

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): July 29, 2019

Bellicum Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36783
(Commission
File Number)

20-1450200
(IRS Employer
Identification No.)

2130 W. Holcombe Blvd., Ste. 800
Houston, TX
(Address of principal executive offices)

77030
(Zip Code)

Registrant's telephone number, including area code: 832-384-1100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	BLCM	The Nasdaq Global Market

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

Emerging growth company x

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. x

Item 8.01 Other Events.

Bellicum Pharmaceuticals, Inc. is filing this Current Report on Form 8-K in connection with the disclosure of information, in the form of a slide presentation, to be given at meetings with institutional investors or analysts. The slide presentation is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Slide presentation.

A photograph of a young girl with light brown hair, smiling and holding a large, white, fluffy stuffed animal. In the background, a blurred figure of a person in a white lab coat is visible. The image is overlaid with several large, white, semi-transparent circular graphic elements on the right side.

Investor Presentation

Striving to deliver cures through controllable cell therapy

July 2019

Forward Looking Statement

This presentation contains estimates, projections and other forward-looking statements, concerning, among other things: our research and development activities relating to our CaspaCIDE® (“iC9”), GoCAR-T® (incorporating “iMC”) and related technologies; our product candidates including rivo-cel™ (previously BPX-501), BPX-601, BPX-603, BPX-802, and rimiducid; the effectiveness of our CaspaCIDE and GoCAR-T programs and their possible range of application and potential curative effects and safety in the treatment of diseases, including as compared to other treatment options and competitive therapies; the success of our collaborations with academic and commercial partners; the timing, progress, enrollment and success of our clinical trials; and the timing of potential European marketing authorization applications for rivo-cel and rimiducid. Our estimates, projections and other forward-looking statements are based on our management’s current assumptions and expectations of future events and trends, which affect or may affect our business, strategy, operations or financial performance. Although we believe that these estimates, projections and other forward-looking statements are based upon reasonable assumptions, they are subject to numerous known and unknown risks and uncertainties and are made in light of information currently available to us. Many important factors, in addition to the factors described in this presentation, may adversely and materially affect our results as indicated in forward-looking statements. All statements other than statements of historical fact are forward-looking statements.

Estimates, projections and other forward-looking statements speak only as of the date they were made, and, except to the extent required by law, we undertake no obligation to update any forward-looking statement. These statements are also subject to a number of material risks and uncertainties that are described more fully in Bellicum’s filings with the Securities and Exchange Commission, including without limitation our annual report on Form 10-K for the year ended December 31, 2018 and our quarterly report on Form 10-Q for the period ended March 31, 2019.

Investment Summary

Rivo-cel

Allogeneic polyclonal T-cells for hematologic malignancies and inherited blood disorders (+HSCT)

European pediatric opportunity clinically de-risked

- 249 patients enrolled in Phase 1 / 2 study
- Rivo-cel achieved primary endpoint in pediatric registrational trial, topline data announced in July 2019
- Consistent with late interim results at ASH in Dec. 2018
- Expect MAA filings in Q4'19 / Q1'20
- European HQ and leadership team in place for commercialization prep

Global trial underway to broaden label

- Phase 2/3 THRIVE study in AML and MDS in patients 12+ years old

Actively seeking strategic partner

GoCAR-T Pipeline

Controllable CAR-T cells designed to optimize efficacy and safety

BPX-601 GoCAR-T promising early clinical data

- Phase 1 / 2 study enrolling in pancreatic cancer
- Initial safety data on 18 pancreatic cancer patients presented at ASCO in June 2019 indicate attractive safety profile and early clinical activity
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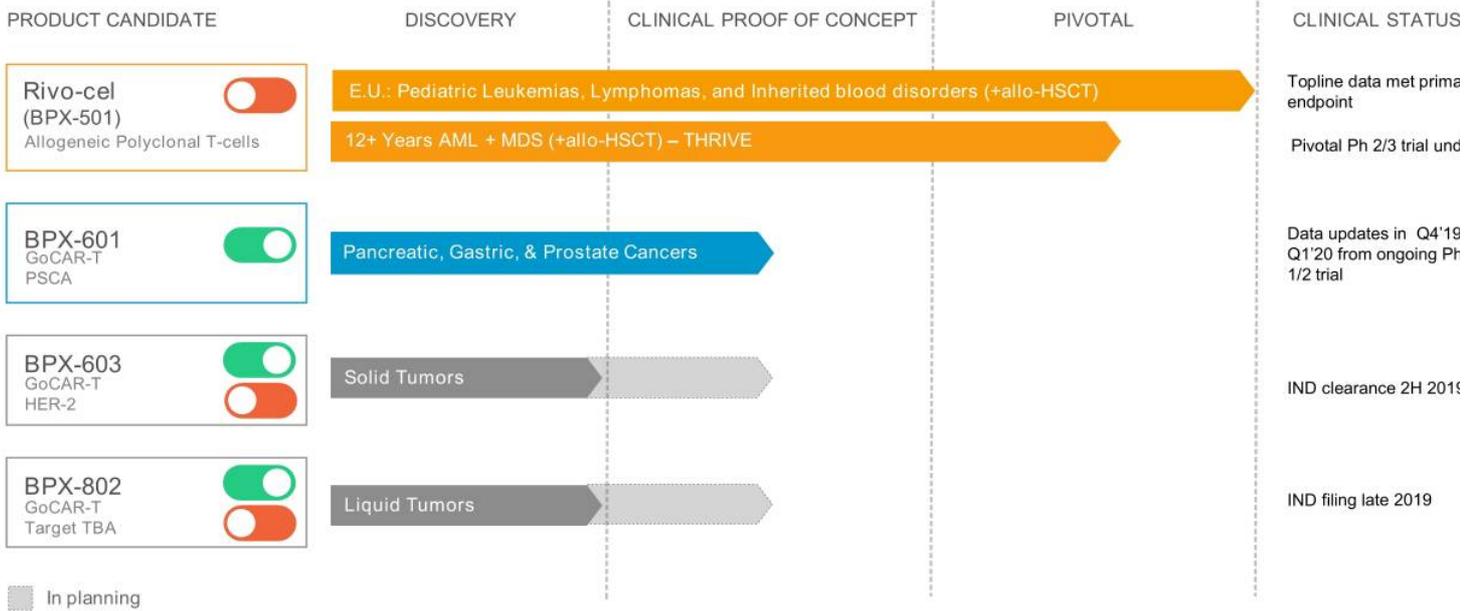
Two dual-switch GoCAR-T candidates headed toward II

