



August 7, 2017

## BioCryst Reports Second Quarter 2017 Financial Results

RESEARCH TRIANGLE PARK, N.C., Aug. 07, 2017 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](http://www.biocryst.com) (NASDAQ:BCRX) announced today financial results for the second quarter ended June 30, 2017.

"We are excited by the positive results previously reported in Parts 1 and 2 of the APeX-1 clinical trial that indicate we have an active oral drug, and look forward to completing the trial and reporting complete trial results in the third quarter of this year," said Jon P. Stonehouse, President & Chief Executive Officer. "These trial results should give us additional information to determine what doses we propose to regulatory authorities later this year for the Phase 3 program, with the goal of starting a pivotal trial early next year."

### Second Quarter Financial Results

For the three months ended June 30, 2017, revenues decreased to \$3.1 million from \$4.8 million in the second quarter of 2016. The decrease in revenue was primarily due to a decrease in collaboration revenue under U.S. Government development contracts.

Research and Development (R&D) expenses for the second quarter of 2017 increased to \$15.8 million from \$14.2 million in the second quarter of 2016, primarily due to increased spending on the Company's hereditary angioedema (HAE) portfolio.

General and administrative (G&A) expenses for the second quarter of 2017 of \$2.8 million were in line with \$2.7 million of G&A expense in the second quarter of 2016.

Interest expense was \$2.1 million in the second quarter of 2017 as compared to \$1.4 million in the second quarter of 2016, an increase related primarily to the September 2016 closing of a \$23 million senior credit facility. Also, a \$400,000 mark-to-market loss on the Company's foreign currency hedge was recognized in the second quarter of 2017, as compared to a \$3.7 million mark-to-market loss in the second quarter of 2016. These losses result from periodic changes in the U.S. dollar/Japanese yen exchange rate. During the second quarters of 2017 and 2016, we also realized currency gains of \$921,000 and \$811,000, respectively, from the exercise of a U.S. Dollar/Japanese yen currency option within our foreign currency hedge.

The net loss for the second quarter of 2017 was \$16.9 million, or \$0.21 per share, compared to a net loss of \$16.3 million, or \$0.22 per share, for the second quarter 2016.

Cash, cash equivalents and investments totaled \$95.6 million at June 30, 2017, and reflect an increase from \$65.1 million at December 31, 2016. Net operating cash use for the second quarter of 2017 was \$12.2 million, and the first six months of 2017 was \$21.0 million, which excludes the impact of \$47.8 million of net proceeds from our March 2017 public offering.

### Year to Date Financial Results

For the six months ended June 30, 2017, revenues increased to \$12.5 million from \$9.6 million in the first half of 2016. The increase in revenue was primarily due to a \$4.3 million increase in royalty revenue from Shionogi & Co. Ltd., Green Cross Corporation and Seqirus, and a \$2.0 million milestone payment from Seqirus associated with the Canadian regulatory approval of RAPIVAB<sup>®</sup>. The increase in royalty revenue was largely the result of continued Japanese Government stockpiling of RAPIACTA<sup>®</sup>. Future government stockpiling orders are difficult to predict, as they are subject to the relevant appropriation and stockpiling processes. These revenue increases were partially offset by a decrease in collaboration revenue under U.S. Government development contracts.

R&D expenses decreased to \$32.5 million from \$34.7 million in the first half of 2016, primarily due to lower development costs for the HAE portfolio of product candidates and, to a lesser extent, a decrease in galidesivir expenses under U.S. Government development contracts.

G&A expenses for the first half of 2017 of \$5.9 million were in line with \$5.9 million of G&A expense in the first half of 2016.

Interest expense was \$4.2 million in the first half of 2017 as compared to \$2.9 million in the first half of 2016, an increase related primarily to the September 2016 closing of a \$23 million senior credit facility. A \$1.9 million mark-to-market loss on the Company's foreign currency hedge was recognized in the first half of 2017, as compared to a \$6.4 million mark-to-market loss in the first half of 2016. These losses result from periodic changes in the U.S. dollar/Japanese yen exchange rate. During 2017 and 2016, we also realized currency gains of \$921,000 and \$811,000, respectively, from the exercise of a U.S. Dollar/Japanese yen currency option within our foreign currency hedge.

The net loss for the first half of 2017 was \$31.1 million, or \$0.40 per share, compared to a net loss of \$39.1 million, or \$0.53 per share, for the first half 2016.

## Clinical Development Update & Outlook

- On May 25, BioCryst announced positive results from a second interim analysis of its Phase 2 APeX-1 clinical trial in HAE. This second interim analysis of pooled data from Parts 1 and 2 evaluated doses of BCX7353 125 mg (n=7), 250 mg (n=6) and 350 mg (n=18) QD versus placebo (n=20) for 28 days. The pre-specified per-protocol (PP) interim analysis included data on a total of 44 subjects with confirmed Type 1 or Type 2 HAE completing 28 days of treatment. The percentage reductions by treatment group in the mean rate of independently-adjudicated angioedema attacks for the pre-defined effective dosing period (weeks 2 through 4) in BCX7353 treated subjects were: 125 mg QD, 73% (p=0.002); 250 mg QD, 37% (p=0.128) and 350 mg QD, 58% (p=0.001) compared to placebo. In the intent-to-treat (ITT) population, corresponding reductions by treatment group were: 125 mg QD, 73% (p=0.004); 250 mg QD, 44% (p=0.090) and 350 mg QD, 45% (p=0.014) compared to placebo.

