UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): February 23, 2019

BioCryst Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-23186**	**62-1413174**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

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)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [ ]

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

Item 7.01. Regulation FD Disclosure.

On February 23, 2019, BioCryst Pharmaceuticals, Inc. (the "Company") reported additional topline data from the Phase 2 ZENITH-1 trial, including new data from the 250 mg and 500 mg dose cohorts. Data from the now complete trial confirm previously reported results showing a single dose of oral 750 mg BCX7353 was well-tolerated and superior to placebo ($p<0.05$) against the majority of efficacy endpoints evaluated in HAE patients suffering an acute attack and demonstrate a clear dose response across the three dose levels.

Also, on February 23, 2019, the Company presented a poster with data from the ZENITH-1 trial of BCX7353 for the acute treatment of hereditary angioedema attacks at the American Academy of Allergy, Asthma & Immunology, or AAAAI, annual meeting, and published the poster on the investor relations section of the Company's website. The poster presented at AAAAI and published on the Company's website contained a typographical error, which incorrectly noted in the table titled *RESULTS—SAFETY* that a serious treatment-emergent adverse event, or TEAE occurred after treatment of 1 attack with 750 mg and 0 attacks treated with placebo. The table should have noted that a serious TEAE occurred after treatment of 0 attacks with 750 mg and 1 attack treated with placebo. On February 25, 2019, the Company published the corrected poster to the Company's website.

On February 23, 2019, the Company issued a news release describing the events in this Item 7.01. A copy of the news release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference. On February 25, 2019, the Company published the corrected poster describing the events in this Item 7.01. A copy of the corrected poster is furnished as Exhibit 99.2 hereto and is incorporated herein by reference.

The information furnished in this Item 7.01, including Exhibits 99.1 and Exhibits 99.2, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Forward Looking Statements

This Current Report on Form 8-K 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 ongoing and future preclinical and clinical development of HAE second generation drug candidates (including APeX-2, APeX-S and APeX-J) may not have positive results, may be more expensive or may not move as quickly as planned; that the FDA, EMA or other applicable regulatory agency may not provide regulatory clearances which may result in delay of planned clinical trials or failure to achieve 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated February 23, 2019 entitled "BioCryst Reports ZENITH-1 Results With Oral BCX7353 Which Confirm Rapid Onset of Action, Sustained Activity and Robust Dose Response for Treatment of Acute HAE Attacks"
99.2	Poster publication dated February 25, 2019 entitled "Oral Plasma Kallikrein Inhibitor BCX7353 is Safe and Effective as an On-Demand Treatment of Angioedema Attacks in Hereditary Angioedema (HAE) Patients: Results of the Zenith 1 Trial

SIGNATURE

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 hereunto duly authorized.

BioCryst Pharmaceuticals, Inc.

Date: February 23, 2019

By: /s/ Alane Barnes
Alane Barnes
Senior Vice President and Chief Legal Officer

EXHIBIT 99.1

BioCryst Reports ZENITH-1 Results With Oral BCX7353 Which Confirm Rapid Onset of Action, Sustained Activity and Robust Dose Response for Treatment of Acute HAE Attacks

—Based on ZENITH-1 data, company plans to commence Phase 3 trial of single-dose 750 mg oral BCX7353 for acute treatment of hereditary angioedema (HAE) attacks in summer 2019—

—Data show excellent clinical dose response in ZENITH-1, as predicted by pK data—

—BCX7353 well-tolerated at all dose levels (250 mg, 500 mg, 750 mg) in ZENITH-1—

—Data presented at American Academy of Allergy, Asthma & Immunology (AAAAI) annual meeting—

RESEARCH TRIANGLE PARK, N.C., Feb. 23, 2019 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today reported additional topline data from the Phase 2 ZENITH-1 trial, including new data from the 250 mg and 500 mg dose cohorts. Data from the now complete trial confirm previously reported results showing a single dose of oral 750 mg BCX7353 was well-tolerated and superior to placebo ($p<0.05$) against the majority of efficacy endpoints evaluated in HAE patients suffering an acute attack, and demonstrate a clear dose response across the three dose levels.

