

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): March 12, 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))

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

In this report, “we,” “us” and “our” refer to Bellicum Pharmaceuticals, Inc.

Item 7.01 Regulation FD Disclosure.

We are furnishing 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.

The information contained in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished pursuant to Item 7.01 and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this item of this report.

By filing this Current Report on Form 8-K, including Exhibit 99.1, and furnishing this information, we make no admission as to the materiality of any information in this report. The information contained in this report is intended to be considered in the context of our filings with the SEC and other public announcements that we make, by press release or otherwise, from time to time. We undertake no duty or obligation to publicly update or revise the information contained in this report, although we may do so from time to time as our management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Slide presentation dated March 12, 2019.

A photograph of a young girl with long brown hair, smiling and holding a large white teddy bear. In the background, a blurred figure of a person in a white lab coat is visible. The image is overlaid with a semi-transparent white circle graphic on the right side.

Investor Presentation

Striving to deliver cures through controllable cell therapy

March 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™ (previous 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 of 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.

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
- Late interim results presented at ASH in Dec. 2018 trend toward meeting primary endpoint
- Expect topline data in 1H 2019; MAA filings in 2H 2019
- European HQ and leadership team in place for commercialization prep

Global trial underway to broaden label

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

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, gastric and prostate cancers
- Initial safety data on 12 pancreatic patients presented at ESMO-IO in Dec. 2018 indicate attractive safety profile and early clinical activity
- Trial amendments to lymphodepletion regimen and activation molecule administration to enhance potential clinical response

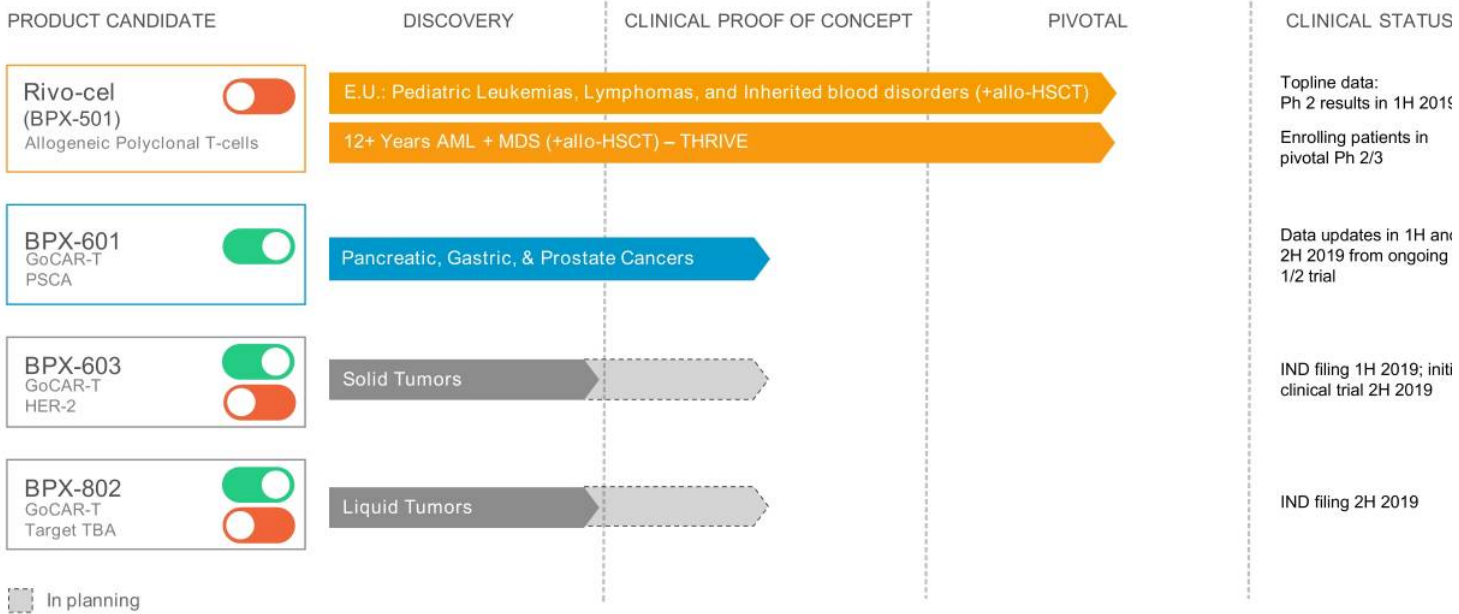
Two dual-switch GoCAR-T candidates to IND in 2019