- BPX-603 targeting HER2 antigen in solid tumors
- BPX-802 targeting liquid tumors, target antigen TBA

Cash, cash equivalents, restricted cash and investment securities of \$78.1MM as of March 31, 2019; Cash runway through

Development Pipeline: Rivo-cel and GoCAR-T

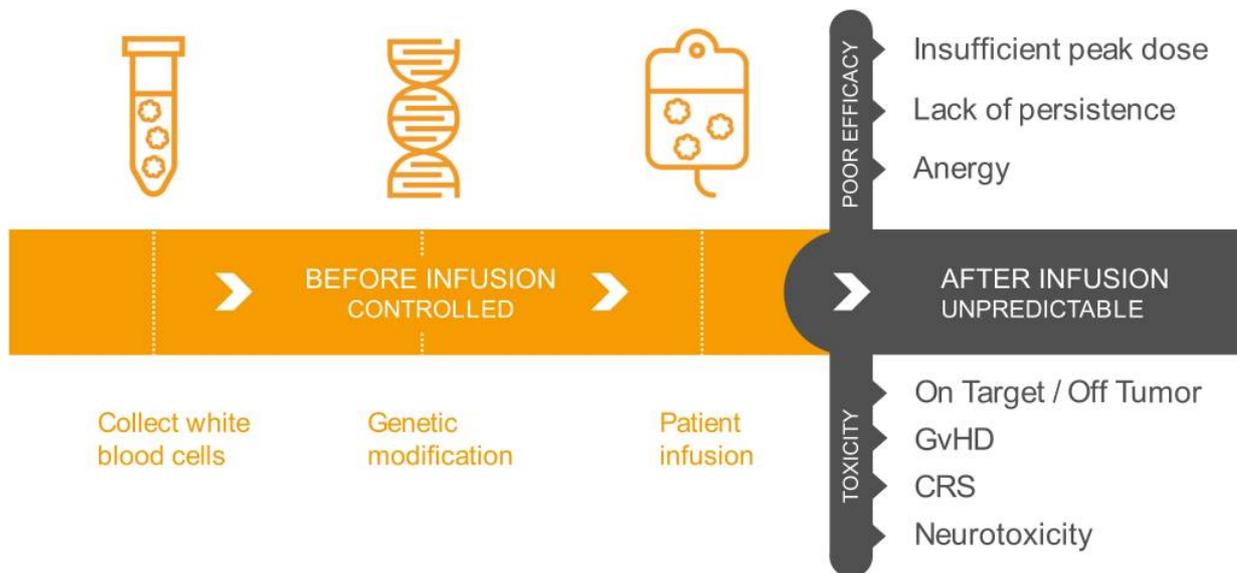
Controllable cell therapies that may represent major advances in liquid and solid tumors



Technology Overview

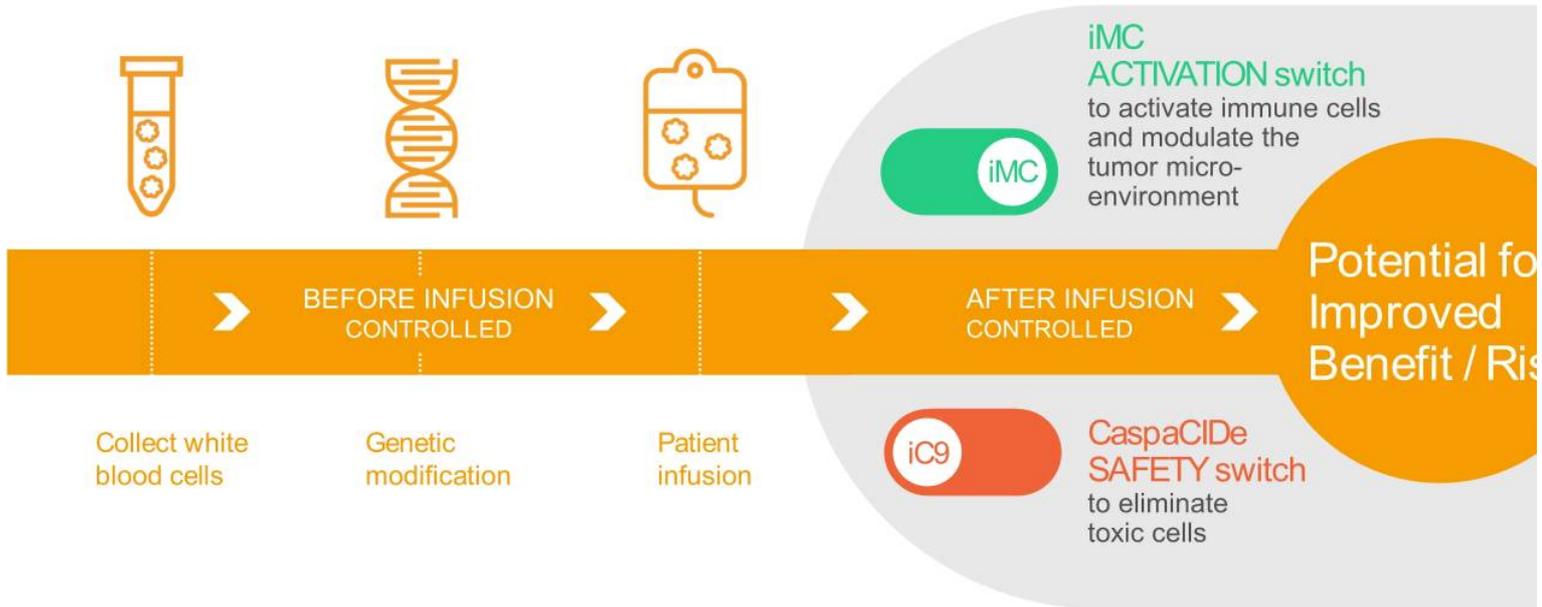
Most Cell Therapies Only Controlled Before Infusion