Based on the results of ZENITH-1, the company plans to meet with the U.S. Food and Drug Administration (FDA) in the second quarter, and to commence a Phase 3 trial with the 750 mg dose of oral BCX7353 in the summer of 2019.

“The results of ZENITH-1, with onset of action within one hour, duration of effect of a single dose over 24 hours, and a robust efficacy dose response across all dose levels are very exciting for patients who have an urgent need for an oral treatment option for acute attacks,” said Dr. William Sheridan, chief medical officer of BioCryst.

“Based on these excellent results, we plan to quickly advance 750 mg oral BCX7353 into a Phase 3 trial that will be designed to support approval in the U.S. and European Union,” Sheridan added.

Efficacy and tolerability data for the 750 mg dose cohort were previously reported by the company in a September 4, 2018 press release. With the 750 mg dose, compared to placebo, improvement in symptoms and Visual Analog Scale (VAS) scores was seen as early as one hour after oral BCX7353 dosing, and was sustained through 24 hours. Through 24 hours, standard of care (SOC) medication use was reduced by 31.6 percent after BCX7353 compared with placebo ($p=0.0029$), and no or mild symptoms were reported in 64.1 percent of attacks treated with BCX7353 compared with 32.3 percent of attacks treated with placebo ($p=0.0038$).

In the additional data reported today at the AAAAI annual meeting, a clear dose response was observed across the 250 mg to 750 mg range. Across dose levels, BCX7353 was generally safe and well-tolerated with no notable differentiation from the adverse event profile of placebo.

The prior press release from September 4, 2018 containing safety and efficacy data from the 750 mg dose cohort, and the poster containing the additional results presented today at the AAAAI annual meeting, including figures highlighting dose response and tolerability across all three dose levels, can be found on the investor relations section of the company’s website at: http://ir.biocryst.com/.

ZENITH-1 Trial Design

ZENITH-1 was a double-blind, placebo-controlled, randomized, cross-over, dose-ranging trial of oral BCX7353 for acute treatment of angioedema attacks in patients with HAE. A total of 63 patients were randomized and 58 received at least one dose of blinded study drug: 11 in the 250 mg cohort, 14 in the 500 mg cohort and 33 in the 750 mg cohort.

ZENITH-1 was designed for compatibility with modern treatment guidelines for at-home self-administered drug administration as early as possible after onset of symptoms. The goals of the trial were to identify activity against clinically meaningful endpoints that the company could use to construct a Phase 3 registration trial, to identify the dose or doses the company could advance, and to assess safety and tolerability.

Adults with HAE Type I or II self-administered a dose of blinded study drug for three attacks; two treated with active drug and one with placebo, in a randomized sequence. Subjects were asked to administer blinded study medicine within one hour of onset of symptoms. Subjects were free to use approved prescribed acute medications but were asked to wait at least four hours post-study drug if possible. Patient completed trial diaries to collect information on symptoms, VAS scores and use of SOC medicines prior to dosing and at 1, 2, 3, 4, 8 and 24 hours after study drug administration. In the 250 mg, 500 mg and 750 mg cohorts respectively, a total of 21, 25 and 64 attacks were treated with BCX7353 and 11, 11 and 31 attacks were treated with placebo.

About BCX7353
Discovered by BioCryst, BCX7353 is a novel, oral, once-daily, selective inhibitor of plasma kallikrein currently in advanced clinical development for the prevention and treatment of angioedema attacks in patients 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, each 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 has also completed the ZENITH-1 clinical trial. ZENITH-1 was a proof-of-concept Phase 2 clinical trial testing oral BCX7353 for the treatment of acute angioedema attacks.

About BioCryst Pharmaceuticals
BioCryst Pharmaceuticals discovers novel, oral small-molecule medicines that treat rare diseases in which significant unmet medical needs exist and an enzyme plays a key role in the biological pathway of the disease. BioCryst has several ongoing development programs of oral drugs for rare diseases including BCX7353, an oral plasma kallikrein inhibitor for treatment of hereditary angioedema; a preclinical program with an oral ALK-2 inhibitor for treatment of fibrodysplasia ossificans progressive, and intravenous galidesivir, a broad-sepctrum viral RNA polymerase inhibitor, as a potential treatment for Marburg virus disease and Yellow Fever, under contracts from NIAID and HHS/BARDA. RAPIVAB® (peramivir injection), an intravenous influenza virus 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 ongoing and future preclinical and clinical development of HAE second generation drug candidates (including APeX-2, APeX-S and APeX-J) may not have positive results, may be more expensive or may not move as quickly as planned; that the FDA, EMA or other applicable regulatory agency may not provide regulatory clearances which may result in delay of planned clinical trials or failure to achieve 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.

