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BioCryst Reports Third Quarter 2017 Financial Results

BCX7353 Phase 3 program agreed with FDA and EMA

U.S. Orphan Drug designation for BCX7353 received from FDA

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

"Now that we have completed our end of Phase 2 regulatory interactions with the FDA and EMA and have agreement on the requirements for marketing authorization applications of BCX7353, we are focused on executing the Phase 3 program to support NDA and MAA filings in 2019," said Jon P. Stonehouse, President & Chief Executive Officer. "We expect to start the single required Phase 3 efficacy and the long-term safety trials in first quarter 2018."

Third Quarter Financial Results

For the three months ended September 30, 2017, revenues increased to \$8.8 million from \$7.8 million in the third quarter of 2016. The increase in revenue was primarily due to a \$5.0 million milestone payment associated with the U.S. Food and Drug Administration (FDA) approval of a supplemental New Drug Application (sNDA) for RAPIVAB[®] (peramivir injection), extending its availability for the treatment of acute uncomplicated influenza to pediatric patients two years and older, and the recognition of \$1.5 million of peramivir product sales to the Company's commercial partner, Green Cross Corporation. These increases were offset by a \$3.1 million decrease in RAPIACTA[®] royalties primarily due to lower government stockpiling sales by the Company's commercial partner in Japan, Shionogi & Co. Ltd. (Shionogi), and lower collaboration revenue under U.S. Government development contracts.

Research and Development (R&D) expenses for the third quarter of 2017 increased to \$17.5 million from \$14.1 million in the third quarter of 2016, primarily due to increased spending on the Company's hereditary angioedema (HAE) portfolio, including the achievement of a performance-based stock option grant related to the successful completion of the APeX-1 clinical trial. These increases were offset by a decrease in the Company's galidesivir expenses under U.S. Government development contracts.

General and administrative (G&A) expenses for the third quarter of 2017 increased to \$3.3 million compared to \$2.8 million of expense in the third quarter of 2016. The increase was primarily due to the achievement of a performance-based stock option grant related to the successful completion of the APeX-1 clinical trial.

Interest expense was \$2.1 million in the third quarter of 2017 as compared to \$1.5 million in the third quarter of 2016, an increase related primarily to the September 2016 closing of a \$23 million senior credit facility. Also, a \$84,000 mark-to-market gain on the Company's foreign currency hedge was recognized in the third quarter of 2017, as compared to a \$931,000 mark-to-market loss in the third quarter of 2016. These changes result from periodic changes in the U.S. dollar/Japanese yen exchange rate. During the third quarter of 2017, the Company also realized a currency gain of \$45,000 from the exercise of a U.S. Dollar/Japanese yen currency option within its foreign currency hedge.

The net loss for the third quarter of 2017 was \$15.1 million, or \$0.18 per share, compared to a net loss of \$11.5 million, or \$0.16 per share, for the third quarter 2016.

Cash, cash equivalents and investments totaled \$169.3 million at September 30, 2017, and reflect an increase from \$65.1 million at December 31, 2016. Net operating cash use for the third quarter of 2017 was \$10.6 million, and was \$31.6 million for the first nine months of 2017, which excludes net proceeds from the March 2017 (\$47.8 million) and September 2017 (\$85.8 million) public offerings.

Year to Date Financial Results

For the nine months ended September 30, 2017, revenues increased to \$21.3 million from \$17.4 million in the first nine months of 2016. The increase in revenue was primarily due to \$7.0 million of milestone payments associated with the

Canadian regulatory and FDA sNDA approvals of RAPIVAB, and to a lesser extent a \$1.2 million increase in royalty revenue from Shionogi & Co. Ltd., Green Cross Corporation and Seqirus. The increase in royalty revenue was largely the result of continued Japanese Government stockpiling of RAPIACTA. Future government stockpiling orders are difficult to predict, as they are subject to the relevant appropriation and stockpiling processes. These revenue increases were offset by a \$5.5 million decrease in collaboration revenue under U.S. Government development contracts.

R&D expenses for the nine months of 2017 increased to \$50.0 million from \$48.9 million in the first nine months of 2016, primarily due to the achievement of a performance-based stock option grant related to the successful completion of the APeX-1 clinical trial. These increases were offset by a decrease in galidesivir expenses under U.S. Government development contracts.

G&A expenses for the nine months of 2017 increased to \$9.2 million compared to \$8.7 million in the first nine months of 2016. The increase was due to the achievement of a performance-based stock option grant related to the successful completion of the APeX-1 clinical trial.

In the nine months of 2017 and 2016, interest expense was \$6.3 million and \$4.4 million, respectively. The increase in interest expense was 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 nine months of 2017, as compared to a \$7.4 million mark-to-market loss in the first nine months 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 \$966,000 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 nine months of 2017 was \$46.2 million, or \$0.58 per share, compared to a net loss of \$50.6 million, or \$0.69 per share for the same period last year.

