanese yen currency option under our foreign currency hedge.

Results of Operations (six months ended June 30, 2016 compared to the six months ended June 30, 2015)

For the six months ended June 30, 2016, total revenues were $9.6 million as compared to $32.7 million for the six months ended June 30, 2015. The decrease in 2016 revenue was primarily due to recognizing $21.7 million of revenue on a portion of the upfront payment from the SUL transaction in the first six months of 2015. Revenues in the first six months of 2016 included $2.5 million of royalty revenue from SUL, Shionogi and Green Cross associated with sales of peramivir in the United States, Japan and Korea, $3.1 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of BCX4430, $2.9 million of reimbursement of collaborative expenses from BARDA/HHS related to the development of RAPIVAB and $0.6 million associated with collaborative revenue amortization from other corporate partnerships. Revenues in the first six months of 2015 included $21.7 million of collaborative revenue related to the SUL Agreement, $1.7 million of royalty revenue from Shionogi and Green Cross associated with sales of peramivir in Japan and Korea, $8.2 million of reimbursement of collaborative expenses from NIAID/HHS and BARDA/HHS related to the development of BCX4430 and $0.6 million associated with collaborative revenue amortization from other corporate partnerships. In addition, we recorded approximately $0.5 million of RAPIVAB revenue under the "Sell-Through" revenue recognition methodology.

R&D expenses increased to $34.7 million for the first six months of 2016 from $33.6 million in 2015. The increase in 2016 R&D expenses, as compared to 2015, reflects increased spending on our RAPIVAB program, somewhat offset

by decreased development activity in our BCX4430 program.

The following table summarizes our R&D expenses for the periods indicated (amounts are in thousands).

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
R&D expenses by program:				
Avoralstat	$3,270	$5,848	$11,634	$12,094
BCX7353	4,881	2,044	9,497	2,044
BCX4430	1,452	3,678	3,751	6,352
2nd generation kallikrein inhibitors	885	2,181	1,030	8,062
RAPIVAB	1,397	892	3,662	2,038
Other research, preclinical and development costs	2,281	1,881	5,171	3,054
Total R&D expenses	$14,166	$16,524	$34,745	$33,644

G&A expenses decreased to $5.9 million for the first six months of 2016 as compared to $7.6 million in 2015. The decrease of $1.7 million was primarily due to lower unrestricted grants awarded to HAE patient advocacy groups, as well as a general reduction of administrative expenses in 2016.

Interest expense, which is primarily related to the non-recourse notes issued in conjunction with the non-dilutive RAPIACTA royalty monetization transaction in March 2011, was $2.9 million in the first six months of 2016, compared to $2.6 million in the first six months of 2015.

A mark-to-market loss of $6.4 million was recognized in the first six months of 2016 related to our foreign currency hedge, compared to a mark-to-market loss of $0.3 million in the same period in the prior year, both resulting from changes in the U.S. dollar/Japanese yen exchange rate in the related time periods. In addition, we realized a currency exchange gain of $0.8 million and $1.5 million, respectively, in the second quarter of 2016 and 2015 related to the exercise of a U.S. dollar/Japanese yen currency option under our foreign currency hedge.

Liquidity and Capital Resources

Cash expenditures have exceeded revenues since our inception and we expect our 2016 operating expenses to exceed our 2016 revenues. Our operations have principally been funded through public offerings and private placements of equity securities; cash from collaborative and other research and development agreements, including U.S. Government contracts for RAPIVAB and BCX4430; and to a lesser extent, the PhaRMA Notes financing. To date, we have been awarded a BARDA/HHS RAPIVAB development contract totaling $234.8 million, which expired on June 30, 2014, a NIAID/HHS BCX4430 development contract totaling $39.5 million, which is ongoing, and a

BARDA/HHS BCX4430 development contract totaling $39.1 million, which is also ongoing. The total amount of NIAID/HHS and BARDA/HHS funding obligated under awarded options in the active contracts is $35.4 million and $20.6 million, respectively. Most recently, we completed a successful public offering in June 2014 of 11.5 million shares of common stock at a price of $10.00 per share, which provided net proceeds to us of approximately $107.8 million. This financing and the recently completed SUL out-licensing transaction provide us liquidity through mid-2017. We may issue securities through private placement transactions or registered public offerings pursuant to a registration statement filed with the SEC. In addition to the above, we have received funding from other sources, including other collaborative and other research and development agreements; government grants; equipment lease financing; facility leases; research grants; and interest income on our investments.

As of June 30, 2016, we had a net working capital deficit of $10.1 million, a decrease of approximately $11.6 million from the working capital surplus of $1.5 million at December 31, 2015. The decrease in working capital was principally due to our normal operating expenses associated with the development of our product candidates. Our principal sources of liquidity at June 30, 2016 were approximately $8.7 million in cash and cash equivalents; approximately $51.2 million in investments considered available-for-sale; and approximately $2.0 million in U.S. Government receivables. We anticipate our cash and investments will fund our operations through mid-2017.

We intend to contain costs and cash flow requirements by closely managing our third party costs and headcount, leasing scientific equipment and facilities, contracting with other parties to conduct certain research and development projects and using consultants. We expect to incur additional expenses, potentially resulting in significant losses, as we continue to pursue our research and development activities and begin to build a commercial infrastructure. We may incur additional expenses related to the filing, prosecution, maintenance, defense and enforcement of patent and other intellectual property claims and additional regulatory costs as our clinical programs advance through later stages of development. The objective of our investment policy is to ensure the safety and preservation of invested funds, as well as maintaining liquidity sufficient to meet cash flow requirements. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of our credit exposure. We have not realized any significant losses on our investments.

We extended and executed additional lease obligations in 2015 for our Birmingham, Alabama operations, which increased the obligations by $5.6 million and extended the new obligations out to 2027. These operating lease obligations encompass future rental obligations of our Birmingham operating facilities.

We plan to finance our needs principally from the following:

- lease or loan financing and future public or private equity financing;
- our existing capital resources and interest earned on that capital;
- payments under existing and executing new contracts with the U.S. Government; and
- payments under collaborative and licensing agreements with corporate partners.

As our programs continue to advance, our costs will increase. Our current and planned clinical trials, plus the related development, manufacturing, regulatory approval process requirements and additional personnel resources and testing required for the continuing development of our product candidates will consume significant capital resources and will increase our expenses. Our expenses, revenues and cash utilization rate could vary significantly depending on many factors, including our ability to raise additional capital, the development progress of our collaborative agreements for our product candidates, the amount and timing of funding we receive from existing U.S. Government contracts for BCX4430, the amount of funding or assistance, if any, we receive from new U.S. Government contracts or other new partnerships with third parties for the development and or commercialization of our product candidates, the progress and results of our current and proposed clinical trials for our most advanced product candidates, the progress made in the manufacturing of our lead product candidates and the progression of our other programs.

With the funds available at June 30, 2016, we believe these resources will be sufficient to fund our operations through mid-2017. Our future liquidity needs, and ability to address those needs, will largely be determined by the success of our product candidates and key development and regulatory events in the future. In order to continue our operations substantially beyond mid-2017, we will need to: (1) successfully secure or increase U.S. Government funding of our programs, including procurement contracts; (2) out-license rights to certain of our products or product candidates, pursuant to which we 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. We may issue securities through private placement transactions or registered public offerings pursuant to a registration statement filed with the SEC.

Our long-term capital requirements and the adequacy of our available funds will depend upon many factors, including:

- our ability to perform under our government contracts and receive reimbursement, and receive stockpiling procurement contracts;
- the magnitude of work under our government contracts;
- the progress and magnitude of our research, drug discovery and development programs;
- changes in existing collaborative relationships or government contracts;
- our ability to establish additional collaborative relationships with academic institutions, biotechnology or pharmaceutical companies and governmental agencies or other third parties;
- the extent to which our partners, including governmental agencies, will share in the costs associated with the development of our programs or run the development programs themselves;
- our ability to negotiate favorable development and marketing strategic alliances for certain product candidates or a decision to build or expand internal development and commercial capabilities;
- successful commercialization of marketed products by either us or a partner;
- the scope and results of preclinical studies and clinical trials to identify and develop product candidates;

- our ability to engage sites and enroll subjects in our clinical trials;
- the scope of manufacturing of our product candidates to support our preclinical research and clinical trials;
- increases in personnel and related costs to support the development and commercialization of our product candidates;
- the scope of manufacturing of our drug substance and product candidates required for future NDA filings;
- competitive and technological advances;
- the time and costs involved in obtaining regulatory approvals;
- post-approval commitments for RAPIVAB and other products that receive regulatory approval; and
- the costs involved in all aspects of intellectual property strategy and protection including the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims.

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates and we may seek to raise capital in the future. Additional funding, whether through additional sales of equity or debt securities, collaborative or other arrangements with corporate partners or from other sources, including governmental agencies in general and existing government contracts specifically, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of the currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds may require us to delay, scale back or eliminate certain of our research and development programs. Our future working capital requirements, including the need for additional working capital, will be largely determined by the advancement of our portfolio of product candidates as well as rate of reimbursement by U.S. Government agencies of our BCX4430 expenses and any future decisions regarding the future of the RAPIVAB and BCX4430 programs, including those relating to stockpiling procurement. More specifically, our working capital requirements will be dependent on the number, magnitude, scope and timing of our development programs; regulatory approval of our product candidates; obtaining funding from collaborative partners; the cost, timing and outcome of regulatory reviews, regulatory investigations, and changes in regulatory requirements; the costs of obtaining patent protection for our product candidates; the timing and terms of business development activities; the rate of technological advances relevant to our operations; the efficiency of manufacturing processes developed on our behalf by third parties; and the level of required administrative support for our daily operations.

Financial Outlook for 2016

Based upon our development plans, expected operations and our awarded government contracts, we expect 2016 operating cash usage to be in the range of $55 to $75 million, and expect our total 2016 operating expenses to be in the range of $78 to $98 million. Our operating expense range excludes equity-based compensation expense due to the

difficulty in accurately projecting this expense as it is significantly impacted by the volatility and price of the Company's stock, as well as vesting of the Company's outstanding performance-based stock options. Our operating cash forecast excludes any impact of our royalty monetization, hedge collateral posted or returned, and any other non-routine cash outflows or inflows. Our ability to remain within our operating expense and operating cash target ranges is subject to multiple factors, including unanticipated or additional general development and administrative costs and other factors described under the Risk Factors located elsewhere in this report.