BCRXW

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Exhibit 99.2

Oral Plasma Kallikrein Inhibitor BCX7353 is Safe and Effective as an On-Demand Treatment of Angioedema Attacks in Hereditary Angioedema (HAE) Patients: Results of the ZENITH-1 Trial

Abstract #41790
Poster #110

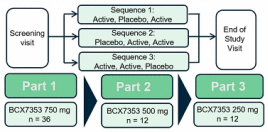
H Longhurst[1], D Moldovan[2], A Bygum[3], M Cicardi[4], A Huissoon[5], E Aygören-Pürsün[6], V Grivcheva-Panovska[7], D Hagin[8], U Steiner[9], M Stobiecki[10], W Aberer[11], C Bethune[12], SN Faust[13], S Kiani[14], D Launay[15], M Maurer[16], W Rae[17], A Reshef[18], M Cornpropst[19], S Dobo[19], S Van Dyke[19], S Murray[19], P Collis[19], W Sheridan[19], H Farkas[20]

Affiliations: [1]Department of Immunology, Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust, Cambridge, United Kingdom, [2]University of Medicine and Pharmacy of Tîrgu Mures, Mures County Hospital, Tîrgu Mures, Romania, [3]Department of Dermatology and Allergy Centre, Odense University Hospital, Odense, Denmark, [4]Department of Biomedical and Clinical Sciences, Luigi Sacco Hospital, University of Milan, ASST Fatebenefratelli Sacco, Milan, Italy, [5]Birmingham Heartlands Hospital, Birmingham, United Kingdom, [6]Department for Children and Adolescents, Angioedema Centre, University Hospital Frankfurt, Goethe University, Frankfurt, Germany, [7]Public Health Institution University Clinic of Dermatology, School of Medicine, University Sts. Cyril and Methodius, Skopje, Macedonia, The former Yugoslav Republic of, [8]Allergy and Clinical Immunology Unit, Tel-Aviv Sourasky Medical Center, Tel-Aviv University, Israel, Tel-Aviv, Israel, [9]Department of Clinical Immunology, University Hospital Zurich, Zurich, Switzerland, [10]Jagiellonian University College, Krakow, Poland, [11]Department of Dermatology and Venereology, Medical University of Graz, Graz, Austria, [12]Department of Immunology and Allergy, University Hospital Plymouth NHS Trust, Plymouth, United Kingdom, [13]NIHR Clinical Research Facility, Southampton General Hospital, Southampton, United Kingdom, [14]Department of Immunology, Barts Health NHS Trust, Royal London Hospital, London, United Kingdom, [15]Department of Internal Medicine, Claude Huriez Hospital, Lille, France, [16]Department of Dermatology and Allergy, Charité - Universitätsmedizin Berlin, Berlin, Germany, [17]Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust, Cambridge, United Kingdom, [18]Allergy, Immunology and Angioedema Center, Barzilai Medical Center, Ashkelon, Israel, [19]BioCryst Pharmaceuticals, inc., Durham, NC, [20]Hungarian Angioedema Reference Center, Third Department of Internal Medicine, Semmelweis University, Budapest, Hungary

Introduction

- Hereditary angioedema (HAE) due to deficiency or dysfunction of C1 inhibitor (C1-INH) is a life-threatening disease characterized by periodic episodes or attacks of swelling
- Plasma kallikrein is a proven target for treatment of HAE attacks
- BCX7353 is an investigational oral kallikrein inhibitor in Phase 3 studies for prevention of HAE attacks, administered in a capsule formulation given once daily.
- When a 750 mg dose was administered as a liquid to HAE patients in a pharmacokinetic study, BCX7353 was rapidly absorbed, with concentrations ≥ 8 x EC_{50} (estimated concentration of drug for a half maximal response) for plasma kallikrein in all subjects from 30 minutes to at least 24 hours post dose[1]. The $t_{1/2}$ of BCX7353 is 70-80 hours[2].
- ZENITH-1 was a Phase 2 study that evaluated the efficacy and safety of single liquid doses of BCX7353 as an acute attack treatment in subjects with HAE (NCT03240133).