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

Cash of \$98.0MM as of December 31, 2018; Cash Runway Through 2019

Development Pipeline: Rivo-cel and GoCAR-T

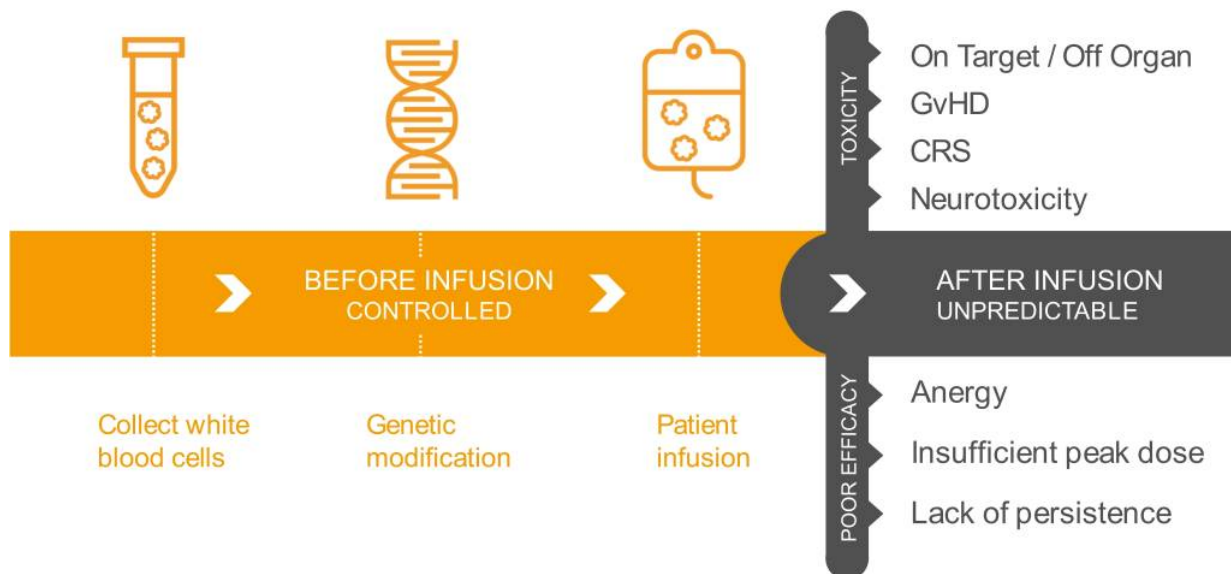
Controllable cell therapies that may represent major advances in liquid and solid tumors



Technology Overview

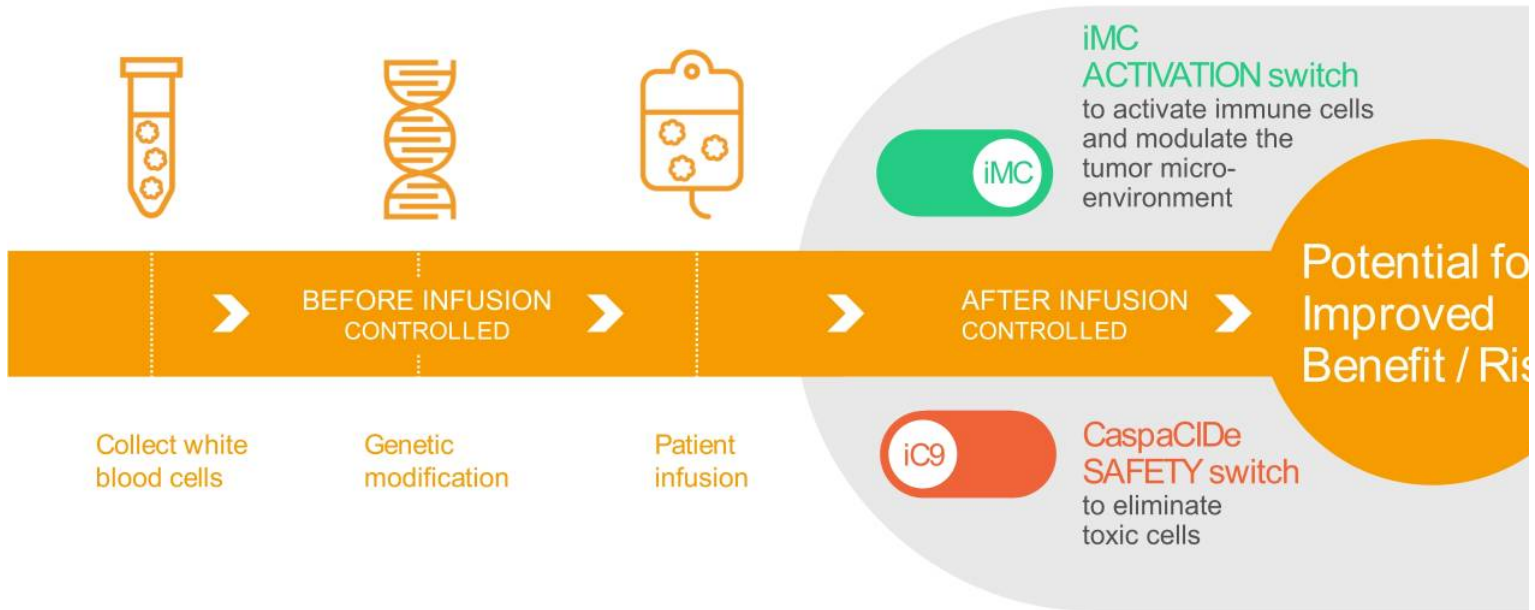
Most Cell Therapies Only Controlled Before Infusion