Clinical Development Update & Outlook

- | In the fourth quarter, BioCryst completed end of Phase 2 regulatory interactions with the FDA and European Medicines Agency (EMA) resulting in finalizing the marketing authorization requirements, including agreement on the design of a single Phase 3 clinical trial and the details regarding a long-term safety trial.
- | On November 1, 2017, the FDA granted orphan drug designation to BCX7353 for the prevention and treatment of angioedema attacks in patients diagnosed with HAE.
- | On September 5, BioCryst announced positive final results from its Phase 2 APeX-1 clinical trial in HAE. APeX-1 was a 3-part dose ranging trial designed to evaluate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of orally administered once-daily BCX7353 for 28 days, as a preventative treatment to reduce the frequency of attacks in HAE patients.
- | On September 15, BioCryst announced the completion of an underwritten public offering of 17,864,078 shares of its common stock, including 2,330,097 shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares. The gross proceeds from this offering, including from the shares sold pursuant to the underwriters' option to purchase additional shares, were \$92 million before deducting underwriting discounts and commissions and other estimated offering expenses.
- | On September 21, BioCryst announced that the U.S. FDA approved a sNDA for RAPIVAB (peramivir injection), an intravenous (i.v.) neuraminidase inhibitor, extending its availability for the treatment of acute uncomplicated influenza to pediatric patients two years and older who have been symptomatic for no more than two days.

Financial Outlook for 2017

Based upon development plans and our awarded government contracts, BioCryst expects its 2017 net operating cash use to be in the upper half of its previously disclosed range of \$30 to \$50 million, and its 2017 operating expenses to be in the upper half of its previously disclosed 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 Tuesday, November 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. 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 recently completed Phase 2 APeX-1 clinical trial for the prophylaxis of angioedema attacks in patients with HAE and in clinical pharmacology studies in healthy volunteers.

About RAPIVAB (peramivir injection)

Approved by FDA in December 2014, RAPIVAB (peramivir injection) is an intravenous viral neuraminidase inhibitor approved for the treatment of acute uncomplicated influenza in patients two years and older who have been symptomatic for no more than two days. Efficacy of RAPIVAB is based on clinical trials of naturally occurring influenza in which the predominant influenza infections were influenza A virus and a limited number of patients infected with influenza B virus. Visit <http://www.rapivab.com> to learn more.

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[®] (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 commitments 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.

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 ZENITH-1 and APeX-2) 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 and EMA 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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Statements of Operations (Unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|--------------------|------------------------------------|--------------------|
| | 2017 | 2016 | 2017 | 2016 |
| Revenues: | | | | |
| Product sales | \$ 1,501 | \$ - | \$ 1,501 | \$ - |
| Royalty revenue | 442 | 3,501 | 7,252 | 6,020 |
| Collaborative and other research and development | 6,817 | 4,262 | 12,543 | 11,350 |
| Total revenues | <u>8,760</u> | <u>7,763</u> | <u>21,296</u> | <u>17,370</u> |
| Expenses: | | | | |
| Cost of products sold | 1,142 | - | 1,142 | - |
| Research and development | 17,509 | 14,105 | 50,038 | 48,850 |
| General and administrative | 3,343 | 2,756 | 9,235 | 8,692 |
| Royalty | 115 | 143 | 431 | 247 |
| Total operating expenses | <u>22,109</u> | <u>17,004</u> | <u>60,846</u> | <u>57,789</u> |
| Loss from operations | (13,349) | (9,241) | (39,550) | (40,419) |
| Interest and other income | 225 | 109 | 537 | 695 |
| Interest expense | (2,140) | (1,465) | (6,334) | (4,356) |
| Gain (loss) on foreign currency derivative | 130 | (931) | (892) | (6,561) |
| Net loss | <u>\$ (15,134)</u> | <u>\$ (11,528)</u> | <u>\$ (46,239)</u> | <u>\$ (50,641)</u> |
| Basic and diluted net loss per common share | <u>\$ (0.18)</u> | <u>\$ (0.16)</u> | <u>\$ (0.58)</u> | <u>\$ (0.69)</u> |
| Weighted average shares outstanding | 83,570 | 73,734 | 79,749 | 73,677 |

Balance Sheet Data (in thousands)

| | September 30, 2017 | December 31, 2016 |
|--|--------------------|-------------------|
| | (Unaudited) | (Note 1) |
| Cash, cash equivalents and investments | \$ 166,163 | \$ 63,576 |
| Restricted cash | 3,122 | 1,546 |
| Receivables from collaborations | 8,985 | 8,768 |
| Total assets | 191,492 | 89,847 |
| Non-recourse notes payable | 28,572 | 28,243 |
| Senior credit facility | 23,106 | 22,777 |
| Accumulated deficit | (612,300) | (566,061) |
| Stockholders' equity | 100,632 | 1,578 |
| Shares of common stock outstanding | 98,389 | 73,782 |

Note 1: Derived from audited financial statements.

Source: BioCryst Pharmaceuticals, Inc.

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