Limited ability to expand a narrow therapeutic window



Bellicum Platform Designed to Enable Control After Infusion

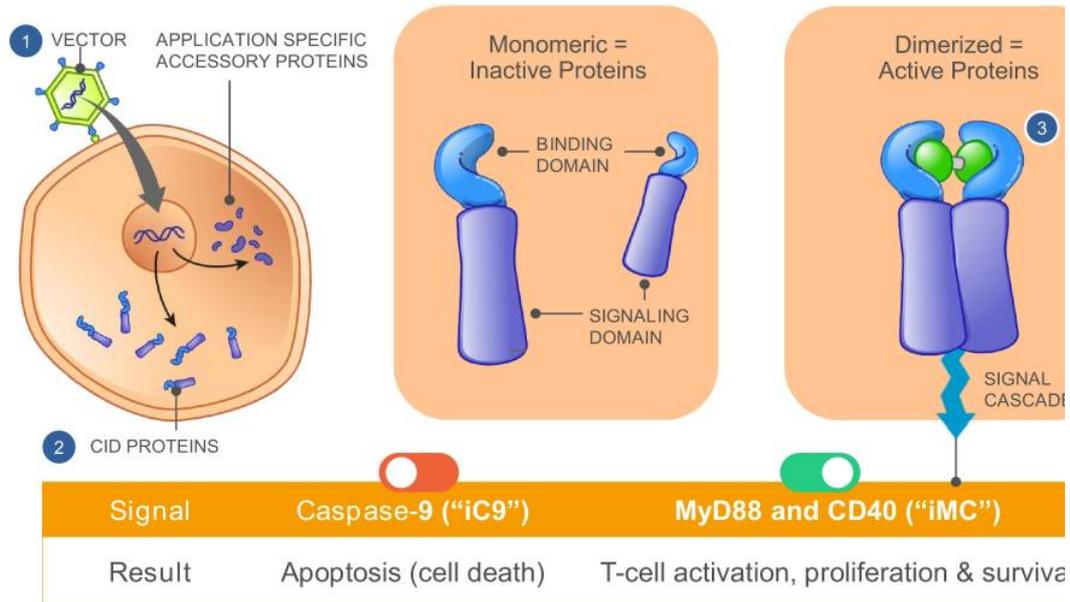
Would provide physicians the ability to expand the therapeutic window in each patient



Chemical Induction of Dimerization (“CID”) Molecular Switch Platform

Rimiducid infusion activates signaling pathways to control T-cell function

- 1 Viral transduction transfers the DNA from a vector into the target cell nucleus.
- 2 Vector-derived DNA directs expression of CID and accessory proteins.
- 3 Rimiducid dimerizes the CID proteins, thus turning on the signal cascade.



GoCAR-T Pipeline

GoCAR-T: Differentiated Approach to Cell Therapy

Current Challenges in Cell Therapy

- ⊗ Limited efficacy in solid tumors
 - Inadequate cell proliferation and persistence to sustain efficacy
 - Inability to overcome immune suppressive factors in tumor microenvironment (TME)

- ⊗ Potential safety issues with more potent approaches

GoCAR-T Benefits

- ✔ Potential for enhanced efficacy in solid tumors via iMC signaling
 - MyD88 and CD40 are superior co-stimulatory molecules with potential for greater cell expansion and persistence
 - Modulates the tumor microenvironment, overriding common inhibitory pathways (PD-1, PGE2, TGF- β)
 - Enhances host immune activity by inducing pro-inflammatory cytokines and chemokines
- ✔ Potential for enhanced safety
 - iMC provides control over timing and frequency of co-activation
 - CaspaCIDE capable of eliminating a majority of CAR-T cells to manage acute toxicities

BPX-601 GoCAR-T Targeting PSCA

Product Summary

- Attractive first-in-class solid tumor CAR-T opportunity
- First-in-human experience with iMC
- Updated Phase 1 results presented in June 2019 continue to demonstrate:
 - Safety
 - iMC-driven T cell activation
 - Biologic activity
- Phase 1 enrollment ongoing

