



BioCryst Reports Second Quarter 2018 Financial Results

August 7, 2018

RESEARCH TRIANGLE PARK, N.C., Aug. 07, 2018 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#) (NASDAQ:BCRX) announced today financial results for the second quarter ended June 30, 2018.

"Building on the clear direction from our shareholders and a strong conviction in the medical community that BCX7353 is a highly differentiated asset which can deliver enormous value to patients and shareholders, we have made substantial progress advancing our prophylactic and acute BCX7353 clinical programs, and significantly strengthened our balance sheet," said Jon P. Stonehouse, BioCryst's President and Chief Executive Officer.

"Enrollment in the ZENITH-1 trial has completed, and we look forward to reporting Part 1 results later this quarter. Enrollment in the APeX-2 and APeX-S trials continues to go extremely well, and we are confident that we will report top-line safety and efficacy in the second quarter of next year. We believe we have the programs, the focused commitment of an experienced team and the financial resources to deliver significant value to patients and shareholders with our existing portfolio and we are excited about the clinical and regulatory milestones ahead of us in the next 12 months," Stonehouse added.

Second Quarter 2018 Financial Results

For the three months ended June 30, 2018, total revenues were \$12.5 million, compared to \$3.1 million in the second quarter of 2017. The increase in revenue was primarily associated with the recognition of \$7.0 million of deferred revenue and a \$5.0 million milestone, both associated with the European Medicines Agency's (EMA) approval of peramivir (ALPIVABTM). These revenues were partially offset by lower collaboration revenue under U.S. Government development contracts.

Research and Development (R&D) expenses for the second quarter of 2018 increased to \$21.0 million from \$15.8 million in the second quarter of 2017, primarily due to increased spending on the Company's hereditary angioedema (HAE) and preclinical programs, as well as additions in R&D personnel. These increases were partially offset by decreased activity under U.S. Government development contracts.

General and administrative (G&A) expenses for the second quarter of 2018 increased to \$9.5 million, compared to \$2.8 million in the second quarter of 2017. The increase was primarily due to a \$4.9 million reserve recorded for concern regarding the collectability of the EMA approval milestone, as well as incurred merger-related costs. As previously disclosed, BioCryst and Seqirus are engaged in a formal dispute resolution that involves many items under the contract including, but not limited to, the EMA approval milestone.

Interest expense was \$2.2 million in the second quarter of 2018, compared to \$2.1 million in the second quarter of 2017. Also, a \$619,000 mark-to-market gain on the Company's foreign currency hedge was recognized in the second quarter of 2018, as compared to a \$400,000 mark-to-market loss in the second quarter of 2017. These changes result from periodic changes in the U.S. dollar/Japanese yen exchange rate. During the second quarters of 2018 and 2017, the Company also realized currency gains of \$889,000 and \$921,000, respectively, from the exercise of a U.S. Dollar/Japanese yen currency option within its foreign currency hedge.

Net loss for the second quarter of 2018 was \$18.5 million, or \$0.19 per share, compared to a net loss of \$16.9 million, or \$0.21 per share, for the second quarter 2017.

Cash, cash equivalents and investments totaled \$122.1 million at June 30, 2018, and reflect a decrease from \$159.0 million at December 31, 2017. Net operating cash use for the second quarter 2018 was \$18.4 million, and the first six months of 2018 was \$41.3 million.

Year to Date 2018 Financial Results

For the six months ended June 30, 2018, total revenues were \$16.5 million, compared to \$12.5 million in the first half of 2017. The increase in revenue was primarily associated with the recognition of \$7.0 million of deferred revenue and a \$5.0 million milestone payment, both associated with the EMA approval of peramivir. These revenues were offset by infrequent revenue events that occurred in 2017 that did not recur in 2018. Those 2017 events were the recognition of \$4.1 million of royalty revenue from Japanese government stockpiling of RAPIACTA[®] and a \$2.0 million payment for the Canadian regulatory approval of RAPIVAB[®]. The increase in revenues was partially offset by lower collaboration revenue under U.S. Government development contracts.

R&D expenses increased to \$39.5 million from \$32.5 million in the first half of 2017, primarily due to increased spending on our HAE and preclinical programs. These increases were partially offset by a decrease in the Company's peramivir and galidesivir development spending in 2018.