Limited ability to expand a narrow therapeutic window



Bellicum Platform Enables Control After Infusion

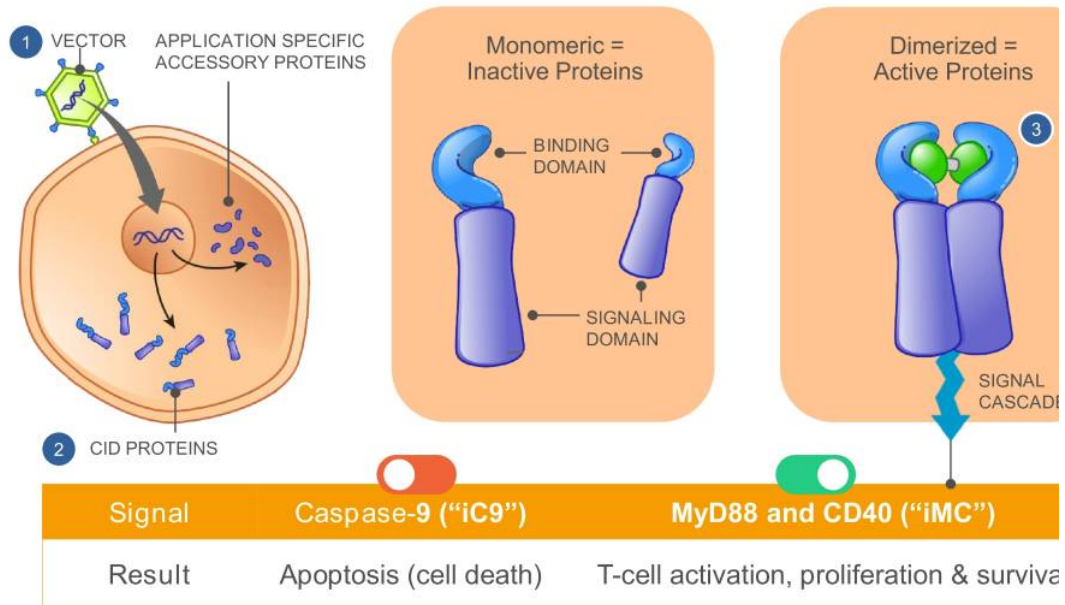
Provides physicians ability to expand the therapeutic window in each patient



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 rapidly eliminates a majority of CAR-T cells to manage acute toxicities

BPX-601 GoCAR-T Targeting Prostate Stem Cell Antigen

Product Summary

- Attractive first-in-class solid tumor CAR-T opportunity
- First-in-human experience with iMC
- Initial Phase 1 results presented in Dec 2018 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)

	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

	Cohort 0 (Lead-in)	Cohort 3	Cohort 4	Cohort 5a	Cohort 5b	Next Cohort
Patient Population	3L+ Pancreatic			2L Pancreatic 2L Gastric HR-Refractory Prostate		2L Pancreatic 2L Gastric HR-Refractory Prostate
BPX-601 Dose x10 ⁶ cells/kg @ Day 0	1.25	1.25	2.5	5.0		5.0
Rimiducid Dose mg/kg @ Day 7	None	Single Dose	Single Dose	Single Dose		Scheduled Repeat Dosing
Conditioning	Cytoxan 1g/m ² @ Day -3			Cytoxan 1g/m ² @ Day -3	Cytoxan 0.5g/m ² Fludarabine 30mg/m ² @ Days -5, -4, -3	Cytoxan 0.5g/m ² Fludarabine 30mg/m ² @ Days -5, -4, -3
Status	Enrolled			Active		Pending