Unmet Need

High unmet need in solid tumors expressing Prostate Stem Cell Antigen (PSCA)

	Annual Incidence (US)	Annual Deaths (US)	% Expressing PSCA
Pancreatic	55k	44k	~60%
Prostate	165k	29k	75-90%
Gastric	26k	11k	76-89%



Incidence and annual deaths: Noone AM, Howlader N, Krapcho M, Miller D, Brest A, Yu M, Ruhi J, Tatalovich Z, Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). SEER Cancer Statistics Review, 1975-2015, National Cancer Institute, Bethesda, MD, https://seer.cancer.gov/csr/1975_2015/, based on November 2017 SEER data submission, posted to the SEER web site, April 2018.
PSCA expression: Argani et al, Cancer Res 2001; Reiter et al., PNAS 1998; Abate-Daga et al, HGT 2014; Data on file

BPX-601: Phase 1 Trial Progression

BP-012 trial in relapsed/refractory pancreatic, gastric, and prostate cancers

	Lead-in (Cohort 0)	Dose Escalation (Cohorts 3, 4, 5A)	Full Conditioning (Cohort 5B)	Efficacy Optimized Regimen (Cohort 5C)
Patient Population	2L to 6L Pancreatic		2L Pancreatic	
BPX-601 Dose x10 ⁶ cells/kg @ Day 0	1.25	1.25, 2.5, 5.0	5.0	
Conditioning	Cytosan 1g/m ² @ Day -3		Cytosan 0.5g/m ² Fludarabine 30mg/m ² @ Days -5, -4, -3	
Rimiducid Dose @ Day 7	None	Single Dose	Single Dose	Scheduled Repeat Dosing
Status	Enrolled & Presented			Pending

Dose escalation designed conservatively to evaluate

- Partial conditioning with monotherapy
- Single dose of rimiducid activate iMC

Recently evaluated impact conditioning

- Standard Flu/Cy regime
- Single dose of rimiducid activate iMC

Next step: efficacy-optimized regimen

- Standard Flu/Cy regime repeat rimiducid dosing
- Data presentation: late

BPX-601: No Dose Limiting Toxicities Observed

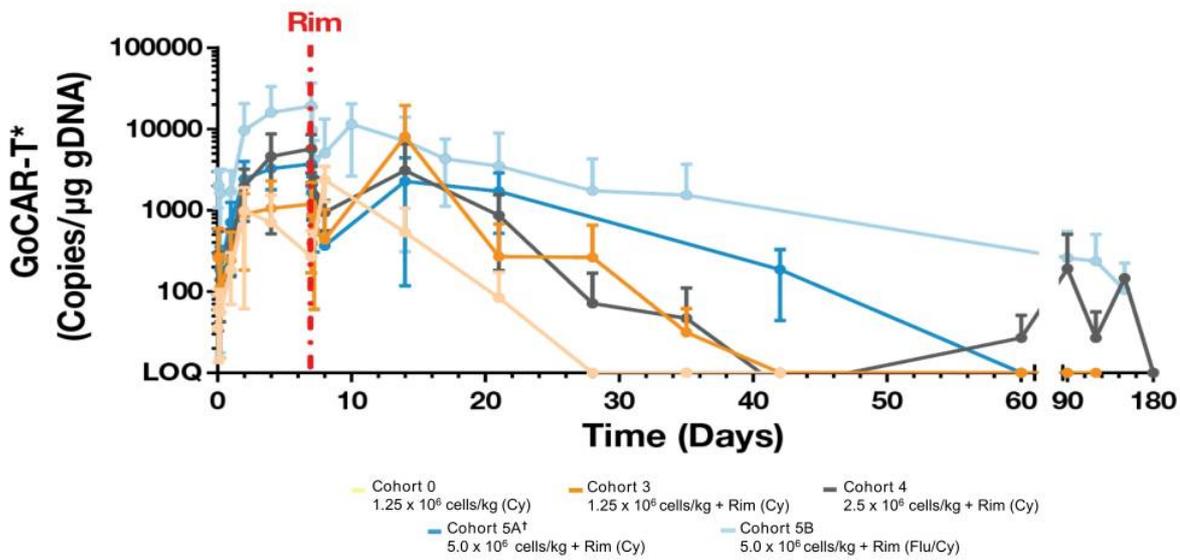
Data presented at ASCO 2019

Patients, n (%)	Cohort 0 n = 3	Cohort 3 n = 3	Cohort 4 n = 3	Cohort 5A n = 4	Cohort 5B n = 5	All Patients N = 18
Any AE	3 (100)	3 (100)	3 (100)	4 (100)	5 (100)	18 (100)
Any SAE	2 (67)	1 (33)	0	3 (75)	4 (80)	10 (56)
Grade 3 & 4 TRAEs	0	0	0	0	1 (20)	1 (<1)
AEs in >15% of all patients, n (%)						
Febrile neutropenia	0	0	0	2 (50)	4 (80)	6 (33)
Fatigue	2 (67)	1 (33)	0	2 (50)	0	5 (28)
Neutropenia	0	0	0	1 (25)	4 (80)	5 (28)
Pyrexia	0	0	1 (33)	2 (50)	2 (40)	5 (28)
Dysuria	0	0	0	0	4 (80)	4 (22)
Hematuria	0	0	0	0	4 (80)	4 (22)
Nausea	2 (67)	0	0	0	2 (40)	4 (22)
Abdominal pain	1 (33)	1 (33)	0	0	1 (20)	3 (17)
Abdominal pain upper	0	1 (33)	1 (33)	1 (25)	0	3 (17)
Anemia	0	0	0	1 (25)	2 (40)	3 (17)
Back pain	1 (33)	1 (33)	0	1 (25)	0	3 (17)
Blood bilirubin increased	0	0	0	1 (25)	2 (40)	3 (17)
Hypotension	0	0	2 (67)	1 (25)	0	3 (17)