Off-Balance Sheet Arrangements

As of June 30, 2016, we do not have any unconsolidated entities or off–balance sheet arrangements.

Critical Accounting Policies

We have established various accounting policies that govern the application of U.S. GAAP, which were utilized in the preparation of our consolidated financial statements. Certain accounting policies involve significant judgments and assumptions by management that have a material impact on the carrying value of certain assets and liabilities. Management considers such accounting policies to be critical accounting policies. The judgments and assumptions used by management are based on historical experience and other factors, which are believed to be reasonable under the circumstances. Because of the nature of the judgments and assumptions made by management, actual results could differ from these judgments and estimates, which could have a material impact on the carrying values of assets and liabilities and the results of operations.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in our 2015 Annual Report on Form 10-K for the year ended December 31, 2015, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Inventory

Our inventories consist of RAPIVAB finished goods and work in process, which are valued at the lower of cost or market using the first-in, first-out (i.e., FIFO) method. Cost includes materials, labor, overhead, shipping and handling costs. Our inventories are subject to expiration dating. We regularly evaluate the carrying value of our inventories and provide valuation reserves for any estimated obsolete, short-dated or unmarketable inventories. In addition, we may experience spoilage of our raw materials and supplies. Our determination that a valuation reserve might be required, in addition to the quantification of such reserve, requires us to utilize significant judgment. In connection with the FDA approval of RAPIVAB in December 2014, we began capitalizing costs associated with the production of RAPIVAB commercial inventories.

Accrued Expenses

We enter into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. We record liabilities under these contractual commitments when an obligation has been incurred. This accrual process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed and estimating the level of service performed and the associated cost when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include:

- fees paid to Clinical Research Organizations (“CROs”) in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of our raw materials, drug substance and product candidates; and
- professional fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of these costs, our actual expenses could differ from our estimates.

Revenue Recognition

We recognize revenues from collaborative and other research and development arrangements and product sales. Revenue is realized or realizable and earned when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

Collaborative and Other Research and Development Arrangements and Royalties

Revenue from license fees, royalty payments, event payments, and research and development fees are recognized as revenue when the earnings process is complete and we have no further continuing performance obligations or we have completed the performance obligations under the terms of the agreement. Fees received under licensing agreements that are related to future performance are deferred and recognized over an estimated period determined by management based on the terms of the agreement and the products licensed. In the event a license agreement contains multiple deliverables, we evaluate whether the deliverables are separate or combined units of accounting. Revisions to revenue or profit estimates as a result of changes in the estimated revenue period are recognized prospectively.

Under certain of our license agreements, we receive royalty payments based upon our licensees' net sales of covered products. We recognize royalty revenues when we can reliably estimate such amounts and collectability is reasonably assured. Royalty revenue paid by Shionogi on their product sales is subject to returns.

For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price ("TPE") and (iii) best estimate of selling price ("BESP"). The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis. In most cases we expect to use TPE or BESP for allocating consideration to each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

In June 2015, we entered into a License Agreement (the "SUL Agreement") granting SUL and its affiliates worldwide rights, excluding Israel, Japan, Korea and Taiwan, to develop, manufacture and commercialize RAPIVAB. The SUL Agreement provides for various types of payments, including a non-refundable upfront fee, milestone payments, and future royalties. Analysis of the SUL Agreement identified three deliverables: (i) license rights, (ii) inventory and (iii) regulatory support to obtain Canadian and EU marketing approvals. We received an upfront payment of $33.7 million from SUL of which $7.0 million was determined to be contingent upon EU marketing approval and will be deferred until that time. Approximately $21.7 million of the upfront payment was allocated to the license rights and recognized as revenue in the second quarter. Approximately $3.7 million of the upfront payment was allocated to the sale of inventory and was recognized in the third quarter when the inventory transfer was completed. Approximately $1.2 million of the revenue from the SUL Agreement will be recognized ratably over the expected period of involvement in these regulatory support activities.

Milestone payments are recognized as licensing revenue upon the achievement of specified milestones if (i) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the SUL Agreement; and (ii) the fees are non-refundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recorded as deferred revenue.

Under the terms of the SUL Agreement, we may receive up to $12.0 million in additional payments related to the successful achievement of regulatory milestones, including marketing approval (i) by the FDA for a pediatric indication, (ii) by the EMA for an adult indication in the EU and (iii) by Health Canada for an adult indication in Canada. We evaluated each event based payment under the provisions of ASU 2010-17, *Milestone Method of Revenue Recognition*, and determined that each event based payment met the criteria to be considered substantive and represents a milestone under the milestone method of accounting. No event based payments were achieved during the periods presented.

Reimbursements received for direct out-of-pocket expenses related to research and development costs are recorded as revenue in the income statement rather than as a reduction in expenses. Under our contracts with BARDA/HHS and NIAID/HHS, revenue is recognized as reimbursable direct and indirect costs are incurred.

Product Sales

We recognize revenue for sales of RAPIVAB when title and substantially all the risks and rewards of ownership have transferred to the customer, which generally occurs on the date of shipment from our specialty distributors, utilizing the Sell-Through revenue recognition methodology. Product sales are recognized when there is persuasive evidence that an arrangement exists, title has passed, the price was fixed and determinable, and collectability is reasonably assured. Product sales are recognized net of estimated allowances, discounts, sales returns, chargebacks and rebates. In the United States, prior to completion of the SUL transaction, we sold RAPIVAB to specialty distributors, who, in turn, sell to physician offices, hospitals and federal, state and commercial health care organizations. With the completion of the SUL worldwide license of RAPIVAB, SUL will be responsible for sales of RAPIVAB, other than U.S. Government stockpiling sales. With the completion of the SUL collaboration, all peramivir sales (i.e., RAPIVAB, RAPIACTA, and PERAMIFLU) will be made by the Company’s partners, except for U.S. Government stockpiling sales, and the Company will be reliant on these partners to generate sales and provide for sales discounts and rebates.

Sales deductions consist of statutory rebates to state Medicaid, Medicare and other government agencies and sales discounts (including trade discounts and distribution service fees). These deductions are recorded as reductions to revenue from RAPIVAB in the same period as the related sales with estimates of future utilization derived from historical experience adjusted to reflect known changes in the factors that impact such reserves.

We utilize data from external sources to help estimate gross-to-net sales adjustments as they relate to the recognition of revenue for RAPIVAB sold. External sourced data includes, but is not limited to, information obtained from specialty distributors with respect to their inventory levels and sell-through to customers, and information from third-party suppliers of market research data to the pharmaceutical industry.

We have categorized and described more fully the following significant sales deductions, all of which involve estimates and judgments, which we consider to be critical accounting estimates, and requires us to use information from external sources.

Rebates and Chargebacks

Statutory rebates to state Medicaid agencies and Medicare are based on statutory discounts to RAPIVAB's selling price. As it can take up to nine months or more for information to be received on actual usage of RAPIVAB in Medicaid and other governmental programs, we maintain reserves for amounts payable under these programs relating to RAPIVAB sales.

Chargebacks claimed by specialty distributors are based on the differentials between product acquisition prices paid by the specialty distributors and lower government contract pricing paid by eligible customers covered under federally qualified programs.

The amount of the reserve for rebates and chargebacks is based on multiple qualitative and quantitative factors, including the historical and projected utilization levels, historical payment experience, changes in statutory laws and interpretations as well as contractual terms, product pricing (both normal selling prices and statutory or negotiated prices), changes in prescription demand patterns and utilization of our product through public benefit plans, and the levels of RAPIVAB inventory in the distribution channel. We acquire prescription utilization data from third-party suppliers of market research data to the pharmaceutical industry. We update our estimates and assumptions each period and record any necessary adjustments to reserves. Settlements of rebates and chargebacks typically occur within nine months from point of sale. To the extent actual rebates and chargebacks differ from our estimates, additional reserves may be required or reserves may need to be reversed, either of which would impact current period product revenue.

Discounts and Sales Incentives

Discounts and other sales incentives primarily consist of Inventory Management Agreement ("IMA") Fees. Per contractual agreements with our specialty distributors, we provide an IMA fee based on a percentage of their purchases of RAPIVAB. The IMA fee rates are set forth in our individual contracts. We track sales to our specialty

distributors each period and accrue a liability relating to the unpaid portion of these fees by applying contractual rates to such sales.

Product Returns

We do not record a product return allowance as we do not offer the ability to return goods once a bona fide shipment has been accepted by a specialty distributor.

Research and Development Expenses

Our research and development costs are charged to expense when incurred. Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as expense when the related goods are delivered or the related services are performed. Research and development expenses include, among other items, personnel costs, including salaries and benefits, manufacturing costs, clinical, regulatory, and toxicology services performed by CROs, materials and supplies, and overhead allocations consisting of various administrative and facilities related costs. Most of our manufacturing and clinical and preclinical studies are performed by third-party CROs. Costs for studies performed by CROs are accrued by us over the service periods specified in the contracts and estimates are adjusted, if required, based upon our on-going review of the level of services actually performed.

Additionally, we have license agreements with third parties, such as AECOM, IRL, and UAB, which require fees related to sublicense agreements or maintenance fees. We expense sublicense payments as incurred unless they are related to revenues that have been deferred, in which case the expenses are deferred and recognized over the related revenue recognition period. We expense maintenance payments as incurred.

Deferred collaboration expenses represent sub-license payments paid to our academic partners upon receipt of consideration from various commercial partners, and other consideration to our academic partners for modification to existing license agreements. These deferred expenses would not have been incurred without receipt of such payments or modifications from our commercial partners and are being expensed in proportion to the related revenue being recognized. We believe that this accounting treatment appropriately matches expenses with the associated revenue.

We group our R&D expenses into two major categories: direct external expenses and indirect expenses. Direct expenses consist of compensation for R&D personnel and costs of outside parties to conduct laboratory studies, develop manufacturing processes and manufacture the product candidate, conduct and manage clinical trials, as well as other costs related to our clinical and preclinical studies. These costs are accumulated and tracked by program. Indirect expenses consist of lab supplies and services, facility expenses, depreciation of development equipment and other overhead of our research and development efforts. These costs apply to work on our clinical and preclinical candidates as well as our discovery research efforts.