ClinicalTrials.gov Identifier: NCT02744287

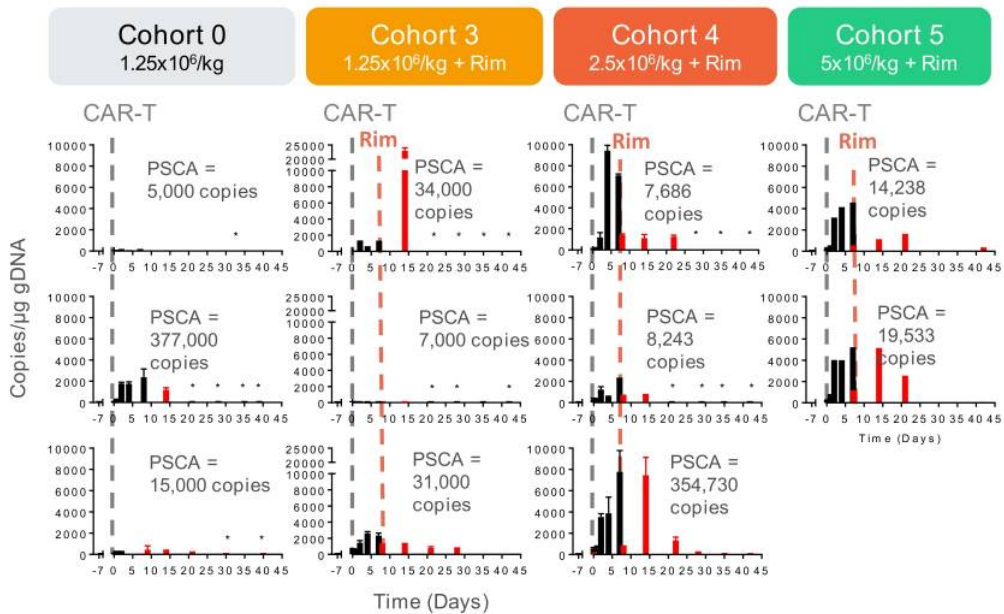
BPX-601: No Dose Limiting Toxicities Observed

Data presented at ESMO Immuno-Oncology Congress 2018 – clinical cut-off October 29, 2018

Most common AEs reported by > 1 patient	Total (N=12)
Any Event, n (%)	12 (100)
Fatigue	4 (33)
Abdominal pain upper	3 (25)
Hypotension	3 (25)
Abdominal pain	2 (17)
Back pain	2 (17)
Diarrhea	2 (17)
Flatulence	2 (17)
Nausea	2 (17)
Pyrexia	2 (17)

- No dose limiting toxicities were observed
- Pyrexia was the only treatment-related AE reported by >1 patient (n=2)
 - Grade 1–2 on Day 0 following BPX-601 infusion
 - Both events resolved within 24–36 hours with supportive care

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



- Limited evidence of LD with CTX-only regimen (79% ± of cells remained)
- Rapid cell expansion by Day 10 but no persistence without
- With single-dose Rim:
 - Cell expansion of 3 to 20- within 7 days in 4 patients
 - Cell persistence of >3 weeks in 3 patients



* Vector copy number < limit of quantification.
 CTX, cyclophosphamide; LD, lymphodepletion; PSCA, prostate stem cell antigen; Rim, rimiducid.

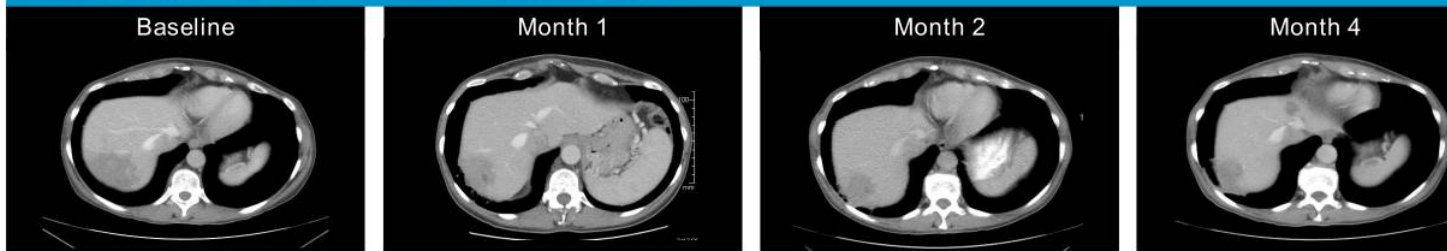
BPX-601: Evidence of Anti-Tumor Activity

Cohort	Best Response (RECIST)			
	CR	PR	SD	PD
0	0	0	1	2
3	0	0	2	1
4	0	0	2	1

Two patients with SD had tumor shrinkage >20%

Disease control without new therapies: 16 and >18 weeks in 1 and 3 patients, respectively

Patient 3A | 2 prior therapies; PSCA = 34,000 copies



- | | | | |
|---|--|---|---|
| <ul style="list-style-type: none"> ▪ Lesion longest diameter: 70 mm ▪ CA19-9: 294 | <ul style="list-style-type: none"> ▪ Lesion longest diameter: 57 mm ▪ CA19-9: 152.6 ▪ Overall response: SD (-15%) | <ul style="list-style-type: none"> ▪ Lesion longest diameter: 49 mm ▪ CA19-9: 207.2 ▪ Possible new lesion ▪ Overall response: SD (-25%) | <ul style="list-style-type: none"> ▪ Lesion longest diameter: 40 mm ▪ CA19-9: 641.4 ▪ New lesion confirmed ▪ Overall response: PD |
|---|--|---|---|



CA19-9, cancer antigen 19-9; CR, complete response; PD, progressive disease; PR, partial response; PSCA, prostate stem cell antigen; SD, stable disease.