- No dose limiting toxicities were observed
- Adverse Events (AEs) were generally consistent with cytotoxic chemotherapy or other cancer immunotherapies
- AEs related to BPX-601/rimidine included:
 - One case of Grade 2 cytotoxic release syndrome (CRS)
 - One case of Grade 2 encephalopathy
 - Four cases of Grade 1-3 urologic toxicity (dysuria, hematuria, cystitis)

BPX-601: iMC-Driven T Cell Expansion & Persistence

Flu/Cy Lymphodepletion Results in Increased BPX-601 Cell Expansion and Persistence



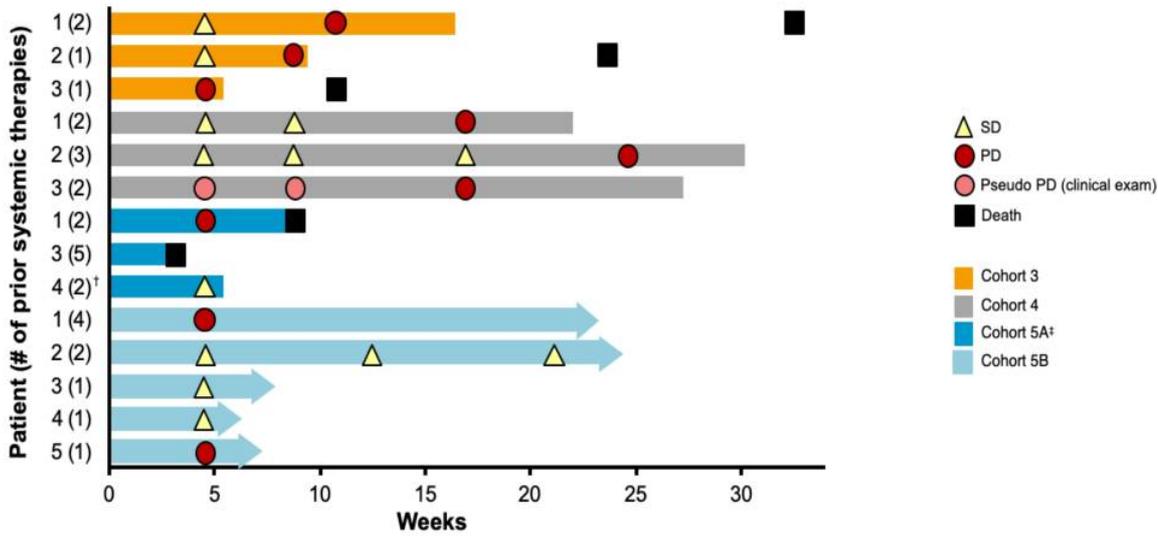
- Peak expansion 4.9-fold higher in Flu/Cy cohort vs Cy alone cohorts
- Persistence improves
 - Administration of rimiducid to activate iMC
 - Higher cell dose
 - Lymphodepletion Flu/Cy

Becerra et al, ASCO 2019

* Data points represent the mean log VCN for each cohort and the dotted red line represents rimiducid administration at Day 7; † Patient 3 in cohort 5A did not have data for time points beyond Day 4 and thus is not included in the summary of cell persistence.

Cy, cyclophosphamide; Flu, fludarabine; LOQ, limit of quantitation; pts, patients; Rim, rimiducid.

BPX-601: Evidence of Anti-Tumor Activity

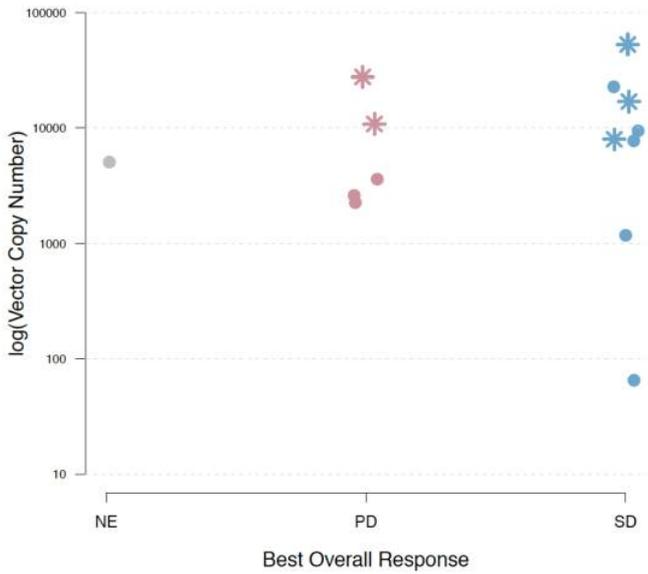


* Right arrow cap indicates ongoing treatment-free interval; † Patient withdrew consent for further follow-up; ‡ Patient 2 was not efficacy evaluable due to non-measurable disease at baseline.
 PD, progressive disease; pseudo, pseudoprogression; SD, stable disease.