ZENITH-1 Study Design/Methods



- Double-blind study in adult subjects with Type I or II HAE
- Subjects treated 3 separate attacks, 2 with BCX7353 and 1 with placebo in a randomized sequence
- Each treated attack was separated by ≥ 14 days
- Investigators approved attacks by phone that were reported to be without airway involvement or vomiting and were within 1 hour of symptom onset prior to subject self-administration with study drug
- Where possible, subjects were asked to refrain from taking their usual attack medication for at least 4 hours post-study drug.
- Subjects recorded HAE symptom severity using a 3-symptom visual analog scale (VAS) and qualitative assessments prior to and at 1, 2, 3, 4, 8, and 24 hours after study drug dosing.

Subject Demographics and Attack Metrics

Demographics	Part 1 750 mg	Part 2 500 mg	Part 3 250 mg
Subjects randomized (n)	36	15	12
Age in years, mean (SD)	43.7 (13)	42.1 (11)	34.9 (11)
Sex, % female	52%	79%	64%
Subjects discontinued (n)	3	3	1
Usual symptoms of an HAE attack, n (%)			
Abdominal pain	30 (91)	12 (86)	10 (91)
Nausea	18 (55)	12 (86)	8 (72)
Substantial fatigue	21 (64)	10 (71)	7 (63)
Diarrhea	12 (36)	7 (50)	8 (73)
Vomiting	10 (30)	8 (57)	5 (46)
Difficulty swallowing	10 (30)	9 (64)	4 (36)
Difficulty breathing	10 (30)	7 (50)	3 (27)
Attack Metrics	**Part 1**	**Part 2**	**Part 3**
Attacks treated (active/placebo)	64/31	25/11	21/11
Subjects treating 0/1/2/3 attacks (n)	3/1/2/30	1/3/0/11	1/0/1/10
Mean pre dose composite VAS (active/placebo; mm)[β]	14.0/15.0	17.7/13.5	14.6/11.3
Median time (minutes) from onset of symptoms to taking blinded study drug (active/placebo)	36/35	40/20	32/30
Proportion (%) of attacks where subjects used rescue medicine within 4 hours of symptom onset	5/95 (5%)	3/36 (8%)	0/32 (0%)

[β]Composite VAS was calculated as the average of the VAS scores for abdominal pain, skin pain, and skin swelling.

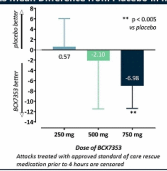
Results—Part 1 Efficacy at 750 mg BCX7353

Endpoint	BCX7353 750mg n=64 attacks	Placebo n=31 attacks	Difference	p-value
Least-squares mean change from baseline in VAS score through 4 hours[¥]	-3.9	+3.1	-6.98	0.0024
Proportion of attacks requiring standard of care treatment through 24 hours	29.7%	61.3%	-31.6%	0.0029
Proportion of attacks with no or mild symptoms through 24 hours[¥]	64.1%	32.3%	+31.8%	0.0038
Time to standard of care acute attack treatment (median)	>24 hours	14 hours	>+10 hours	0.0043
Proportion of attacks with improved or stable symptoms through 24 hours[¥]	64.1%	35.5%	+28.6%	0.0092
Proportion of attacks with improved or stable VAS score through 24 hours[¥]	62.5%	35.5%	+27.0%	0.0125
Proportion of attacks with improved or stable symptoms through 4 hours[¥]	82.3%	60.0%	+22.3%	0.0192
Proportion of attacks with improved or stable VAS score through 4 hours[¥]	67.7%	46.7%	+21.0%	0.0387
Time to stable or improved VAS (median)[¥]	1 hour	2 hours	-1 hour	0.0452
Proportion of attacks with no or mild symptoms through 4 hours[¥]	69.4%	50.0%	+19.4%	0.0552
Time to ≥ 50% reduction in VAS through 24 hours (median)[¥]	8 hours	24 hours	-16 hours	0.0671
Time to initial symptom relief (median)[¥]	5.1 hours	19.4 hours	- 14.3 hours	0.0978
Time to almost complete symptom relief (median)[¥]	23.1 hours	23.6 hours	-0.5 hours	0.6767
Time to complete symptom relief (median)[¥]	35.1 hours	41.3 hour	-6.2 hours	0.8900