Stock-Based Compensation

All share-based payments, including grants of stock option awards and restricted stock unit awards, are recognized in our Consolidated Statements of Comprehensive Loss based on their fair values. Stock-based compensation cost is estimated at the grant date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period of the award. Determining the appropriate fair value model and the related assumptions for the model requires judgment, including estimating the life of an award, the stock price volatility, and the expected term. We utilize the Black-Scholes option-pricing model to value our awards and recognize compensation expense on a straight-line basis over the vesting periods. The estimation of share-based payment awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. In addition, we have outstanding performance-based stock options for which no compensation expense is recognized until "performance" has occurred. Significant management judgment is also required in determining estimates of future stock price volatility and forfeitures to be used in the valuation of the options. Actual results, and future changes in estimates, may differ substantially from our current estimates.

Currency Hedge Agreement

In connection with our issuance of the PhaRMA Notes, we entered into a foreign Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, we have the right to purchase dollars and sell yen at a rate of 100 yen per dollar for which we may be required to pay a premium in each year from 2017 through 2020, provided the Currency Hedge Agreement remains in effect. A payment of $2.0 million will be required if, on May 18 of the relevant year, the U.S. dollar is worth 100 yen or less as determined in accordance with the Currency Hedge Agreement. In conjunction with establishing the Currency Hedge Agreement, we will be required to post collateral to the counterparty, which may cause us to experience additional quarterly volatility in our financial results. We will not be required at any time to post collateral exceeding the maximum premium payments remaining payable under the Currency Hedge Agreement. In establishing the hedge, we provided initial funds of approximately $2.0 million to support our potential hedge obligations. As of June 30, 2016, the maximum amount of hedge collateral we may be required to post is $7.8 million.

The Currency Hedge Agreement does not qualify for hedge accounting treatment and therefore mark to market adjustments will be recognized in our Consolidated Statements of Comprehensive Loss. Mark to market adjustments

are determined by quoted prices in markets that are not actively traded and for which significant inputs are observable directly or indirectly, representing the Level 2 in the fair value hierarchy as defined by generally accepted accounting principles ("U.S. GAAP"). The Company is also required to post collateral in connection with the mark to market adjustments based on defined thresholds. As of June 30, 2016, $1.6 million of collateral was posted under the agreement.

Tax

We account for uncertain tax positions in accordance with U.S. GAAP. Significant management judgment is required in determining our provision for income taxes, deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets. We have recorded a valuation allowance against all potential tax assets, due to uncertainties in our ability to utilize deferred tax assets, primarily consisting of certain net operating losses carried forward, before they expire. The valuation allowance is based on estimates of taxable income in each of the jurisdictions in which we operate and the period over which our deferred tax assets will be recoverable.

Information Regarding Forward-Looking Statements

This filing contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created in Section 21E. All statements other than statements of historical facts contained in this filing are forward-looking statements. These forward-looking statements can generally be identified by the use of words such as "may," "will," "intends," "plans," "believes," "anticipates," "expects," "esti "predicts," "potential," the negative of these words or similar expressions. Statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Discussions containing these forward-looking statements are principally contained in "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as any amendments we make to those sections in filings with the SEC. These forward-looking statements include, but are not limited to, statements about:

- the preclinical development, clinical development, commercialization, or post-marketing studies of our product candidates and products, including our HAE program, RAPIVAB, BCX4430, and early stage discovery programs;
- the potential funding from our contracts with NIAID/HHS and BARDA/HHS for the development of BCX4430;
- the potential for government stockpiling orders of RAPIVAB, additional regulatory approvals of RAPIVAB or milestones royalties or profit from commercial sales of RAPIVAB by us or our partners;
- the potential use of RAPIVAB as a treatment for H1N1, H5N1, and H7N9 or other strains of influenza;
- the implementation of our business model, strategic plans for our business, products, product candidates and technology;
- our ability to establish and maintain collaborations or out-license rights to our drug candidates;
- plans, programs, progress and potential success of our collaborations, including SUL for RAPIVAB, Mundipharma for forodesine and Shionogi and Green Cross for peramivir in their territories;
- Royalty Sub's ability to service its payment obligations in respect of the PhaRMA Notes, and our ability to benefit from our equity interest in Royalty Sub;
- the foreign currency hedge agreement entered into by us in connection with the issuance by Royalty Sub of the PhaRMA Notes;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, revenues, capital requirements, annual cash utilization, and our needs for additional financing;
- the timing or likelihood of regulatory filings or regulatory agreements, deferrals, and approvals;
- our ability to raise additional capital to fund our operations;
- our financial performance; and
- competitive companies, technologies and our industry.

These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors." Any forward-looking statement reflects our current

views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are subject to interest rate risk on our investment portfolio and borrowings under our PhaRMA Notes.

We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve capital, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure to any single issue, issuer or type of investment. We place our excess cash with high credit quality financial institutions, commercial companies, and government agencies in order to limit the amount of credit exposure. Some of the securities we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate.

Our investment exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our portfolio, changes in the market value due to changes in interest rates and other market factors as well as the increase or decrease in any realized gains and losses. Our investment portfolio includes only marketable securities and instruments with active secondary or resale markets to help ensure portfolio liquidity. A hypothetical 100 basis point drop in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest sensitive financial instruments. We generally have the ability to hold our fixed-income investments to maturity and therefore do not expect that our operating results, financial position or cash flows will be materially impacted due to a sudden change in interest rates. However, our future investment income may fall short of expectations due to changes in interest rates, or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates or other factors, such as changes in credit risk related to the securities' issuers. To minimize this risk, we schedule our investments to have maturities that coincide with our expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we do not believe that we have material exposure to interest rate risk arising from our investments. Generally, our investments are not collateralized. We have not realized any significant losses from our investments.

We do not use interest rate derivative instruments to manage exposure to interest rate changes. We ensure the safety and preservation of invested principal funds by limiting default risk, market risk and reinvestment risk. We reduce default risk by investing in investment grade securities.

Foreign Currency Risk

The majority of our transactions occur in U.S. dollars and we do not have operating subsidiaries or investments in foreign countries. Therefore, we are not subject to significant foreign currency exchange risk in our normal operations.

In connection with the issuance by Royalty Sub of the PhaRMA Notes, we entered into a Currency Hedge Agreement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the Currency Hedge Agreement, we are required to post collateral based on our potential obligations under the Currency Hedge Agreement as determined by periodic mark-to-market adjustments. Provided the Currency Hedge Agreement remains in effect, we may be required to pay an annual premium in the amount of $2.0 million from May 2017 through May 2020. Such payment will be required if, in May of the relevant year, the spot rate of exchange for Japanese yen-U.S. dollars (determined in accordance with the Currency Hedge Agreement) is such that the U.S. dollar is worth 100 yen or less.

Item 4. Controls and Procedures

We maintain a set of disclosure controls and procedures that are designed to ensure that information relating to BioCryst Pharmaceuticals, Inc. required to be disclosed in our periodic filings under the Exchange Act is recorded, processed, summarized and reported in a timely manner under the Exchange Act. We carried out an evaluation, under

the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2016, the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports filed or submitted by it under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and include controls and procedures designed to ensure that information required to be disclosed by the Company in such reports is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer of the Company, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2016 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. ***RISK FACTORS***

An investment in our stock involves risks. You should carefully read this entire report and consider the following uncertainties and risks, which may adversely affect our business, financial condition or results of operations, along with all of the other information included in our other filings with the Securities and Exchange Commission, before deciding to buy our common stock.

Risks Relating to Our Business

We have incurred losses since our inception, expect to continue to incur such losses, and may never be profitable.

Since our inception, we have not achieved sustained profitability. We expect to incur additional losses for the foreseeable future, and our losses could increase as our research and development efforts progress. We expect that such losses will fluctuate from quarter to quarter and losses and fluctuations may be substantial.

To become profitable, we, or our collaborative partners, must successfully manufacture and develop product candidates, receive regulatory approval, and successfully commercialize and/or enter into profitable agreements with other parties. It could be several years, if ever, before we receive significant revenue from any current or future license agreements or revenues directly from product sales.

Because of the numerous risks and uncertainties associated with developing our product candidates and their potential for commercialization, we are unable to predict the extent of any future losses. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and sustain profitability, the market value of our common stock will likely decline.

Our success depends upon our ability to advance our products through the various stages of development, especially through the clinical trial process.

To receive the regulatory approvals necessary for the sale of our product candidates, we or our partners must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective. The

development process and related regulatory process are complex and uncertain. Because of the cost and duration of clinical trials, we may decide to discontinue development of product candidates that are unlikely to show good results in the clinical trials, unlikely to help advance a product to the point of a meaningful collaboration, or unlikely to have reasonable commercial potential. We may suffer significant setbacks in pivotal pre-clinical studies and clinical trials (e.g. BCX4430, BCX7353, other kallikrein inhibitors and our other rare disease product candidates), even after earlier clinical trials show promising results. The development of our product candidates, including our clinical trials, may not be adequately designed or executed, which could affect the potential outcome and analysis of study results. Any of our product candidates may produce undesirable side effects in humans. The pre-clinical and clinical data from our product candidates could cause us or regulatory authorities to interrupt, delay, modify or halt preclinical or clinical trials of a product candidate. Undesirable or inconclusive data or side effects in humans could also result in the FDA or foreign regulatory authorities refusing to approve the product candidate for any targeted indications. In addition, the FDA or other regulatory agencies may determine that study data from our product candidates necessitates additional studies or study designs which differ from our planned development strategy, and regulatory agencies may also require patient monitoring and testing or may implement restrictions or other conditions on our development activities, any of which could materially impact the cost and timing of our planned development strategy. We, our partners, the FDA or foreign regulatory authorities may suspend or terminate clinical trials at any time if we or they believe the trial participants face unacceptable health risks. Clinical trials may fail to demonstrate that our product candidates are safe or effective and have acceptable commercial viability. Regulatory authorities may interrupt, delay or halt clinical trials for a product candidate for any number of reasons.