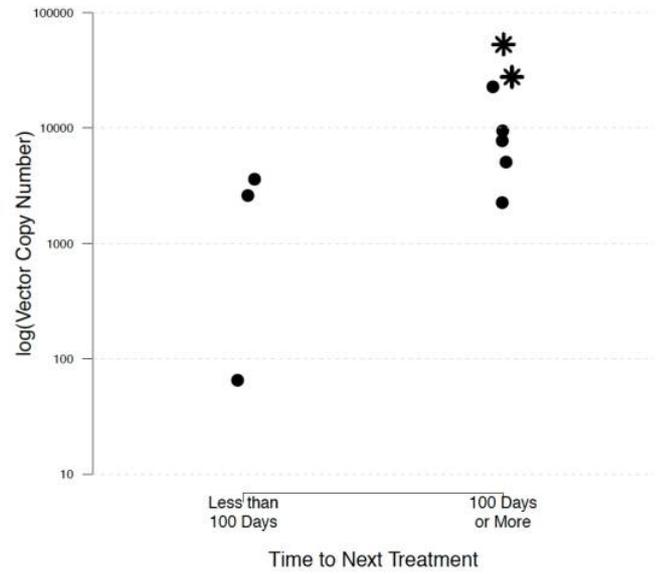
- 8 (62%) of 13 evaluable patients treated with BPX-601 and single-dose cyclophosphamide achieved stable disease and 10-24% had tumor shrinkage
- With 9.1 weeks median follow-up (range: 2.5-30.3), median time to next therapy in patients that received subsequent treatment was 16.6 weeks (range 5.6-30.3)
- In Flu/Cy cohort, 2 patients with >median follow-up had time to next treatment >22 weeks (ongoing)

BPX-601: Clinical Activity and VCN Trends

Peak Vector Copy Number vs Best Overall Response



Peak Vector Copy Number vs Time to Next Tx



* Indicates subject in Flu/Cy Cohort 5B. Only subjects with >100 days of follow-up included in right panel

BPX-603 Dual Switch GoCAR-T Targeting HER2

Product Summary

- HER2 is a validated tumor antigen and is expressed on numerous solid tumors with high unmet need
- Historical HER2 CAR-T studies have shown modest overall activity and off-tumor / on-target toxicity
- BPX-603 may address these limitations
 - iMC may increase cell proliferation & persistence, modulate the TME, and enhance host immunity
 - CaspaCIDE may mitigate treatment emergent toxicities

Unmet Need

Indication	Incidence ¹	HER2 ⁺	5-year (Stage)
Gastric	28,000	10-30% ³	<20%
Colorectal	145,000	10% ⁴	<15%
Ovarian	22,000	20-30% ⁵	<30%
Uterine/ Endometrial	61,000	50-80% ⁶	14-69%
Glioblastoma	12,000	20-30% ²	<20%

¹National Cancer Database, American Cancer Society, <https://www.cancer.org>, accessed 21 December 2018; ²Liu et al., Cancer Res 2004; ³Gravalos et al., Annals Oncol 2008; ⁴Tu et al., Exp Ther Med 2018; ⁵Berchuck et al., Cancer Res 1990, Bartlett et al., Brit J Cancer 1996; ⁶Grushko et al., Gynecologic Oncol 2008

Historical HER2 Studies: Modest Clinical Outcomes

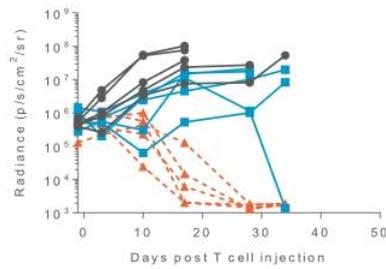
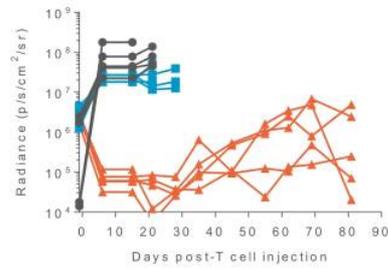
Study Properties	Morgan, 2010	Ahmed, 2015	Feng, 2017	Ahmed, 2017	Hegde, 2019
Construct	4D5-28-BB-z	FRP5-28-z	Her2-BB-z	FRP5-28-z	FRP5-28-z
Indication(s)	Metastatic colon	Sarcomas	CCA and PCa	GBM	Sarcomas
Patient number	1	19	11	17	10
HER2 expression	≥2+ (IHC)	≥1+ (IHC)	>50% positive	≥1+ (IHC)	≥1+ (IHC)
CAR-T dose	10 ¹⁰	10 ⁴ - 10 ⁸	10 ⁶	10 ⁶ - 10 ⁸	10 ⁸
CAR-T expansion	NE	Negligible	>1,000 copies	Negligible	>10,000 copies
Toxicity	Lung reactivity	No DLTs	Mild AEs	Mild AEs	Mild AEs
Outcome	Grade 5 toxicity	1 PR	1 PR	1 PR	2 CR
Total Responses	2 CR, 3 PR, 5/58 (8.6% ORR)				

BPX-603 Pre-Clinical Studies Demonstrate Potential Clinical Benefits

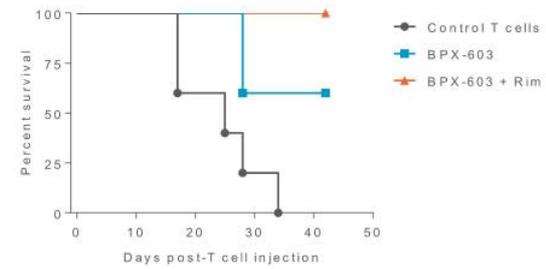
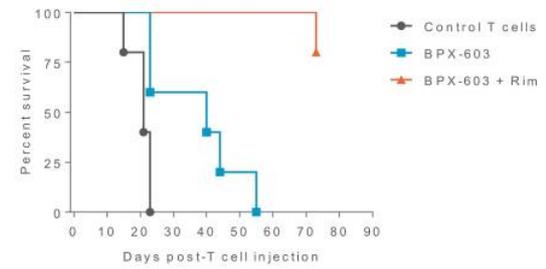
HER2⁺ A549
Lung Carcinoma
(1x10⁴ T cells)

