
**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): September 13, 2021

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.)

3730 Kirby Drive, Ste. 1200, Houston, TX 77098
(Address of principal executive offices, including 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 Capital 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

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 8.01 Other Events.

On September 13, 2021, Bellicum Pharmaceuticals, Inc. made available on its website an updated corporate presentation. A copy of the corporate 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	Corporate presentation.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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.

Bellicum Pharmaceuticals, Inc.

Dated: September 13, 2021

By: /s/ Richard A. Fair
Richard A. Fair
President and Chief Executive Officer
(Principal Executive Officer and Financial Officer)

Investor Presentation

Building a powerful new future in cellular IO

September 2021



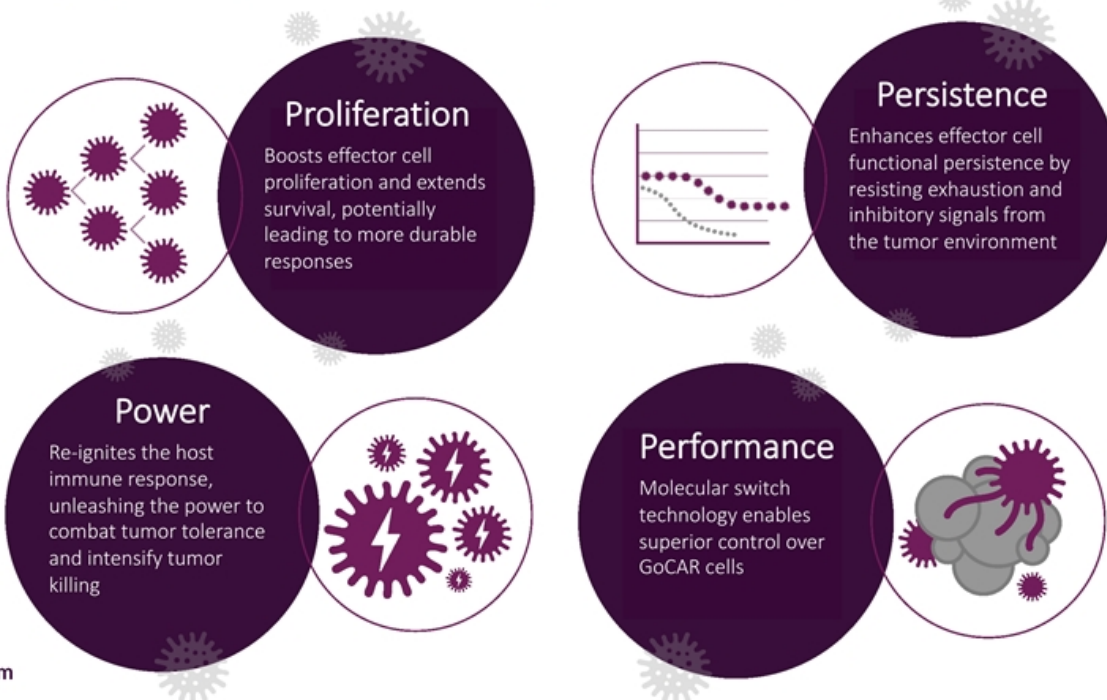
Forward Looking Statement

This presentation contains estimates, projections and other forward-looking statements, concerning, among other things: our research and development activities relating to our GoCAR™ platform, our CaspaCIDE safety switch, and related technologies; our product candidates including BPX-601, BPX-603, and rimiducid; the timing and success of our current and planned clinical trials, including the timing of receipt of data from such clinical trials and the timing of our reports of such data; the possible range of applications of our cell therapy programs and potential curative effects and safety in the treatment of diseases, including as compared to other treatment options and competitive therapies; our expected cash runway; and the potential to expand the use of our switch technology through additional license opportunities. Our estimates, projections and other forward-looking statements are based on 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, 2020 and our quarterly report on Form 10-Q for the period ended June 30, 2021.

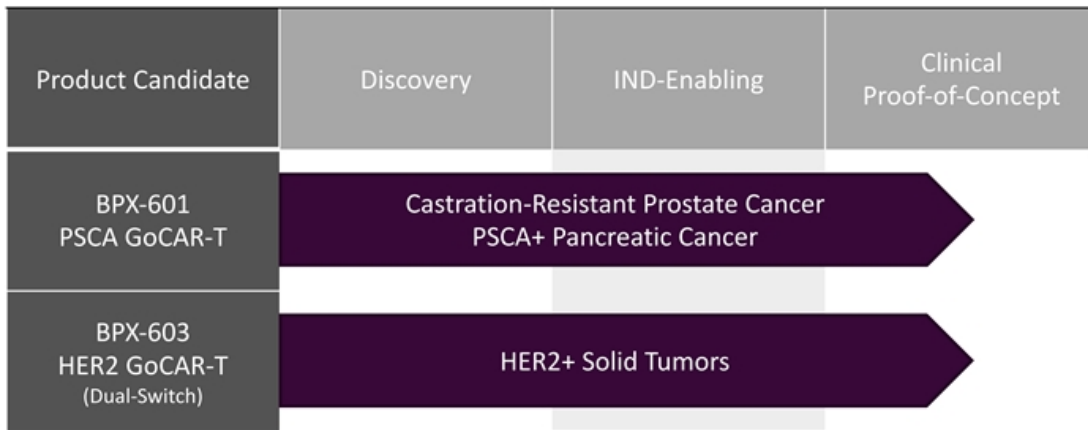
Building a Powerful New Future in Cellular IO