Our ability to successfully complete clinical trials is dependent upon many factors, including but not limited to:

- our ability to find suitable clinical sites and investigators to enroll patients;
- the ability to maintain contact with patients to provide complete data after treatment;
- our product candidates may not prove to be either safe or effective;
- clinical protocols or study procedures may not be adequately designed or followed by the investigators;
- formulation improvements may not work as expected, which could negatively impact commercial demand for our product candidates;
- manufacturing or quality control problems could affect the supply of product candidates for our trials; and
- delays or changes in our planned development strategy, the regulations or guidelines, or other unexpected conditions or requirements by governmental agencies.

Clinical trials are lengthy and expensive. We or our partners incur substantial expense for, and devote significant time to, preclinical testing and clinical trials, yet we cannot be certain that the tests and trials will ever result in the commercial sale of a product. For example, clinical trials require adequate supplies of drug and sufficient patient enrollment. Lack of adequate drug supply or delays in patient enrollment can result in increased costs and longer development times. Even if we or our partners successfully complete clinical trials for our product candidates, we or our partners might not file the required regulatory submissions in a timely manner and may not receive regulatory approval for the product candidates.

We focus on rare diseases, which may create additional risks and challenges.

Because we focus on developing drugs as treatments for rare diseases, we may seek orphan drug, breakthrough therapy or fast track designations for our product candidates in the United States or the equivalent designations elsewhere in the world. Often, regulatory agencies have broad discretion in determining whether or not to grant such designations. We cannot guarantee that we will be able to receive orphan drug status from the FDA or equivalent regulatory designations elsewhere. We also cannot guarantee that we will obtain breakthrough therapy or fast track designation, which may provide certain potential benefits such as more frequent meetings with the FDA to discuss the development plan, intensive guidance on an efficient drug development program, and potential eligibility for rolling review or priority review. Even if we are successful in obtaining any such designation by the FDA or other regulatory agency for our product candidates, such designations may not lead to faster development or regulatory review or approval, and it does not increase the likelihood that our product candidates will receive marketing approval. We may not be able to obtain or maintain such designations for our product candidates, and our competitors may obtain these designations for their product candidates, which could impact our ability to develop and commercialize our product candidates or compete with such competitors, which may adversely impact our business, financial condition or results of operations.

Although we have received Sakigake designation for BCX7353 in Japan, we may not experience a faster development, review or approval process compared to the conventional process.

Our clinical trials may not adequately show that our product candidates are safe or effective.

Progression of our product candidates through the clinical development process is dependent upon our trials indicating our product candidates have adequate safety and efficacy in the patients being treated by achieving pre-determined safety and efficacy endpoints according to the clinical trial protocols. Failure to achieve any of these endpoints in any of our programs, including BCX7353, and our other rare disease product candidates, could result in delays in our trials or require the performance of additional unplanned trials. This could result in delays in the development of our product candidates and could result in significant unexpected costs or the termination of programs.

If our development collaborations with third parties, such as our development partners and contract research organizations, fail, the development of our product candidates will be delayed or stopped.

We rely heavily upon third parties for many important stages of our product candidate development, including but not limited to:

- discovery of compounds that cause or enable biological reactions necessary for the progression of the disease or disorder, called enzyme targets;
- licensing or designing of enzyme inhibitors for development as product candidates;
- execution of certain preclinical studies and late-stage development for our compounds and product candidates;
- management of our clinical trials, including medical monitoring and data management;
- execution of additional toxicology studies that may be required to obtain approval for our product candidates;
- formulation improvement strategies and methods; and
- manufacturing the starting materials and drug substance required to formulate our products and the product candidates to be used in our clinical trials, toxicology studies and any potential commercial product.

Our failure to engage in successful collaborations at any one of these stages would greatly impact our business. If we do not license enzyme targets or inhibitors from academic institutions or from other biotechnology companies on acceptable terms, our drug development efforts would suffer. Similarly, if the contract research organizations that conduct our initial or late-stage clinical trials, conduct our toxicology studies, manufacture our starting materials, drug substance and product candidates or manage our regulatory function breached their obligations to us or perform their services inconsistent with industry standards and not in accordance with the required regulations, this would delay or prevent both the development of our product candidates and the availability of any potential commercial product.

If we lose our relationship with any one or more of these parties, we could experience a significant delay in both identifying another comparable provider and then contracting for its services. We may be unable to retain an alternative provider on reasonable terms, if at all. Even if we locate an alternative provider, it is likely that this provider may need additional time to respond to our needs and may not provide the same type or level of service as the original provider. In addition, any provider that we retain will be subject to applicable FDA current Good Laboratory Practices ("cGLP"), current Good Manufacturing Practices ("cGMP") and current Good Clinical Practices ("cGCP"), and comparable foreign standards. We do not have control over compliance with these regulations by these providers. Consequently, if these practices and standards are not adhered to by these providers, the development and commercialization of our product candidates could be delayed. If any of the foregoing risks are realized, our business, financial condition and results of operations could be materially adversely affected.

Because we have limited manufacturing experience, we depend on third-party manufacturers to manufacture our product, product candidates and the materials for our product candidates. Often, especially early in the development and commercialization process, we have only one source for manufacturing. If we cannot rely on existing third-party manufacturers, we will be required to incur significant costs and potential delays in finding new third-party manufacturers.

We have limited manufacturing experience and only a small scale manufacturing facility. We currently rely upon a very limited number of third-party manufacturers to manufacture the materials required for our product, product candidates and most of the preclinical and clinical quantities of our product candidates. We depend on these third-party manufacturers to perform their obligations in a timely manner and in accordance with applicable governmental regulations. Our third-party manufacturers, which may be the only manufacturer we have engaged for a particular product, may encounter difficulties with meeting our requirements including but not limited to problems involving:

- inconsistent production yields;
- product liability claims or recalls of commercial product;
- difficulties in scaling production to commercial and validation sizes;
- interruption of the delivery of materials required for the manufacturing process;
- scheduling of plant time with other vendors or unexpected equipment failure;

- potential catastrophes that could strike their facilities or have an effect on infrastructure;
- potential impurities in our drug substance or products that could affect availability of product for our clinical trials or future commercialization;
- poor quality control and assurance or inadequate process controls; and
- lack of compliance or cooperation with regulations and specifications or requests set forth by the FDA or other foreign regulatory agencies, particularly associated with RAPIVAB and planned studies for BCX7353, BCX4430 and our early stage compounds.

These contract manufacturers may not be able to manufacture the materials required for our product candidates at a cost or in quantities necessary to make them commercially viable. We also have no control over whether third-party manufacturers breach their agreements with us or whether they may terminate or decline to renew agreements with us. To date, our third-party manufacturers have met our manufacturing requirements, but they may not continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug is manufactured or a change of a third-party manufacturer, may require prior review and approval in accordance with the FDA's cGMP and comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a product. The FDA or similar foreign regulatory agencies may at any time implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties any of which could be costly to the Company and could result in a delay or shortage of product.

If we are unable to maintain current manufacturing or other contract relationships, or enter into new agreements with additional manufacturers on commercially reasonable terms, or if there is poor manufacturing performance or failure to comply with any regulatory agency on the part of any of our third-party manufacturers, we may not be able to complete development of, seek timely approval of, or market, our product candidates.

Our raw materials, drug substances, and product candidates are manufactured by a limited group of suppliers, including some at a single facility. If any of these suppliers were unable to produce these items, this could significantly impact our supply of product candidate material for further preclinical testing and clinical trials.

We face intense competition, and if we are unable to compete effectively, the demand for our products, if any, may be reduced.

The biotechnology and pharmaceutical industries are highly competitive and subject to rapid and substantial technological change. There are many companies seeking to develop products for the same indications that we currently target. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies and specialized biotechnology firms. Most of these competitors have greater resources than we do, including greater financial resources, larger research and development staffs and more experienced marketing and manufacturing organizations. In addition, most of our competitors have greater experience than we do in conducting clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals of product candidates more rapidly than we do. Companies that complete clinical trials, obtain required regulatory approvals, and commence commercial sale of their drugs before we do may achieve a significant competitive advantage, including patent and FDA exclusivity rights that would delay our ability to market products. We face, and will continue to face, competition in the licensing of potential product candidates for desirable disease targets licensing of desirable product candidates, and development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Competition may also arise from, among other things:

- other drug development technologies;
- methods of preventing or reducing the incidence of disease, including vaccines; and
- new small molecule or other classes of therapeutic agents.

Developments by others may render our product candidates or technologies obsolete or noncompetitive.

We and our partners are performing research on or developing products for the treatment of several disorders including HAE and recurrent/refractory peripheral T-cell lymphoma, as well as broad spectrum antivirals that may be developed as medical countermeasures. We expect to encounter significant competition for any of the pharmaceutical products we plan to develop. Companies that complete clinical trials, obtain required funding or government support,

obtain required regulatory approvals and commence commercial sales or stockpiling orders of their products before their competitors may achieve a significant competitive advantage. Such is the case with Eisai Co. Ltd.'s TARGRETIN ® for cutaneous T-lymphoma; the current neuraminidase inhibitors marketed by GSK and Roche for influenza; CINRYZE ® , KALBITOR ® and FIRAZYR ® , marketed by Shire Pharmaceuticals, Inc. for HAE; and BERINERT ® , marketed by CSL for HAE. Therapeutic products with potentially promising data to treat Ebola include Mapp Biopharmaceutical, Inc.'s ZMapp (antibody-based) and Gilead Sciences, Inc.'s product currently under development (small molecule), both of which have been used in Ebola infected patients. Further, several pharmaceutical and biotechnology firms, including major pharmaceutical companies and specialized structure-based drug design companies, have announced efforts in the field of structure-based drug design and molecules in development in the fields of HAE and in other therapeutic areas where we have discovery and development efforts ongoing. If one or more of our competitors' products or programs are successful, the market for our products may be reduced or eliminated.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical testing experience;
- manufacturing and marketing experience; and
- production facilities.

Any of these competitive factors could impede our funding efforts, render technology and product candidates noncompetitive or eliminate or reduce demand for our product candidates.

We face risks related to our government-funded programs; if BARDA/HHS or NIAID/HHS were to eliminate, reduce or delay funding from our contracts, this would have a significant negative impact on the programs associated with such funding and could have a significant negative impact on our revenues and cash flows.