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; ²Lui et al., Cancer Res 2004; ³Gravolos 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

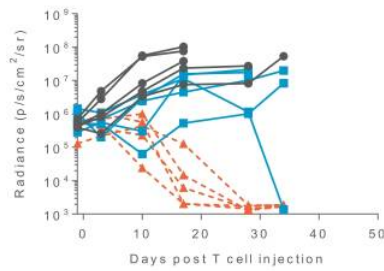
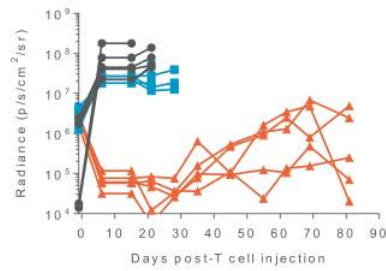
Study Properties	Morgan, 2010	Ahmed, 2015	Hegde, 2017	Feng, 2017	Ahmed, 2017
Construct	4D5-28-BB-z	FRP5-28-z	FRP5-28-z	Her2-BB-z	FRP5-28-z
Indication(s)	Metastatic colon	Sarcomas	Sarcomas	CCA and PCa	GBM
Patient number	1	19	6	11	17
HER2 expression	≥2+ (IHC)	≥1+ (IHC)	≥1+ (IHC)	>50% positive	≥1+ (IHC)
CAR-T dose	10 ¹⁰	10 ⁴ - 10 ⁸	10 ⁸	10 ⁶	10 ⁶ - 10 ⁸
CAR-T expansion	NE	Negligible	>10,000 copies	>1,000 copies	Negligible
Toxicity	Lung reactivity	No DLTs	Mild AEs	Mild AEs	Mild AEs
Outcome	Grade 5 toxicity	1 PR, 3 SD, 13 PD	2 CR, 2 SD	1 PR, 5 SD	1 PR, 7 PD
Total Responses	2 CR, 3 PR, 5/54 (9.3% ORR)				

BPX-603 Pre-Clinical Studies Demonstrate Potential Clinical Benefits

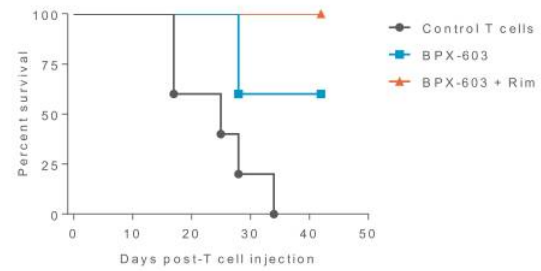
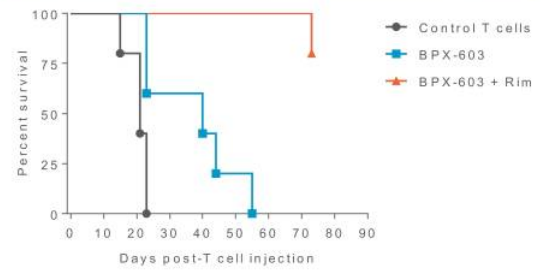
HER2⁺ A549
Lung Carcinoma
(1x10⁴ T cells)

HER2⁺ OE19
Esophageal Carcinoma
(5x10⁶ T cells)

Tumor growth

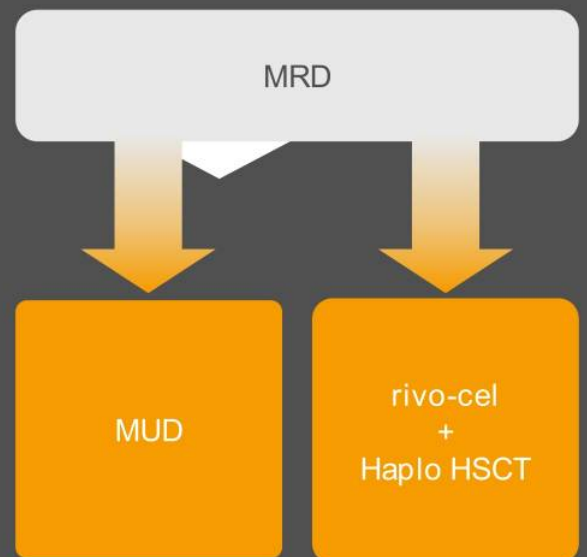
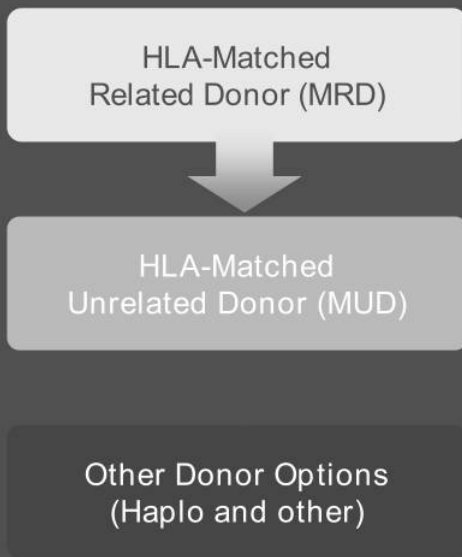