Our GoCAR platform is engineered to break through the limitations of current cell therapies



Product Pipeline

Establishing the clinical value of GoCAR-T in solid tumors to propel cellular IO forward

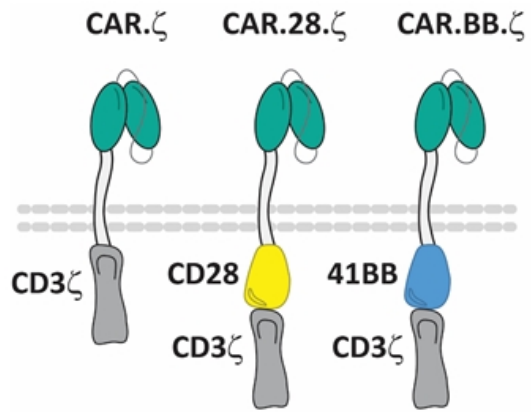




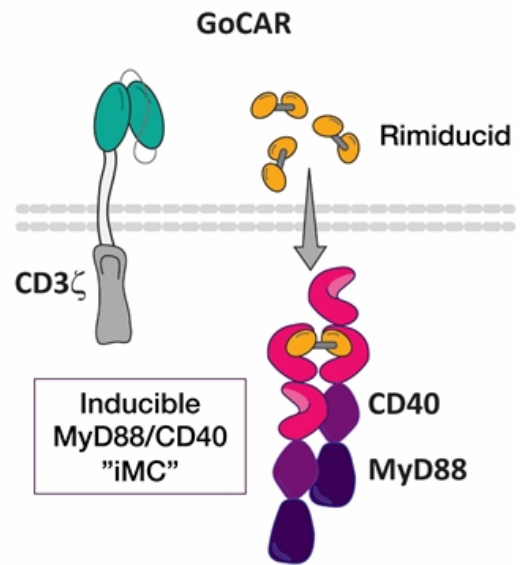
Technology Overview

GoCAR: Differentiated Technology Platform

Current Generation CAR Technology

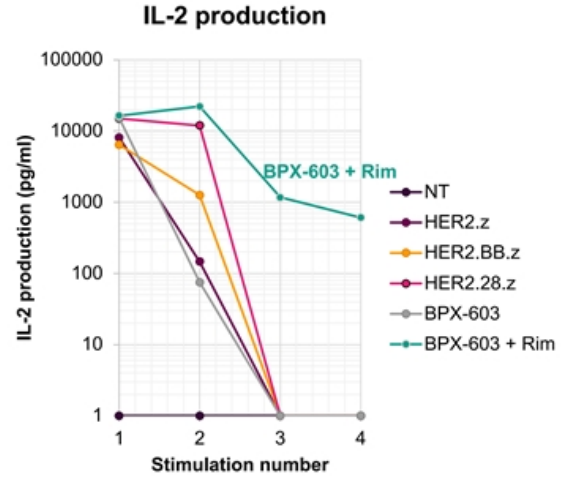
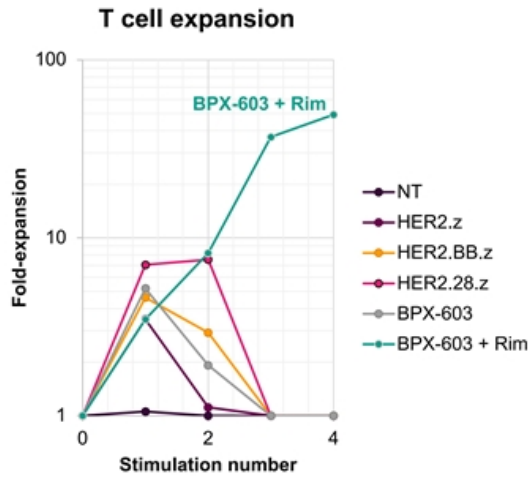
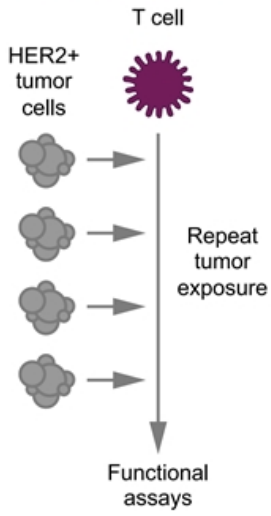