Our projections of revenues and incoming cash flows are substantially dependent upon BARDA/HHS and NIAID/HHS reimbursement for the costs related to our BCX4430 program. If BARDA/HHS or NIAID/HHS were to eliminate, reduce or delay the funding for these programs or disallow some of our incurred costs, we would have to obtain additional funding for continued development or regulatory registration for these product candidates or significantly reduce or stop the development effort.

In contracting with BARDA/HHS and NIAID/HHS, we are subject to various U.S. Government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement or if we are found to be in violation could result in contract termination. If the U.S. Government terminates any of its contracts with us for its convenience, or if we default by failing to perform in accordance with the contract schedule and terms, significant negative impact on our cash flows and operations could result.

Our government contracts with BARDA/HHS and NIAID/HHS have special contracting requirements, which create additional risks of reduction or loss of funding.

We have completed work under a contract with BARDA/HHS for the development of our neuraminidase inhibitor, RAPIVAB. We also have entered into contracts with BARDA/HHS and NIAID/HHS for the development of BCX4430 as a treatment for diseases caused by RNA pathogens, including Marburg virus disease and Ebola virus disease. In contracting with these government agencies, we are subject to various U.S. Government contract requirements, including general clauses for a cost-reimbursement research and development contract, which may limit our reimbursement or, if we are found to be in violation, could result in contract termination.

U.S. Government contracts typically contain a number of extraordinary provisions that would not typically be found in commercial contracts and which may create a disadvantage and additional risks to us as compared to competitors that do not rely on U.S. Government contracts. These risks include the ability of the U.S. Government to unilaterally:

- terminate or reduce the scope of our contract with or without cause;
- interpret relevant regulations (federal acquisition regulation clauses);

- require performance under circumstances which may not be favorable to us;
- require an in process review where the U.S. Government will review the project and its options under the contract;
- control the timing and amount funding, which impacts the development progress of our programs; and
- audit and object to our contract-related costs and fees, including allocated indirect costs.

Our government contracts with BARDA/HHS and NIAID/HHS have termination and audit provisions which create additional risks to us.

The U.S. Government may terminate its contracts with us either for its convenience or if we default by failing to perform in accordance with the contract schedule and terms. Termination for convenience provisions generally enable us to recover only our costs incurred or committed, and settlement expenses and profit on the work completed prior to termination. Termination does not permit these recoveries under default provisions. In the event of termination or upon expiration of a contract, the U.S. Government may dispute wind-down and termination costs and may question prior expenses under the contract and deny payment of those expenses. Should we choose to challenge the U.S. Government for denying certain payments under a contract, such a challenge could subject us to substantial additional expenses which we may or may not recover. Further, if the U.S. Government terminates its contracts with us for its convenience, or if we default by failing to perform in accordance with the contract schedule and terms, significant negative impact on our cash flows and operations could result.

As a U.S. Government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. Government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Audits conducted by the U.S. Government for the completed BARDA/HHS contract have been performed and concluded through fiscal 2009; all subsequent fiscal years are still open and auditable. Audits under the active BARDA/HHS and NIAID/HHS contracts may occur at the election of the U.S. Government and have been concluded through fiscal 2013. Based on the results of its audits, the U.S. Government may adjust our contract-related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenues reported on a historic basis and could impact our cash flows under the contracts prospectively. In addition, in the event BARDA/HHS or NIAID/HHS determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, BARDA/HHS or NIAID/HHS would be entitled to recoup any overpayment from us as a result. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our contracts, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. Government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us. In addition, under U.S. Government purchasing regulations, some of our costs may not be reimbursable or allowed under our contracts. Further, as a U.S. Government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies.

If we fail to reach milestones or to make annual minimum payments or otherwise breach our obligations under our license agreements, our licensors may terminate our agreements with them and seek additional remedies.

If we are unable or fail to meet payment obligations, performance milestones relating to the timing of regulatory filings, product supply obligations, post approval commitments for RAPIVAB, or development and commercial diligence obligations; are unable or fail to make milestone payments or material data use payments in accordance with applicable provisions; or fail to pay the minimum annual payments under our respective licenses, our licensors may terminate the applicable license or seek other available remedies. As a result, our development of the respective product candidate or commercialization of the product would cease.

If we fail to obtain additional financing or acceptable partnership arrangements, we may be unable to complete the development and commercialization of our product candidates or continue operations.

As our programs advance, our costs are likely to increase. Our current and planned discovery activities, pre-clinical and clinical trials, the related development, manufacturing, regulatory approval process requirements, and the additional personnel resources and testing required for supporting the development of our product candidates will consume significant capital resources. Our expenses, revenues and cash utilization rate could vary significantly depending on many factors, including: our ability to raise additional capital; the development progress of our collaborative agreements for our product candidates; the amount of funding we receive from NIAID/HHS and BARDA/HHS for BCX4430 or from other new partnerships with third parties for the development of our product candidates, including BCX7353 and our other rare disease product candidates; the commercial success of peramivir

achieved by our partners; the amount or profitability of any orders for RAPIVAB or BCX4430 by any government agency or other party; the progress and results of our current and proposed clinical trials for our most advanced product candidates, including BCX7353 and our other rare disease product candidates; the progress made in the manufacture of our lead products and the progression of our other programs.

We expect that we will be required to raise additional capital to complete the development and commercialization of our current product candidates and we may seek to raise capital at any time. Additional funding, whether through additional sales of securities or collaborative arrangements with partners, including governmental agencies in general and from any BARDA/HHS or NIAID/HHS contract specifically, may not be available when needed or on terms acceptable to us. The issuance of preferred or common stock or convertible securities, with terms and prices significantly more favorable than those of the currently outstanding common stock, could have the effect of diluting or adversely affecting the holdings or rights of our existing stockholders. In addition, collaborative arrangements may require us to transfer certain material rights to such corporate partners. Insufficient funds or lack of an acceptable partnership may require us to delay, scale-back or eliminate certain of our research and development programs.

In order to continue future operations and continue our drug development programs, we will be required to raise additional capital. In addition to seeking strategic partnerships, transactions and government funding, we may decide to access the equity or debt markets or seek other sources to meet liquidity needs. Our ability to raise additional capital may be limited and may greatly depend upon the success of ongoing development related to our current drug development programs, including post approval studies for RAPIVAB, the progress, timeline and ultimate outcome of our kallikrein inhibitor, including the BCX7353 program (including, but not limited to, formulation progress, phase 3 trials, long-term human safety studies, and the timing of carcinogenicity or other required studies), the progress our other rare disease product candidates, funding for and continued successful development of BCX4430, and the progress of our early discovery programs. In addition, constriction and volatility in the equity and debt markets may restrict our future flexibility to raise capital when such needs arise. Furthermore, we have exposure to many different industries, financing partners and counterparties, including commercial banks, investment banks and partners (which include investors, licensing partners, and the U.S. Government) which may be unstable or may become unstable in the current economic and political environment. Any such instability may impact these parties’ ability to fulfill contractual obligations to us or they might limit or place burdensome conditions upon future transactions with us. Also, it is possible that suppliers may be negatively impacted. Any such unfavorable outcomes in our current programs or unfavorable economic conditions could place severe downward pressure on the price of our common stock and may decrease opportunities to raise capital in the capital or credit markets, and further could reduce the return available on invested corporate cash, which, if severe and sustained, could have a material and adverse impact on our results of operations and cash flows and limit our ability to continue development of our product candidates.

If we fail to successfully commercialize or establish collaborative relationships to commercialize certain of our product candidates, or if any partner terminates or fails to perform its obligations under agreements with us, potential revenues from commercialization of our product candidates could be reduced, delayed or eliminated.

Our business strategy is to increase the asset value of our product candidate portfolio. We believe this is best achieved by retaining full product rights or through collaborative arrangements with third parties as appropriate. As needed, potential third-party relationships could include preclinical development, clinical development, regulatory approval, marketing, sales and distribution of our product candidates.

Currently, we have established collaborative relationships with Mundipharma for the development and commercialization of forodesine and with each of Shionogi and Green Cross for the development and commercialization of peramivir, in Japan, Taiwan and South Korea. Most recently we have established a collaborative relationship with Seqirus UK Limited for RAPIVAB in the United States and countries other than Israel, Japan, Korea and Taiwan. The process of establishing and implementing collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, including post approval clinical commitments, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements may expire;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration;
- we do not have day to day control over the activities of our partners and have limited control over their decisions;
- our ability to generate future event payments and royalties from our partners depends upon their abilities to establish the safety and efficacy of our product candidates, obtain regulatory approvals and achieve market acceptance of products developed from our product candidates;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may utilize our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- we or our partners may not devote sufficient capital or resources towards our product candidates; and
- we or our partners may not comply with applicable government regulatory requirements.

If we or our partners fail to fulfill our responsibilities in a timely manner, or at all, our commercialization efforts related to that collaboration could be reduced, delayed or terminated, or it may be necessary for us to assume responsibility for activities that would otherwise have been the responsibility of our partner. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to delay or discontinue further

development of one or more of our product candidates, undertake commercialization activities at our own expense or find alternative sources of funding. Any delay in the development or commercialization of our product candidates would severely affect our business, because if our product candidates do not progress through the development process or reach the market in a timely manner, or at all, we may not receive additional future event payments and may never receive milestone, product sales or royalty payments.

We do not have a great deal of experience in commercializing our products or technologies, and our future revenue generation is uncertain.

We do not have a great deal of experience in commercializing our products or technologies. We currently have limited marketing and commercial capability, no direct or third-party sales force and limited distribution capabilities. We may be unable to establish or sufficiently increase these capabilities for products we currently, or plan to, commercialize. In addition, our revenue from collaborative agreements may be dependent upon the status of our preclinical and clinical programs. If we fail to advance these programs to the point of being able to enter into successful collaborations, we will not receive any potential future event or other collaborative payments.

Our ability to receive revenue from products we commercialize presents several risks, including:

- we or our collaborators may fail to successfully complete clinical trials, or satisfy post-marketing commitments, sufficient to obtain and keep FDA marketing approval;
- many competitors are more experienced and have significantly more resources, and their products could reach the market faster, be more cost effective or have a better efficacy or tolerability profile than our product candidates;
- we may fail to employ a comprehensive and effective intellectual property strategy, which could result in decreased commercial value of our Company and our products;
- we may fail to employ a comprehensive and effective regulatory strategy, which could result in a delay or failure in commercialization of our products;
- our ability to successfully commercialize our products is affected by the competitive landscape, which cannot be fully known at this time;
- reimbursement is constantly changing, which could greatly affect usage of our products; and
- future revenue from product sales would depend on our ability to successfully complete clinical studies, obtain regulatory approvals, and manufacture, market and commercialize our approved drugs.