HER2⁺ OE19
Esophageal Carcinoma
(5x10⁶ T cells)

Tumor growth



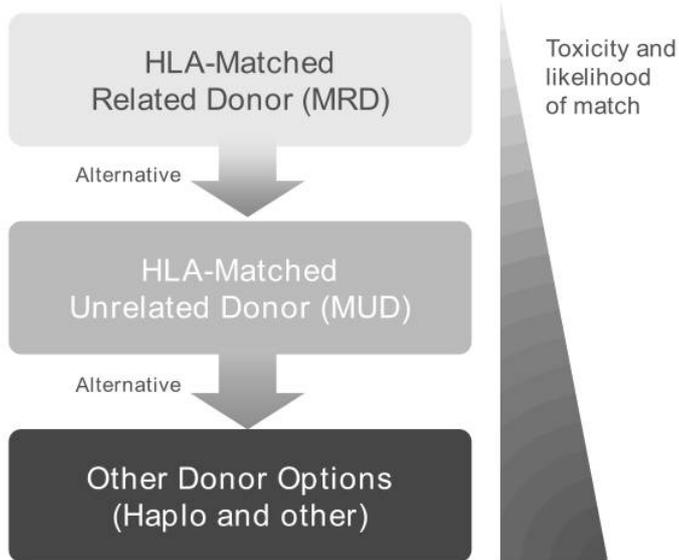
Survival



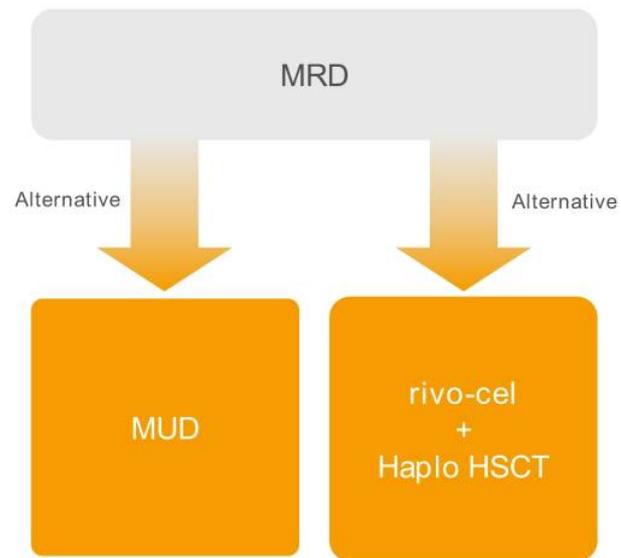
RIVO-CEL

Rivo-cel: Opportunity To Transform Treatment Paradigm

Current HSCT Treatment paradigm



Potential Future HSCT Treatment Paradigm



BP-004 Study: Basis for European Pediatric Approval

Phase 1/2 study of rivo-cel in pediatric patients following TCR $\alpha\beta$ depleted allo-HSCT

High risk pediatric malignancies and non-malignant disorders



$\alpha\beta$ T-cell and B-cell depleted haplo-HSCT without GvHD Prophylaxis



Rivo-cel



Rimiducid for patients who develop visceral GvHD or are refractory to SOC treatment

Enrolled Populations

N = 249 (EU and US Patients)

Malignant (N = 117)	Non-Malignant (N = 132)
Diagnosis	Diagnosis
Acute lymphocytic leukemia (ALL)	Primary Immune Deficiencies
Acute myeloid leukemia (AML)	β Thalassemia Major
Other	Other Erythroid Disorders
	Bone Marrow Failure Disorders

Outcomes

Rivo-cel:

- Event-free survival at 180 days (regulatory endpoint)
 - TRM/NRM, severe GvHD, and life-threatening infections
- Progression-free survival
- Disease status

Rimiducid:

- GvHD response



TRM, transplant-related mortality; NRM, non-relapse mortality; GvHD, graft versus host disease; SOC, standard of care; HSCT, hematopoietic stem cell transplantation. ClinicalTrials.gov Identifiers: NCT01744223, NCT02065869.

Rivo-cel Met Primary Endpoint for EU Registrational Clinical Trial BP-004 ¹

All pre-specified key secondary endpoints also demonstrated non-inferiority

- Primary endpoint of non-inferiority for event free survival (EFS) at 180 days of 90.9% (95% CI: 84.8, 94.6) achieved for patients receiving haplo-transplant
 - Composite EFS endpoint consisted of transplant-related or non-relapse mortality, severe graft-versus-host-disease (GvHD) and life-threatening infections
- Compared to patients who received a MUD HLA 10/10 transplant in C/CP-004 comparator trial with EFS at 180 days of 89.9% (95%CI: 82.4, 94.3)
- Key secondary endpoints including transplant related mortality, GvHD, relapse-free survival, and disease-free survival also demonstrated non-inferiority
- Adding rivo-cel to stem cell transplants in patients lacking a matched donor show comparable outcome to HLA-matched unrelated donor (MUD) transplants and may allow it to become an alternative therapy for these patients