Survival



RIVO-CEL

Potential Future HSCT Treatment Paradigm



Rivo-cel Addresses Key Shortcomings

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

% of Current Market		Rivo-cel Target Market			Rivo-cel +HSCT
		Matched Related Donor (MRD) 25-30%	Matched Unrelated Donor (MUD) ~50%	Haplo and Other ~20-25%	
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	

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	
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

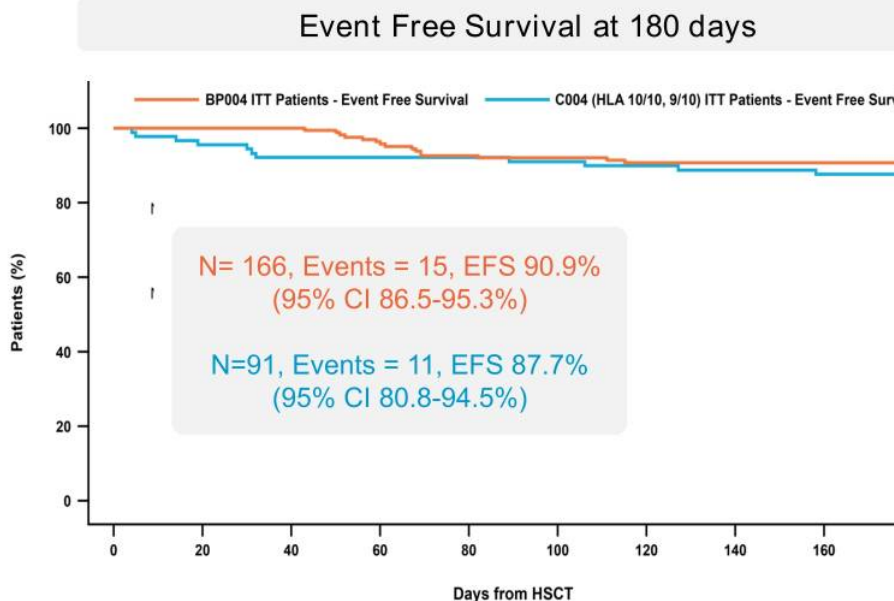


TRM, transplant-related mortality; NRM, non-relapse mortality; GvHD, graft versus host disease; SOC, standard of care; HSCT, hematopoietic stem cell transplantation. ClinicalTrials.gov Identifiers: NCT01744223, NCT02065869.

Rivo-cel Interim Results Trend Towards Meeting Primary Endpoint

Interim six-month event-free survival comparable to MUD HSCT

- C-004 is an observational trial of pediatric patients with malignant (67%) or non-malignant (33%) disease who underwent a MUD HSCT
- Non-inferiority of rivo-cel EFS at 180 days to MUD HSCT is required for EMA approval
- Full analysis with statistical comparisons of patients who received rivo-cel or a MUD HSCT planned for 2019



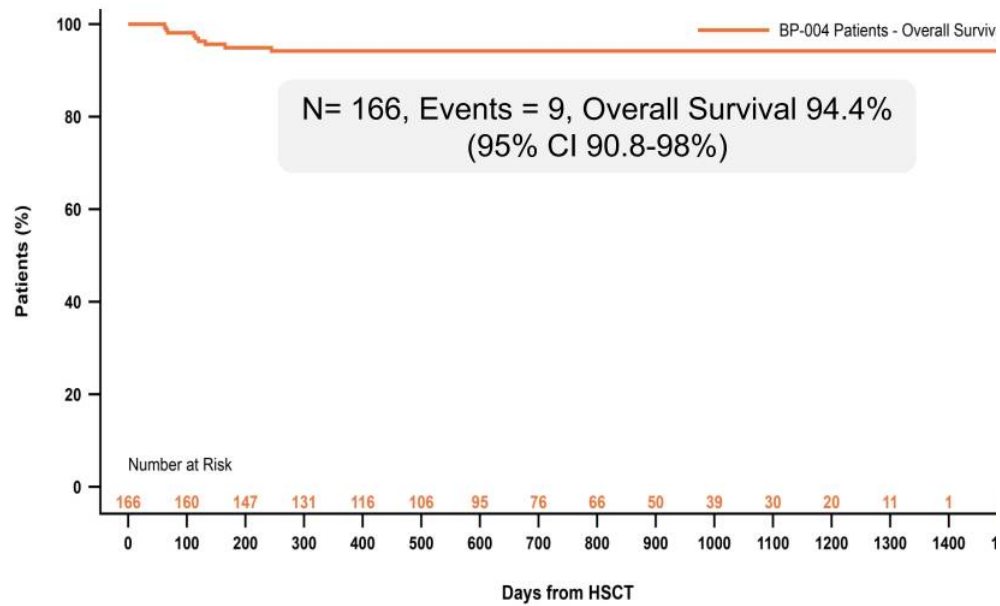
EFS, event free survival; MUD, matched unrelated donor; HSCT, Hematopoietic Stem Cell Transplantation
Data presented at 60th ASH Annual Meeting – December, 2018