Commercialization of RAPIVAB by our partners is subject to the potential commercialization risks described herein and numerous additional risks. Any potential revenue benefits to us in the form of milestone payments, royalties or other consideration are highly speculative.

Commercialization success of RAPIVAB is uncertain and is subject to all the risks and uncertainties disclosed in our other risk factors relating to drug development and commercialization. In addition, commercialization of RAPIVAB is subject to further risks and may be negatively impacted by a number of factors, including, but not limited to, the following:

- RAPIVAB may not prove to be adequately safe and effective for market approval in markets other than the United States;
- necessary funding for post-marketing commitments and further development of RAPIVAB may not be available timely, at all, or in sufficient amounts;
- flu prevention or pandemic treatment concerns may not materialize at all, or in the near future;
- advances in flu vaccines or other antivirals, including competitive i.v. antivirals, could substantially replace potential demand for RAPIVAB;
-

a limited number of governmental entities are expected to be the primary potential stockpiling customers for RAPIVAB and if we are not successful at marketing RAPIVAB to these entities for any reason, we will not receive substantial revenues from stockpiling orders;

- government and third party payors may not provide sufficient coverage or reimbursement which would negatively impact the demand for RAPIVAB;

- we may not be able to supply commercial material to our partners and our partners may not be able to maintain or establish sufficient and acceptable commercial manufacturing, either directly or through third-party manufacturers;

- the commercial demand and acceptance for RAPIVAB by healthcare providers and by patients may not be sufficient to result in substantial revenues of RAPIVAB to our partners and may result in little to no milestones or royalties to us;

- effectiveness of marketing efforts for RAPIVAB by our partners;

- market satisfaction with existing alternative therapies;

- perceived efficacy relative to other available therapies;

- disease prevalence;

- cost of treatment;

- pricing and availability of alternative products;
- marketing and sales activities of competitors;
- shifts in the medical community to new treatment paradigms or standards of care; and
- relative convenience and ease of administration.

We are subject to various federal and state laws related to RAPIVAB and other products under development and, if we or our partners do not comply with these regulations, we could face substantial penalties.

Our or our partners' activities related to RAPIVAB, or any of our other products under development and following their regulatory approval, are subject to regulatory and law enforcement authorities in addition to the FDA, including the Federal Trade Commission, the Department of Justice, and state and local governments. In the case of our collaboration with SUL, although SUL is responsible for RAPIVAB marketing and commercialization efforts, we continue to carry certain risks associated with RAPIVAB because we hold the RAPIVAB NDA. For example, we are responsible for reporting adverse drug experiences, we have responsibility for certain post-approval studies, we may have responsibilities and costs related to a recall or withdrawal of RAPIVAB from sale, we may incur liability associated with RAPIVAB manufacturing contracted by us or in support of any of our partners, we are required to maintain records and provide data and reports to regulatory agencies related to RAPIVAB (e.g. risk evaluation and mitigation strategies, track and trace requirements, adverse events), and we may incur certain promotional regulatory and government pricing risks, all of which could have a material adverse impact on our operations and financial condition. In addition, we are now subject to the federal physician sunshine act and certain similar legislation in various states. We are subject to various federal and state laws pertaining to health care "fraud and abuse," including both federal and state anti-kickback laws. Although we seek to comply with these statutes, it is possible that our practices, or those of our distributors, might be challenged under anti-kickback or similar laws. Violations of the physician sunshine act and similar state legislation or the fraud and abuse laws may be punishable by civil or criminal sanctions, including fines and civil monetary penalties, and future exclusion from participation in government healthcare programs.

We have a number of outstanding post-marketing commitments to the FDA that we retain, despite our partnership with SUL, which we may not complete successfully or on time for any number of reasons, including but not limited to lack of funds to complete the studies and insufficient interest by appropriate sites, investigators or study subjects. For example, as a condition of the approval of RAPIVAB, we are required to complete a pediatric patient study of RAPIVAB and to submit the final results of this clinical trial to the FDA. Depending on the outcome of this clinical trial, we may be unable to expand the indication for RAPIVAB or we may be required to include specific warnings or limitations on dosing this product, which could negatively impact sales of RAPIVAB and negatively impact our relationship with our partner. We may be subject to penalties if we fail to comply with post-approval legal and regulatory requirements and our products could be subject to continual recordkeeping and reporting requirements, review and periodic inspections by the FDA and other regulatory bodies. Regulatory approval of a product may be subject to limitations on the indicated uses for which the product may be marketed or to the other restrictive conditions of approval that limit our ability to promote, sell or distribute a product. Furthermore, the approval of RAPIVAB and any other future product candidates may be subject to requirements for costly post-marketing testing and surveillance to monitor its safety or efficacy.

Advertising and promotion are subject to stringent FDA rules and oversight and as the holder of the NDA we may be held responsible for any advertising and promotion conducted by our partner that is not in compliance with the rules and regulations. In particular, the claims in all promotional materials and activities must be consistent with the FDA approvals for approved products, and must be appropriately substantiated and fairly balanced with information on the safety risks and limitations of the products. Adverse event information concerning approved products must be reviewed and as the NDA holder of RAPIVAB we are required to make expedited and periodic adverse event reports to the FDA and other regulatory authorities.

In addition, the research, manufacturing, distribution, sale and promotion of products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. Until we can successfully transfer the pricing responsibilities to our partner, we remain responsible for pricing and rebate programs. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

If our operations with respect to RAPIVAB or our other products that are subject to healthcare laws and regulations are found to be in violation of any of the healthcare fraud and abuse laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. 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. Moreover, achieving and sustaining compliance with all applicable federal and state fraud and abuse laws may be costly.

We and our partners may be subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance and adversely affect our or our partners' ability to market our products, including RAPIVAB, obtain collaborators and raise capital.

The Patient Protection and Affordable Care Act, or PPACA, made extensive changes to the delivery of health care in the U.S. The PPACA includes numerous provisions that affect pharmaceutical companies, some of which became effective immediately and others of which will be taking effect over the next several years. For example, the PPACA seeks to expand health care coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA will also impose substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit, an annual fee imposed on all manufacturers of brand prescription drugs in the U.S., and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics. The PPACA also contains cost containment measures that could reduce reimbursement levels for health care items and services generally, including pharmaceuticals. It also will require reporting and public disclosure of payments and other transfers of value provided by pharmaceutical companies to physicians and teaching hospitals. We cannot predict what effect the PPACA or other healthcare reform initiatives that may be adopted in the future will have on our business. Further, it remains unclear whether there will be any changes made to provisions of the PPACA or other health care laws through acts of Congress in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our development efforts. In addition, pharmaceutical and device manufacturers will also be required to report and disclose investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties for payments, transfers of value or ownership or investment interests not reported in an annual submission. Compliance with the PPACA and state laws with similar provisions is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. In particular, legislation has been enacted in certain states and proposed at a federal level that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. Compliance with these electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens. In addition, our compliance may be deemed insufficient and we could face a material adverse effect on our business, financial condition, results of operations and growth prospects. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

Managed care organizations are increasingly challenging the prices charged for medical products and services and, in some cases, imposing restrictions on the coverage of particular drugs. Many managed care organizations negotiate the price of medical services and products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization's patient population. The process for obtaining coverage can be lengthy and costly, and we expect that it could take

several months before a particular payor initially reviews our product and makes a decision with respect to coverage. For example, third-party payors may require cost-benefit analysis data from us in order to demonstrate the cost-effectiveness of RAPIVAB or any other product we might bring to market. For any individual third-party payor, we may not be able to provide data sufficient to gain reimbursement on a similar or preferred basis to competitive products, or at all which may have a material adverse effect on our business, financial condition and results of operations.

There are risks related to the potential government use or sale of peramivir (RAPIVAB).

United States Government use or sale of RAPIVAB in emergency situations, or otherwise, may result in the use of RAPIVAB outside of its approved use. To the extent that RAPIVAB is used as a treatment for influenza by the U.S. Government or peramivir by any other government entity, there can be no assurance that it will prove to be generally safe, well-tolerated and effective. Such government use of peramivir may create certain liabilities for us or our partners in the case of government use outside of the U.S. There is no assurance that we or our manufacturers will be able to fully meet the demand for peramivir in the event of additional orders. Further, we may not achieve a favorable price for additional orders of RAPIVAB in the U.S. or peramivir in any other country. Our competitors may develop products that could compete with or replace peramivir. We may face competition in markets where we have no existing intellectual property protection or are unable to successfully enforce our intellectual property rights.

There is no assurance that the non-U.S. partnerships that we have entered into for peramivir will result in any order for peramivir in those countries. There is no assurance that peramivir will be approved for any use or will achieve market approval in additional countries. In the event that any emergency use or market approval is granted, there is no assurance that any government order or commercialization of peramivir in any countries will be substantial or will be profitable to us. In addition, the sale of peramivir, emergency use or other use of peramivir in any country may create certain liabilities for us and our partners.

If we or our partners do not obtain and maintain governmental approvals for our product candidates under development, we or our partners will not be able to sell these potential products, which would significantly harm our business because we will receive no revenue.

We or our partners must obtain regulatory approval before marketing or selling our future product candidates. If we or our partners are unable to receive regulatory approval and do not market or sell our future product candidates, we will never receive any revenue from such product sales. In the United States, we or our partners must obtain FDA approval for product candidates that we intend to commercialize. The process of preparing for and obtaining FDA approval may be lengthy and expensive, and approval is never certain. Products distributed abroad are also subject to foreign government regulation and export laws of the United States. Because of the risks and uncertainties in biopharmaceutical development, our product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. If the FDA delays regulatory approval of our product candidates, our management's credibility, our value and our operating results may suffer. Even if the FDA or foreign regulatory agencies approve a product candidate, the approval may limit the indicated uses for a product candidate and/or may require post-approval studies.