G&A expenses for the first half of 2018 increased to \$17.1 million, compared to \$5.9 million in the first half of 2017. The increase was primarily due to approximately \$6.4 million of merger-related costs associated with the Company's failed merger with Idera Pharmaceuticals, Inc. (Idera) and a \$4.9 million reserve for collectability of the EMA approval milestone of peramivir.

Interest expense was \$4.4 million in the first half of 2018, compared to \$4.2 million in the first half of 2017. Also, a \$1.2 million mark-to-market loss on the Company's foreign currency hedge was recognized in the first half of 2018, as compared to a \$1.9 million mark-to-market loss in the first half of 2017. These changes result from periodic changes in the U.S. dollar/Japanese yen exchange rate. During 2018 and 2017, the Company also realized currency gains of \$889,000 and \$921,000, respectively, from the exercise of a U.S. Dollar/Japanese yen currency option within its foreign currency hedge.

Net loss for the first half of 2018 was \$44.2 million, or \$0.45 per share, compared to a net loss of \$31.1 million, or \$0.40 per share, for the first half 2017.

Clinical Development Update & Outlook

- On August 6, 2018, BioCryst announced it had received Fast Track Designation by the U.S. Food and Drug Administration (FDA) for BCX7353 for the prevention of angioedema attacks in patients with HAE.
- On August 6, 2018, BioCryst announced the full exercise of the underwriters' option to purchase additional shares and the completion of its public offering resulting in the sale of 10,454,546 shares of its common stock at a price of \$5.50 per share. The net proceeds from this offering are approximately \$53.5 million, after deducting underwriting discounts and commissions and other estimated offering expenses.
- On July 11, 2018, BioCryst announced it had completed enrollment in all three cohorts of its ZENITH-1 clinical trial, a proof-of-concept Phase 2 clinical trial liquid formulation of BCX7353 for treatment of acute HAE attacks.
- On July 25, 2018, BioCryst announced that results from the Phase 2, APeX-1 trial of BCX7353 for the prevention of attacks in patients with HAE were published in the July 26th issue of The New England Journal of Medicine.
- On July 20, 2018, BioCryst entered into a \$30 million secured loan facility with MidCap Financial Trust as administrative agent and lender (MidCap), pursuant to the terms and conditions of that certain Amended and Restated Credit and Security Agreement. The Credit Agreement replaces the Credit and Security Agreement dated as of September 23, 2016.
- On July 10, 2018, BioCryst announced that it had terminated the previously announced merger agreement with Idera following the Company's stockholders' failure to approve the adoption of the merger agreement. Pursuant to the merger agreement, the Company reimbursed Idera \$6 million in July.
- On June 25, 2018, BioCryst announced that the Company had reached agreement on the design of a Phase 3 trial and regulatory requirements for marketing authorization of BCX7353 for HAE with the Pharmaceuticals and Medical Devices Agency in Japan.
- On May 24, 2018, BioCryst announced that the EMA Committee for Orphan Medicinal Products issued a positive opinion on BioCryst's application for orphan designation of BCX7353 for the treatment of HAE. In addition, the United Kingdom's Medicines and Healthcare products Regulatory Agency has granted a Promising Innovative Medicine designation to BCX7353.

Financial Outlook for 2018

Based upon development plans, merger-related incurred costs from the recently terminated merger agreement with Idera and awarded government contracts, BioCryst expects its 2018 net operating cash use to be in the range of \$85 to \$105 million, and its 2018 operating expenses to be in the range of \$90 to \$110 million. The Company's operating expense range excludes equity-based compensation expense due to the difficulty in reliably projecting this expense, as it is impacted by the volatility and price of the Company's stock, as well as by the vesting of the Company's outstanding performance-based stock options.

Conference Call and Webcast

BioCryst's leadership team will host a conference call and webcast Tuesday, August 7, 2018 at 11:00 a.m. Eastern Time to discuss these financial results and recent corporate developments. To participate in the conference call, please dial 1-877-303-8027 (United States) or 1-760-536-5165 (International). No passcode is needed for the call. The webcast can be accessed live or in archived form in the "Investors" section of the Company's website at www.BioCryst.com. An accompanying slide presentation may also be accessed via the BioCryst website. Please connect to the website at least 15 minutes prior to the start of the conference call to ensure adequate time for any software download that may be necessary.