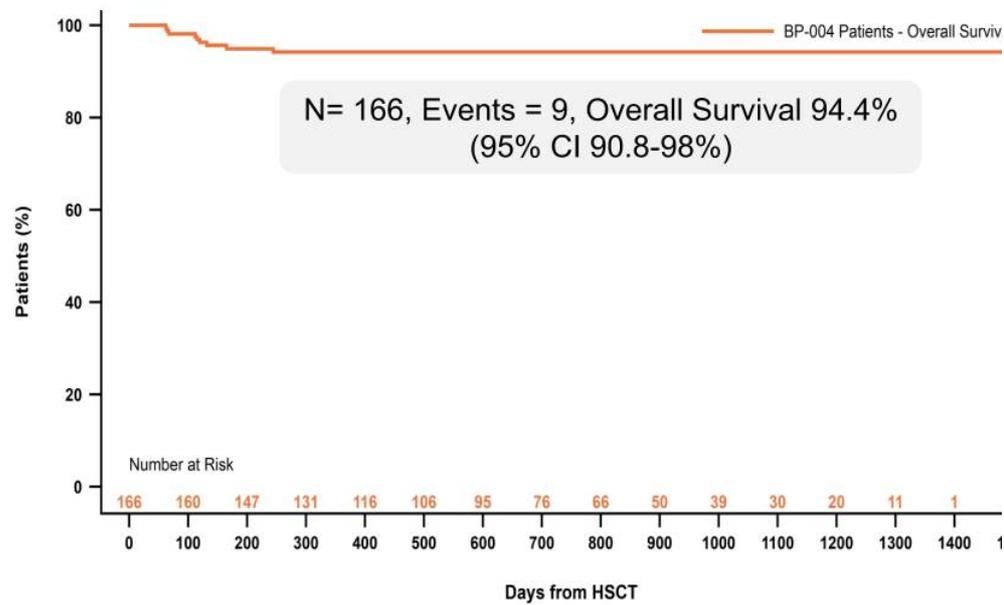
¹ | Topline results announced for BP-004 in July 8, 2019 news release

Rivo-cel: High Rates of Disease-Free and Overall Survival

Interim survival results¹

With median follow-up of 20.3 months (0.5 – 47.4 months):

- Relapse-free survival 82.9% in malignant patients
- Disease-free survival 95.2% in non-malignant patients



HSCT, Hematopoietic Stem Cell Transplantation

¹ Data presented at 60th ASH Annual Meeting – December, 2018

Rivo-cel: High Rates of GvHD Response to Rimiducid

Interim results¹ of response in patients refractory to standard of care treatment

Methods & Evaluable Population

Patients who developed visceral GvHD or were refractory to SOC treatment were eligible to receive ≥ 1 dose (up to 3 at 48 hour intervals) of rimiducid (0.4 mg/kg)

Of 238 GvHD-evaluable patients:

- 35.7% (85/238) experienced any grade acute or chronic GvHD
- 28.2% (24/85) of patients with GvHD received rimiducid

Efficacy Results

Best overall response of 70% 7 days post-rimiducid

- 9 CR and 7 PR
- Median time to response of 1 day (1 - 4 days)

Four patients in PR or not evaluable at day 7 achieved CR within 30 days post-rimiducid

Translational Results

Reduction in rivo-cel serum level observed in all patients receiving rimiducid²

Rimiducid eliminates the most highly activated rivo-cel T cells which express the highest level of iC9³, leaving remaining cells to re-expand

- 79% (11/14) malignant patients receiving rimiducid remain relapse free



GvHD: acute graft versus host disease; SOC, Standard of Care; PR, Partial Response; CR, Complete Response, ¹ Data presented at 60th ASH Annual Meeting – December, 2018, ² N = 10 with translational data at time of interim, ³ Zhou et al. ASH 2018, a3496

Rivo-cel Addresses Key Shortcomings

Rivo-cel addresses shortcomings of stem cell transplants to treat hematological malignancies and inherited blood disorders

		Rivo-cel Target Market			
% of Current Market		Matched Related Donor (MRD) 25-30%	Matched Unrelated Donor (MUD) ~50%	Haplo and Other ~20-25%	Rivo-cel +HSCT
Leading Causes of Mortality and Morbidity	Disease Relapse	●	●	●	✓ ●
	Infection	●	●	●	✓ ●
	GvHD	●	●	●	✓ ●
Likelihood to Find Donor		Low	Low-Medium	High	✓ High
Time to Identify Donor		Short	Long	Short	✓ Short

Rivo-cel: Significant Market Opportunity

Potential List Price

Patient Population

Market Opportunity

Additional Opportur



- Geographic expansion
 - U.S. Pediatric
 - Asia
- Patient population growth
- Expansion of HSCT eligibility
- Development in other malignancies



*As of 2016. EBMT Transplant Activity Survey; CIBMTR Current Uses & Outcomes of HCT; internal company analysis
Market share expectations represented by green (strong) and yellow (moderate)

Anticipated 2H'19 and 2020 Key Program Milestones

	Milestone	Timing
BPX-601	Presentation of updated Phase 1 results with repeat rimiducid dosing	Q4'19 / Q1'20
	Updated Phase 1 and Phase 2 results	2020
CAR-T PIPELINE	IND clearance for BPX-603	2H'19
	IND submission for BPX-802	Late 2019
	BPX-603 Phase 1 data	2020
Rivo-cel	MAA submissions for rivo-cel and rimiducid for pediatric patients	Q4'19 / Q1'20
	Potential MAA approval	Q4'20 / Q1'21

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