The FDA regulates, among other things, the record keeping and storage of data pertaining to potential pharmaceutical products. We currently store most of our preclinical research data, our clinical data and our manufacturing data at our facility. While we do store duplicate copies of most of our clinical data offsite and a significant portion of our data is included in regular backups of our systems, we could lose important data if our facility incurs damage, or if our vendor data systems fail, suffer damage or are destroyed. If we receive approval to market our potential products, whether in the United States or internationally, we will continue to be subject to extensive regulatory requirements. These requirements are wide ranging and govern, among other things:

- adverse drug experience reporting regulations;
- product promotion;
- product manufacturing, including good manufacturing practice requirements; and
- product changes or modifications.

Our failure to comply with existing or future regulatory requirements, or our loss of, or changes to, previously obtained approvals, could have a material adverse effect on our business because we will not receive product or

royalty revenues if we or our partners do not receive approval of our products for marketing.

Royalties and milestone payments from Shionogi under our license agreement with Shionogi (the "Shionogi Agreement") will be required to be used by Royalty Sub to service its obligations under its PhaRMA Notes, and generally will not be available to us for other purposes until Royalty Sub has repaid in full its obligations under the PhaRMA Notes.

In March 2011, our wholly-owned subsidiary Royalty Sub issued $30.0 million in aggregate principal amount of PhaRMA Notes. The PhaRMA Notes are secured principally by (i) certain royalty and milestone payments under the Shionogi Agreement, pursuant to which Shionogi licensed from us the rights to market peramivir in Japan and, if approved for commercial sale, Taiwan, (ii) rights to certain payments under a Japanese yen/U.S. dollar foreign currency hedge arrangement put into place by us in connection with the issuance of the PhaRMA Notes and (iii) the pledge by us of our equity interest in Royalty Sub. Payments from Shionogi to us under the Shionogi Agreement will generally not be available to us for other purposes until Royalty Sub has repaid in full its obligations under the PhaRMA Notes. Accordingly, these funds will be required to be dedicated to Royalty Sub's debt service and not available to us for product development or other purposes. As of September 1, 2014, the payments from Shionogi were insufficient for Royalty Sub to service its obligations under the PhaRMA Notes, resulting in an event of default with respect to the PhaRMA Notes. As a result of this event of default, the holders of the PhaRMA Notes may be able to pursue acceleration of the PhaRMA Notes and foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub and may exercise other remedies available to them under the indenture or other documents related to the PhaRMA Notes. In such event, we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes, we may incur legal costs and we might otherwise be adversely affected.

Because an event of default has occurred under the PhaRMA Notes, the holders of the PhaRMA Notes may be able to pursue acceleration of the PhaRMA Notes and foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub, in which case we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes and we could otherwise be adversely affected.

Royalty Sub's ability to service its payment obligations in respect of the PhaRMA Notes, and our ability to benefit from our equity interest in Royalty Sub, is subject to numerous risks. Royalty Sub's ability to service the PhaRMA Notes may be adversely affected by, among other things, changes in or any termination of our relationship with Shionogi, reimbursement, regulatory, manufacturing and/or intellectual property issues, product returns, product recalls, product liability claims and allegations of safety issues, as well as other factors. As Royalty Sub has been unable to service its obligations under the PhaRMA Notes and an event of default has occurred under the PhaRMA Notes, the holders of the PhaRMA Notes may be able to pursue acceleration of the PhaRMA Notes and foreclose on the collateral securing the PhaRMA Notes and our equity interest in Royalty Sub and may exercise other remedies available to them under the indenture or other documents related to the PhaRMA Notes. In such event, we may not realize the benefit of future royalty payments that might otherwise accrue to us following repayment of the PhaRMA Notes, we may incur legal costs and we might otherwise be adversely affected.

We may be required to pay significant premiums under the foreign currency hedge arrangement entered into by us in connection with the issuance of the PhaRMA Notes. In addition, because our potential obligations under the foreign currency hedge are marked to market, we may experience additional quarterly volatility in our operating results and cash flows attributable to the foreign currency hedge arrangement.

In connection with the issuance by Royalty Sub of the PhaRMA Notes, we entered into a foreign currency hedge arrangement to hedge certain risks associated with changes in the value of the Japanese yen relative to the U.S. dollar. Under the foreign currency hedge agreement, we may be required to pay an annual premium in the amount of $2.0 million in each May continuing through May 2020. Such payment will be required if, in May of the relevant year, the spot rate of exchange for Japanese yen-U.S. dollars (determined in accordance with the foreign currency hedge arrangement) is such that the U.S. dollar is worth 100 yen or less. We will be required to mark-to-market our potential obligations under the currency hedge and post cash collateral, which may cause us to experience additional quarterly volatility in our operating results and cash flows as a result. Additionally, we may be required to pay significant premiums or a termination fee under the foreign currency hedge agreement entered into by us in connection with the issuance of the PhaRMA Notes. We are required to maintain a foreign currency hedge at 100 yen per dollar under the agreements governing the PhaRMA Notes.

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of those rights would diminish.

Our success will depend in part on our ability and the abilities of our partners to obtain, protect and enforce viable intellectual property rights including but not limited to trade name, trademark and patent protection for our Company and its products, methods, processes and other technologies we may license or develop, to preserve our trade secrets,

and to operate without infringing the proprietary rights of third parties both domestically and abroad. The patent position of biotechnology and pharmaceutical companies is generally highly uncertain, involves complex legal and factual questions and has recently been the subject of much litigation. Neither the United States Patent and Trademark Office ("USPTO"), the Patent Cooperation Treaty offices, nor the courts of the United States and other jurisdictions have consistent policies nor predictable rulings regarding the breadth of claims allowed or the degree of protection afforded under many biotechnology and pharmaceutical patents. Further, we may not have worldwide patent protection for all of our product candidates and our intellectual property rights may not be legally protected or enforceable in all countries throughout the world. In some jurisdictions, some of our product candidates in certain programs, including our HAE program, may have short or no composition of matter patent life and we may therefore rely on orphan drug exclusivity or data exclusivity. There can be no assurance that we will obtain orphan drug exclusivity or data exclusivity in every jurisdiction. Further, in some jurisdictions, we may rely on formulation patents or method of use patents. Both the ability to achieve issuance and the enforcement of formulation and method of use patents can be highly uncertain and can vary from jurisdiction to jurisdiction, and such patents may therefore not adequately prevent competitors and potential infringers in some jurisdictions. The validity, scope, enforceability and commercial value of the rights protected by such patents, therefore, is highly uncertain.

We also rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborators and advisors, our ability to receive patent protection or protect our proprietary information may be imperiled.

We may be involved in lawsuits to protect or enforce our patents, the patents of our partners or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming and unsuccessful. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk. Our success depends in part on avoiding the infringement of other parties' patents and other intellectual property rights as well as avoiding the breach of any licenses relating to our technologies and products. In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not published until the patent issues. As a result, avoiding patent infringement may be difficult and we may inadvertently infringe third-party patents or proprietary rights. These third parties could bring claims against us, our partners or our licensors that even if resolved in our favor, could cause us to incur substantial expenses and, if resolved against us, could additionally cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, our partners or our licensors, we or they could be forced to stop or delay research, development, manufacturing or sales of any infringing product in the country or countries covered by the patent we infringe, unless we can obtain a license from the patent holder. Such a license may not be available on acceptable terms, or at all, particularly if the third party is developing or marketing a product competitive with the infringing product. Even if we, our partners or our licensors were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property.

If we or our partners are unable or fail to adequately initiate, protect, defend or enforce our intellectual property rights in any area of commercial interest or in any part of the world where we wish to seek regulatory approval for our products, methods, processes and other technologies, the value of the product candidates to produce revenue would diminish. Additionally, if our products, methods, processes, and other technologies or our commercial use of such products, processes, and other technologies, including but not limited to any trade name, trademark or commercial strategy infringe the proprietary rights of other parties, we could incur substantial costs. The USPTO and the patent offices of other jurisdictions have issued to us a number of patents for our various inventions and we have in-licensed several patents from various institutions. We have filed additional patent applications and provisional patent applications with the USPTO. We have filed a number of corresponding foreign patent applications and intend to file additional foreign and U.S. patent applications, as appropriate. We have also filed certain trademark and trade name applications worldwide. We cannot assure you as to:

- the degree and range of protection any patents will afford against competitors with similar products;
- if and when patents will issue;
- if patents do issue we cannot be sure that we will be able to adequately defend such patents and whether or not we will be able to adequately enforce such patents; or
- whether or not others will obtain patents claiming aspects similar to those covered by our patent applications.

If the USPTO or other foreign patent office upholds patents issued to others or if the USPTO grants patent applications filed by others, we may have to:

- obtain licenses or redesign our products or processes to avoid infringement;

- stop using the subject matter claimed in those patents; or

- pay damages.

We may initiate, or others may bring against us, litigation or administrative proceedings related to intellectual property rights, including proceedings before the USPTO or other foreign patent office. Any judgment adverse to us in any litigation or other proceeding arising in connection with a patent or patent application could materially and adversely affect our business, financial condition and results of operations. In addition, the costs of any such proceeding may be substantial whether or not we are successful.

Our success is also dependent upon the skills, knowledge and experience, none of which is patentable, of our scientific and technical personnel. To help protect our rights, we require all employees, consultants, advisors and partners to enter into confidentiality agreements that prohibit the disclosure of confidential information to anyone outside of our company and require disclosure and assignment to us of their ideas, developments, discoveries and inventions. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information, and if any of our proprietary information is disclosed, our business will suffer because our revenues depend upon our ability to license or commercialize our product candidates and any such events would significantly impair the value of such product candidates.

We face an inherent risk of liability in the event that the use or misuse of our products results in personal injury or death and our product liability insurance coverage may be insufficient.