About BCX7353

Discovered by BioCryst, BCX7353 is a novel, oral, once-daily, selective inhibitor of plasma kallikrein currently in development for the prevention and treatment of angioedema attacks in patients diagnosed with HAE. BCX7353 was generally safe and well tolerated in the Phase 2 APeX-1 clinical trial. BioCryst is currently conducting the Phase 3 APeX-2 clinical trial and the long-term safety APeX-S clinical trial, both evaluating two dosage strengths of BCX7353 administered orally once-daily as a preventive treatment to reduce the frequency of attacks in patients with HAE. BioCryst is also conducting the ZENITH-1 clinical trial. ZENITH-1 is a proof-of-concept Phase 2 clinical trial testing an oral liquid formulation of BCX7353 for the treatment of acute angioedema attacks.

About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals designs, optimizes and develops novel small-molecule medicines that address both common and rare conditions. BioCryst has several ongoing development programs including BCX7353, an oral treatment for hereditary angioedema, galidesivir, a potential treatment for filoviruses, and a preclinical program to develop oral ALK-2 inhibitors for the treatment of fibrodysplasia ossificans progressiva. RAPIVAB[®] (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, is BioCryst's first approved product and has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan, Korea and the European Union. Post-marketing commitments for RAPIVAB are ongoing. For more

information, please visit the Company's website at www.BioCryst.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause BioCryst's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that developing any HAE product candidate may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical development of HAE second generation drug candidates (including ZENITH-1, APeX-2, APeX-S and APeX-J) may not have positive results; that BioCryst may not be able to enroll the required number of subjects in planned clinical trials of product candidates; that the Company may not advance human clinical trials with product candidates as expected; that the FDA, EMA or other applicable regulatory agency may require additional studies beyond the studies planned for product candidates, or may not provide regulatory clearances which may result in delay of planned clinical trials, or may impose a clinical hold with respect to such product candidate, or withhold market approval for product candidates. Please refer to the documents BioCryst files periodically with the Securities and Exchange Commission, specifically BioCryst's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, all of which identify important factors that could cause the actual results to differ materially from those contained in BioCryst's projections and forward-looking statements.

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CONTACT: Thomas Staab, BioCryst Pharmaceuticals, +1-919-859-7910

BIOCRYST PHARMACEUTICALS, INC. CONSOLIDATED FINANCIAL SUMMARY

(in thousands, except per share)

Statements of Operations (Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Revenues:				
Royalty revenue	\$ 142	\$ 489	\$ 3,803	\$ 6,810
Collaborative and other research and development	12,352	2,610	12,667	5,726
Total revenues	<u>12,494</u>	<u>3,099</u>	<u>16,470</u>	<u>12,536</u>
Expenses:				
Research and development	21,010	15,759	39,451	32,529
General and administrative	9,492	2,834	17,101	5,892
Royalty	243	22	383	316
Total operating expenses	<u>30,745</u>	<u>18,615</u>	<u>56,935</u>	<u>38,737</u>
Loss from operations	(18,251)	(15,516)	(40,465)	(26,201)
Interest and other income	493	203	955	312
Interest expense	(2,195)	(2,094)	(4,416)	(4,194)
Gain (loss) on foreign currency derivative	1,507	521	(297)	(1,022)
Net loss	<u>\$ (18,446)</u>	<u>\$ (16,886)</u>	<u>\$ (44,223)</u>	<u>\$ (31,105)</u>
Basic and diluted net loss per common share	<u>\$ (0.19)</u>	<u>\$ (0.21)</u>	<u>\$ (0.45)</u>	<u>\$ (0.40)</u>
Weighted average shares outstanding	98,787	80,418	98,690	77,807

Balance Sheet Data (in thousands)

	June 30, 2018 (Unaudited)	December 31, 2017 (Note 1)
Cash, cash equivalents and investments	\$ 114,484	\$ 155,692
Restricted cash	7,625	3,286
Receivables from collaborations	2,342	6,117
Total assets	136,644	178,259
Non-recourse notes payable	28,902	28,682
Senior credit facility	19,999	23,214
Accumulated deficit	(674,940)	(631,843)
Stockholders' equity	46,184	83,767
Shares of common stock outstanding	98,928	98,411

Note 1: Derived from audited financial statements.



Source: BioCryst Pharmaceuticals, Inc.