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

Interim survival results

With median 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



Rivo-cel: High Rates of GvHD Response to Rimiducid

Interim results 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 rimiducid¹

Rimiducid eliminates the most highly activated rivo-cel T cells which express the highest level of iC9², leaving remaining cells to re-expand

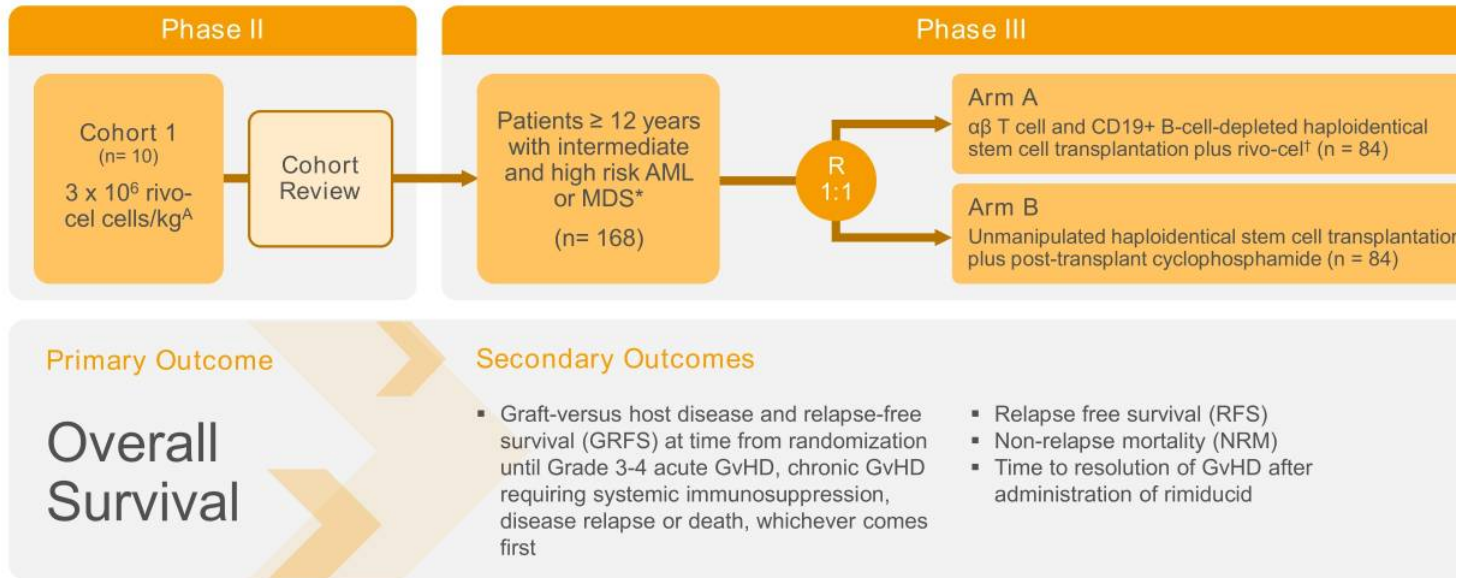
- 79% (11/14) malignant patients receiving rimiducid remain relapse free



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

THRIVE: Registrational Trial in Adults & Adolescents

Phase 2/3 study of rivo-cel in intermediate and high risk AML & MDS in patients 12+ years old



A If dose level 1 exceeds the MTD, alternative dose levels (dose level -1: 1 x 10⁶ BPX-501 cells/kg) will be explored

† No GvHD prophylaxis will be given. Rimiducid will be administered to inactivate rivo-genecleucel (rivo-cel) in the event of GVHD not responsive to standard of care treatment