If the use or misuse of peramivir or any other regulatory body-approved products we or a partner may sell in the future harms people, we may be subject to costly and damaging product liability claims brought against us by consumers, healthcare providers, pharmaceutical companies, third-party payors or others. The use of our product candidates in clinical trials, including post marketing clinical studies, could also expose us to product liability claims. We cannot predict all of the possible harms or side effects that may result from the use of our products or the testing of product candidates and, therefore, the amount of insurance coverage we currently may not be adequate to cover all liabilities or defense costs we might incur. A product liability claim or series of claims brought against us could give rise to a substantial liability that could exceed our resources. Even if claims are not successful, the costs of defending such claims and potential adverse publicity could be harmful to our business.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face even greater risks upon any commercialization by us of our product candidates. We have product liability insurance covering our commercial sale of RAPIVAB and our clinical trials. Clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance or increase our existing coverage at a reasonable cost to protect us against losses that could have a material adverse effect on our business. An individual may bring a product liability claim against us if one of our products or product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any product liability claim brought against us, with or without merit, could result in:

- liabilities that substantially exceed our product liability insurance, which we would then be required to pay from other sources, if available;
- an increase of our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, or at all;
- withdrawal of clinical trial volunteers or patients;
- damage to our reputation and the reputation of our products, resulting in lower sales;
- regulatory investigations that could require costly recalls or product modifications;
- litigation costs; and
- the diversion of management's attention from managing our business.

Insurance coverage is increasingly more costly and difficult to obtain or maintain.

While we currently have insurance for our business, property, directors and officers, and our products insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to claims or suffer a loss or damage in excess of our insurance coverage, we will be required to bear any loss in excess of our insurance limits. If we are subject to claims or suffer a loss or damage that is outside of our insurance coverage, we may incur significant uninsured costs associated with loss or damage that could have an adverse effect on our operations and financial position. Furthermore, any claims made on our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all.

If our facility incurs damage or power is lost for a significant length of time, or if we incur significant cost overruns or delays in the construction of our new research facility in Birmingham, Alabama, our business will suffer.

We store clinical and stability samples at our facility that could be damaged if our facility incurs physical damage or in the event of an extended power failure. We have backup power systems in addition to backup generators to

maintain power to all critical functions, but any loss of these samples could result in significant delays in our drug development process.

In addition, we store most of our preclinical and clinical data at our facilities. Duplicate copies of most critical data are secured off-site. Any significant degradation or failure of our computer systems could cause us to inaccurately calculate or lose our data. Loss of data could result in significant delays in our drug development process and any system failure could harm our business and operations.

We also face the risk that the costs and time required in connection with the construction of our new research facility in Birmingham, Alabama could exceed our current expectations. If there is a significant cost overrun or significant delay in the completion of the construction, our business, financial condition, and results of operations could be adversely affected.

A significant disruption in our information technology systems or a cyber-security breach could adversely affect our business.

We are increasingly dependent on information technology systems to operate our business. Like other companies in our industry, our networks and infrastructure may be vulnerable to cyber-attacks or intrusions, including by computer hackers, foreign governments, foreign companies or competitors, or may be breached by employee error, malfeasance or other disruption. A breakdown, invasion, corruption, destruction or interruption of critical information technology systems could negatively impact operations. If our systems are damaged, fail to function properly or otherwise become unavailable, we may incur substantial costs to repair or replace them, and we may experience loss of critical data and interruptions or delays in our ability to perform critical functions, which could adversely affect our business, financial condition or results of operations. Any compromise of our data security could also result in a violation of applicable privacy and other laws, significant legal and financial exposure, damage to our reputation, loss or misuse of the information and a loss of confidence in our data security measures, which could harm our business. There can be no assurance that our efforts to protect our data and information technology systems will prevent breakdowns or breaches in our systems, or those of third parties with which we do business, and any such events could adversely affect our business.

If we fail to retain our existing key personnel or fail to attract and retain additional key personnel, the development of our product candidates and commercialization of our products and the related expansion of our business will be delayed or stopped.

We are highly dependent upon our senior management and scientific team, the unexpected loss of whose services might impede the achievement of our development and commercial objectives. Competition for key personnel with the experience that we require is intense and is expected to continue to increase. Our inability to attract and retain the required number of skilled and experienced management, commercial, operational and scientific personnel will harm our business because we rely upon these personnel for many critical functions of our business.

If because of our use of hazardous materials, we violate any environmental controls or regulations that apply to such materials, we may incur substantial costs and expenses in our remediation efforts.

Our research and development involves the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and some waste products. Accidental contamination or injury from these materials could occur. In the event of an accident, we could be liable for any damages that result and any liabilities could exceed our resources. Compliance with environmental laws and regulations or a violation of such environmental laws and regulations could require us to incur substantial unexpected costs, which would materially and adversely affect our results of operations.

Risks relating to investing in our common stock

Our existing principal stockholders hold a substantial amount of our common stock and may be able to influence significant corporate decisions, which may conflict with the interest of other stockholders.

Several of our stockholders own greater than 5% of our outstanding common stock. Our top ten stockholders own more than 50% of BioCryst and can individually, and as a group, influence our operations based upon their concentrated ownership. These stockholders, if they act together, may be able to influence the outcome of matters requiring approval of the stockholders, including the election of our directors and other corporate actions.

Our stock price has been, and is likely to continue to be, highly volatile, which could cause the value of an investment in our common stock to decline significantly.

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. Moreover, our stock price has fluctuated frequently, and these fluctuations are often not related to our financial results. For the twelve months ended June 30, 2016, the 52-week range of the market price of our stock was from $1.63 to $16.83 per share. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights;
- additional dilution through sales of our common stock or other derivative securities;
- status of new or existing licensing or collaborative agreements and government contracts;
- announcements relating to the status of our programs;
- developments and announcements regarding new and virulent strains of influenza;
- we or our partners achieving or failing to achieve development milestones;
- publicity regarding actual or potential medical results relating to products under development by us or our competitors;
- publicity regarding certain public health concerns for which we are or may be developing treatments;

- regulatory developments in both the United States and foreign countries;
- public concern as to the safety of pharmaceutical products;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- changes in the structure of healthcare payment systems, including developments in price control legislation;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel or members of our board of directors;
- purchases or sales of substantial amounts of our stock by existing stockholders, including officers or directors;
- economic and other external factors or other disasters or crises; and
- period-to-period fluctuations in our financial results.

Future sales and issuances of securities may dilute the ownership interests of our current stockholders and cause our stock price to decline.

Future sales of our common stock by current stockholders into the public market could cause the market price of our stock to fall. As of July 31, 2016, there were 73,700,542 shares of our common stock outstanding. We may from time to time issue securities in relation to a license arrangement, collaboration, merger or acquisition. We may also sell, for our own account, shares of common stock or other equity securities, from time to time at prices and on terms to be determined at the time of sale.

As of July 31, 2016, there were 12,771,523 stock options and restricted stock units outstanding, 2,071,866 shares available for issuance under our Amended and Restated Stock Incentive Plan, and 463,227 shares available for issuance under our Employee Stock Purchase Plan. In addition, we could also make equity compensation grants outside of our Stock Incentive Plan. The shares underlying existing stock options, restricted stock units and possible future stock options, stock appreciation rights and stock awards have been registered pursuant to registration statements on Form S-8.

If some or all of such shares are sold or otherwise issued into the public market over a short period of time, our current stockholders' ownership interests may be diluted and the value of all publicly traded shares is likely to decline, as the market may not be able to absorb those shares at then-current market prices. Additionally, such sales and issuances may make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable, or at all.

We have anti-takeover provisions in our corporate charter documents that may result in outcomes with which you do not agree.

Our board of directors has the authority to issue up to 4,800,000 shares of undesignated preferred stock and to determine the rights, preferences, privileges and restrictions of those shares without further vote or action by our stockholders. The rights of the holders of any preferred stock that may be issued in the future may adversely affect the rights of the holders of common stock. The issuance of preferred stock could make it more difficult for third parties to acquire a majority of our outstanding voting stock.

In addition, our certificate of incorporation provides for staggered terms for the members of the board of directors and supermajority approval of the removal of any member of the board of directors and prevents our stockholders from acting by written consent. Our certificate also requires supermajority approval of any amendment of these provisions. These provisions and other provisions of our by-laws and of Delaware law applicable to us could delay or make more difficult a merger, tender offer or proxy contest involving us.

We have never paid dividends on our common stock and do not anticipate doing so in the foreseeable future.

We have never paid cash dividends on our stock. We currently intend to retain all future earnings, if any, for use in the operation of our business. Accordingly, we do not anticipate paying cash dividends on our common stock in the foreseeable future.

Item 6. Exhibits

See the Exhibit Index attached to this quarterly report and incorporated herein by reference.

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 on this 8th day of August, 2016.

BIOCRYST PHARMACEUTICALS, INC.

/s/ Jon P. Stonehouse
Jon P. Stonehouse
President and Chief Executive Officer

(Principal Executive Officer)

/s/ Thomas R. Staab, II
Thomas R. Staab, II
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Principal Accounting Officer)

INDEX TO EXHIBITS

Number	Description
3.1	Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed December 22, 2006.
3.2	Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed July 24, 2007.
3.3	Certificate of Increase of Authorized Number of Shares of Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed November 4, 2008.
3.4	Certificate of Amendment to the Third Restated Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed May 8, 2014.
3.5	Certificate of Increase of Authorized Number of Shares of Series B Junior Participating Preferred Stock. Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed May 8, 2014.
3.6	Amended and Restated Bylaws of Registrant effective October 29, 2008. Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed November 4, 2008.
(10.1)†	Amendment #5 to the Agreement between BioCryst Pharmaceuticals, Inc. and the Biomedical Advanced Research and Development Authority within the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, dated April 11, 2016. (Portions omitted pursuant to request for confidential treatment.)
(10.2)†	Amendment #6 to the Agreement between BioCryst Pharmaceuticals, Inc. and the Biomedical Advanced Research and Development Authority within the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, dated May 20, 2016. (Portions omitted pursuant to request for confidential treatment.)
(10.3)†	Amendment #18 to the Agreement between BioCryst Pharmaceuticals, Inc. and the National Institute of Allergy and Infectious Diseases, dated June 30, 2016. (Portions omitted pursuant to request for confidential treatment.)
10.4	Amended and Restated Stock Incentive Plan. Incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8 filed May 23, 2016
(31.1)	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(31.2)	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32.1)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(32.2)	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
(101)	Financial statements from the Quarterly Report on Form 10-Q of BioCryst Pharmaceuticals, Inc. for the three months ended June 30, 2016, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Cash Flows, and (iv) Notes to Consolidated Financial Statements.

( )Filed or furnished herewith.
† Confidential treatment requested.