Oral BCX7353 once-daily for 28 days was generally safe and well tolerated in subjects with HAE. There were no serious AEs and no severe AEs. Three subjects in the BCX7353 350 mg treatment arm discontinued study drug before day 28. The most common treatment-emergent adverse events were the common cold and diarrhea. The gastrointestinal AEs previously observed in the 350 mg arm were not seen at the 125 mg dose. Additionally, no significant laboratory abnormalities were observed in the two lower dose groups.

- On August 2, BioCryst announced the dosing of the first subject into ZENITH-1, a clinical trial studying up to three dosage strengths of a liquid formulation of BCX7353 given as a single oral dose for the acute treatment of angioedema attacks in patients with HAE.
- On June 5, BioCryst announced that the U.S. Food and Drug Administration (FDA) has accepted for review the supplemental New Drug Application (sNDA) for a pediatric indication of RAPIVAB<sup>®</sup> (peramivir injection), which was submitted in March 2017. The sNDA has been classified by the FDA as a priority review and has a Prescription Drug User Fee Act (PDUFA) goal date for a decision by the end of September 2017.
- After discussions with the FDA, NIAID and BARDA, we have delayed the initiation of the galidesivir IV Phase 1 clinical trial. Based upon ongoing conversations, we expect the next step in galidesivir's development will be to conduct an additional nonclinical efficacy study in a delayed treatment setting in Ebola disease before finalizing the Phase 1 clinical trial protocol design.
- On May 30, BioCryst announced the appointment of Robert A. Ingram as Chairman of its Board of Directors.

## Financial Outlook for 2017

Based upon development plans and our awarded government contracts, BioCryst continues to expect its 2017 net operating cash use to be in the range of \$30 to \$50 million, and its 2017 operating expenses to be in the range of \$53 to \$73 million. Our 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 Monday, August 7, 2017 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 by logging onto [www.BioCryst.com](http://www.BioCryst.com). 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 has been generally safe and well tolerated in the ongoing Phase 2 APeX-1 clinical trial for prophylaxis and in clinical pharmacology studies in healthy volunteers.

## About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in rare diseases. BioCryst has several ongoing development programs: BCX7353 and other second generation oral inhibitors of plasma kallikrein for hereditary angioedema, and galidesivir, a broad spectrum viral RNA polymerase inhibitor that is a potential treatment for filoviruses. RAPIVAB<sup>®</sup> (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, Japan, Taiwan and Korea. Post-marketing commitment development activities for RAPIVAB are ongoing, as well as activities to support regulatory approvals in other territories. For more information, please visit the Company's website at [www.BioCryst.com](http://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 drug 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 APeX-1 and ZENITH-1) 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 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; that BioCryst may not receive additional government funding to further support the development of galidesivir; that galidesivir development may not be successful; that BARDA and/or NIAID may further condition, reduce or eliminate future funding; that revenue from peramivir injection is unpredictable and may never result in significant revenue for the Company; that the Company may not be able to continue development of ongoing and future development programs; that such development programs may never result in future products; that actual financial results may not be consistent with expectations, including that 2017 operating expenses and cash usage may not be within management's expected ranges. 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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**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,	
	2017	2016	2017	2016
Revenues:				
Royalty revenue	\$ 489	\$ 629	\$ 6,810	\$ 2,519
Collaborative and other research and development	2,610	4,158	5,726	7,088
Total revenues	<u>3,099</u>	<u>4,787</u>	<u>12,536</u>	<u>9,607</u>
Expenses:				
Research and development	15,759	14,166	32,529	34,745
General and administrative	2,834	2,724	5,892	5,936
Royalty	22	27	316	104

Total operating expenses	<u>18,615</u>	<u>16,917</u>	<u>38,737</u>	<u>40,785</u>
Loss from operations	(15,516)	(12,130)	(26,201)	(31,178)
Interest and other income	203	147	312	586
Interest expense	(2,094)	(1,421)	(4,194)	(2,891)
Gain (loss) on foreign currency derivative	<u>521</u>	<u>(2,877)</u>	<u>(1,022)</u>	<u>(5,630)</u>
Net loss	\$ <u>(16,886)</u>	\$ <u>(16,281)</u>	\$ <u>(31,105)</u>	\$ <u>(39,113)</u>
Basic and diluted net loss per common share	\$ <u>(0.21)</u>	\$ <u>(0.22)</u>	\$ <u>(0.40)</u>	\$ <u>(0.53)</u>
Weighted average shares outstanding	80,418	73,695	77,807	73,648

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**Balance Sheet Data** (in thousands)

	June 30, 2017 <u>(Unaudited)</u>	December 31, 2016 <u>(Note 1)</u>
Cash, cash equivalents and investments	\$ 90,276	\$ 63,576
Restricted cash	5,357	1,546
Receivables from collaborations	3,325	8,768
Total assets	113,509	89,847
Non-recourse notes payable	28,463	28,243
Senior credit facility	22,996	22,777
Accumulated deficit	(597,166)	(566,061)
Stockholders' equity	24,076	1,578
Shares of common stock outstanding	80,428	73,782

Note 1: Derived from audited financial statements.

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 [Primary Logo](#)

Source: BioCryst Pharmaceuticals

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