VAS = composite VAS
[¥] Data censored for LSM or endpoint = failure (proportions) for timepoints after a subject took rescue medication

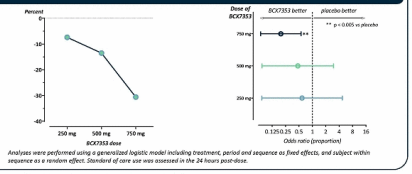
Results—Dose Response

Change from Baseline in 3-Composite VAS at 4 hours Post-dose (LS Mean Difference from Placebo in mm, 95% CI)



Attacks treated with approved standard of care rescue medication prior to 4 hours are censored

Use of Approved Standard of Care Medication Following BCX7353 Treatment for an HAE Attack (left panel: difference compared to placebo; right panel: model odds ratio)



Analyses were performed using a generalized logistic model including treatment, period and sequence as fixed effects, and subject within sequence as a random effect. Standard of care use was assessed in the 24 hours post-dose.

Presented at AAAAI 2019, San Francisco CA, Feb 22-25

Results—Safety

Number of attacks	BCX7353 750 mg	BCX7353 500 mg	BCX7353 250 mg	All Placebo
Treated	64	25	21	53
With a treatment-emergent (TE) adverse events (AE)	16 (25%)	10 (40%)	10 (48%)	17 (32%)
With a drug-related TEAE	7 (11%)	5 (20%)	6 (29%)	6 (11%)
With a serious TEAE[¥]	0	1 (4.0%)	0	1 (1.9%)
With a drug-related serious TEAE	0	0	0	0
With TEAEs leading to permanent discontinuation from study drug	1 (1.6%)[†]	1 (4.0%)[€]	0	1 (1.9%)[§]
With Grade 3 or 4 TEAEs	0	1 (4.0%)[Δ]	0	0
With Grade 3 or 4 TE lab abnormalities	0	0	0	0
Most common TEAEs				
Diarrhea	3 (4.7%)	3 (12%)	0	2(3.8%)
Abdominal pain	2 (3.1%)	3 (12%)	1 (4.8%)	1 (1.9%)
Nausea	2 (3.1%)	2 (8.0%)	2 (9.5%)	0
Nasopharyngitis	4 (6.3%)	0	0	1 (1.9%)
Headache	3 (4.7%)	0	3 (14%)	1 (1.9%)

[¥] Motor vehicle accident and ankle fracture, neither related to study drug
[†] Discontinuation on BCX7353 occurred in a subject who developed a small red macule on the forearm 11 hours after taking BCX7353 for an HAE attack occurring in the same anatomic location. The macule lasted for 4 hours and resolved without treatment.
[€] Discontinuation on BCX7353 occurred in a subject who experienced Grade 2 vomiting and nausea.
[§] Discontinuation on placebo occurred in a subject who experienced abdominal pain on both active and placebo drug. The decision to stop study drug occurred after the placebo dose.
[Δ] Grade 3 unrelated ankle fracture

Conclusions

- The ZENITH-1 Phase 2 placebo-controlled trial was a novel, early-intervention trial of self-administered oral BCX7353 for the treatment of HAE attacks
- A single dose of BCX7353 750 mg resulted in significant improvements compared to placebo in multiple subject-reported endpoints that evaluated reductions in symptom severity and use of rescue medication in the 24 hours following treatment of attacks
- A dose response in efficacy was observed across the 250 mg to 750 mg dose range
- Across dose levels, BCX7353 was generally safe and well-tolerated with no notable differentiation from the adverse event profile of placebo
- These results support selection of the 750 mg dose level for further evaluation in Phase 3 studies

[1]Mathias A, et al. *Annals Allergy Asthma Immunol*, 2018; 121(5): S32.
[2]Cornpropst M, et al. *J Allergy Clin Immunol*, 2016; 137(2): AB401.
The study was sponsored by BioCryst Pharmaceuticals, Inc.