Updated 8 Nov 2018. Clinicaltrials.gov identifier: NCT03699475

Rivo-cel: Significant Market Opportunity

Potential List Price

Patient Population

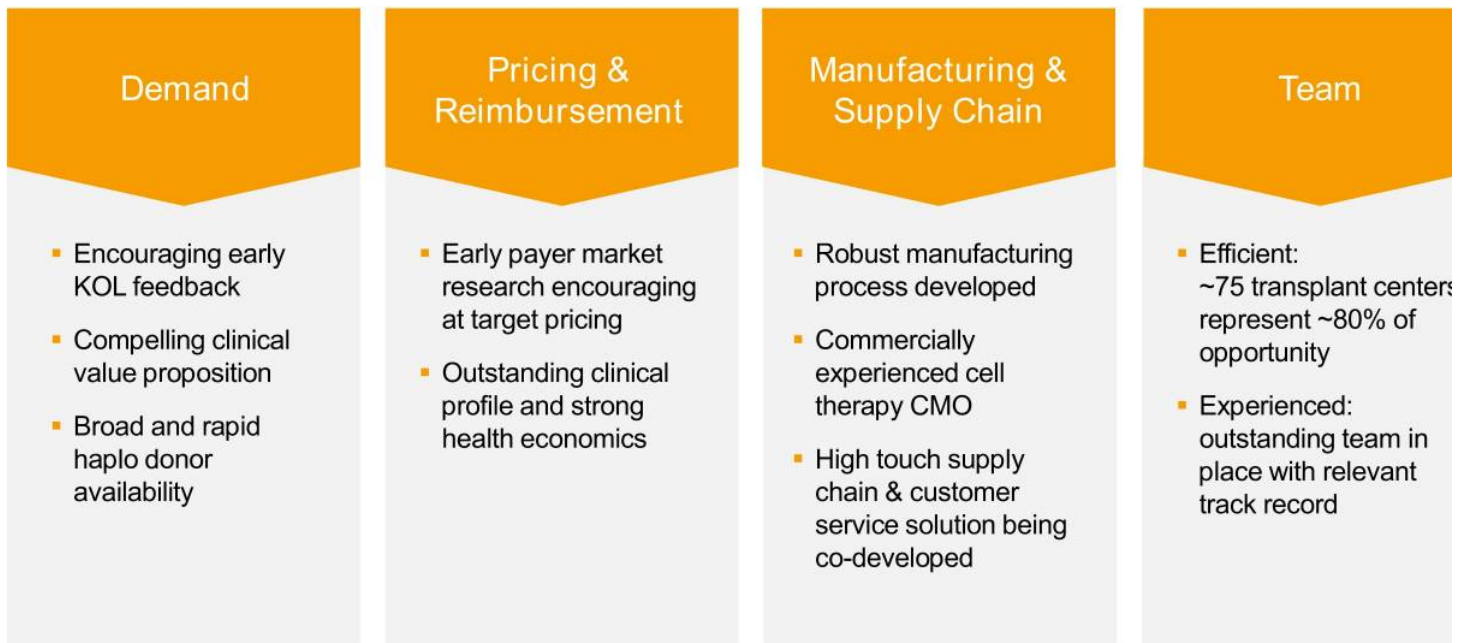
Market Opportunity

Additional Opportur



*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)

Rivo-cel: Significant Opportunity for EU Pediatric Launch



Execution of Key Objectives

Bellicum Leadership Team



Rick Fair
President & CEO



William Grossman
Chief Medical Officer



Atabak Mokari
Chief Financial Officer



Gregory Naeve
Chief Business Officer



Aaron Foster
Senior Vice President
Head of Research



Alan Smith
Exec. Vice President
Tech Operations



Shane Ward
General Counsel &
Corporate Secretary



Thierry Darcis
General Manager, Europe



Substantial Progress Achieved in 2018

Delivered on commitments and strengthened the organization

2018 To-Do List	
BPX-601	Complete enrollment in cell dose escalation portion of BP-012 Phase 1/2 study
	Present initial clinical data at medical meeting
Rivo-cel	Complete enrollment & present IA on BP-004 and C/CP-004 comparator studies
	Initiate Phase 2/3 study in adult & adolescent AML & MDS
	Confirm pediatric approval pathway in US
	Initiate commercial launch preparation in Europe
BPX-701	Present initial clinical data at medical meeting
PIPELINE	Complete dual-switch constructs for two new GoCAR-T candidates
ORG	Complete build-out of Houston cell & viral vector manufacturing facility
	Establish site in San Francisco Bay Area and European HQ
	Strengthen the leadership team

Anticipated 2019 and 2020 Key Program Milestones

	1H'19	2H'19	2020
BPX-601	<p>Presentations of updated Phase 1 results (Cy/flu regimen)</p> <p>Amend BP-012 to allow for scheduled dosing of rimiducid to reactivate iMC</p>	<p>Presentation of updated Phase 1 results (repeat rimiducid dosing)</p>	<p>Updated Phase 1 and Phase 2 results</p>
CAR-T PIPELINE	<p>IND submission for BPX-603</p>	<p>First patient treated in BPX-603 Phase 1 trial</p> <p>IND submission for BPX-802</p>	<p>BPX-603 Phase 1 data</p> <p>BPX-802 Phase 1 data</p>
Rivo-cel	<p>Final analyses of BP-004 and C/CP-004 trials</p>	<p>MAA submissions for rivo-cel and rimiducid for pediatric patients</p>	<p>MAA Approval</p> <p>THRIVE Phase 2 interim data</p>

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