Next Generation GoCAR Technology



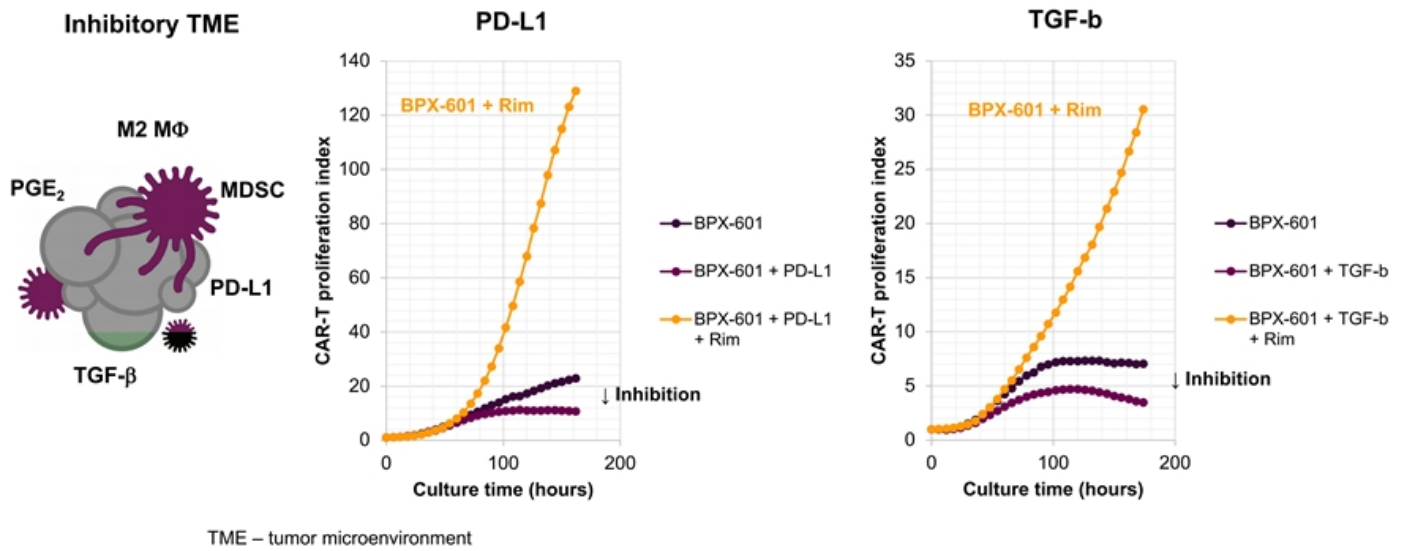
GoCAR Proliferation: Superior Expansion and Resistance to T Cell Exhaustion

iMC activation limits T cell dysfunction in repeat tumor stimulation exhaustion assay



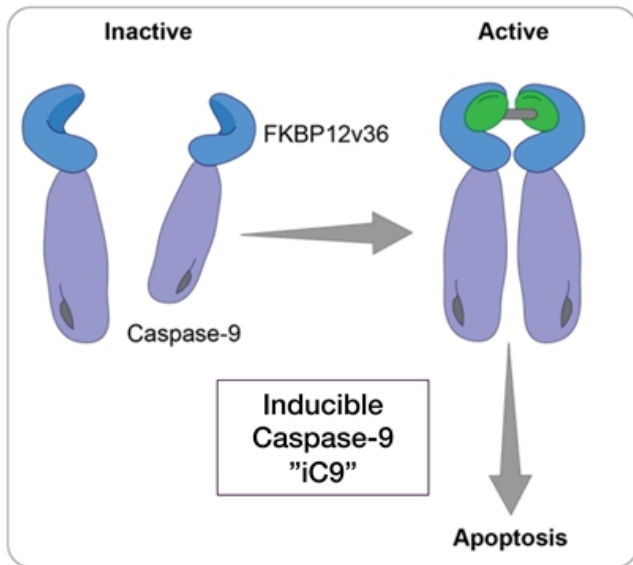
GoCAR Persistence: Resistance to Immune Suppressive TME

iMC overrides common inhibitory molecules in the tumor microenvironment



CaspaCIDE Safety Switch

Inducible apoptosis to mitigate cell therapy-mediated adverse events



Potential Applications

- Controlling toxicity associated with cell therapies
 - Cytokine Release Syndrome
 - ICANS
- Targeting antigens with known or potential high-risk side effects
- Developing next-generation, higher-potency cell therapy constructs
- Managing GvHD associated with adoptive T cell therapy with allogeneic T cells

Clinical Experience with CaspaCIDE (iC9)

Experience from Rivo-cel Program¹

24 pediatric haplo-HSCT patients experienced advanced or steroid-refractory GvHD from iC9-containing allogeneic T cells and received rimiducid to trigger iC9

70% Overall Response Rate* (n=24)

Median Time to Response
1 Day (Range 1-4 Days)

Immunological Response

- All evaluable patients receiving rimiducid had reduction in circulating rivo-cel cells
- Majority of reduction observed within 4 hours

Four additional patients achieved CR by Day 30

* Evaluated at Day 7 post-rimiducid administration

CAR-T Case Report from University of North Carolina²

26-year-old female with relapsed B-ALL received CD19.iC9 CAR-T; received rimiducid to treat refractory ICANS

Rapid Results After Rimiducid Administration

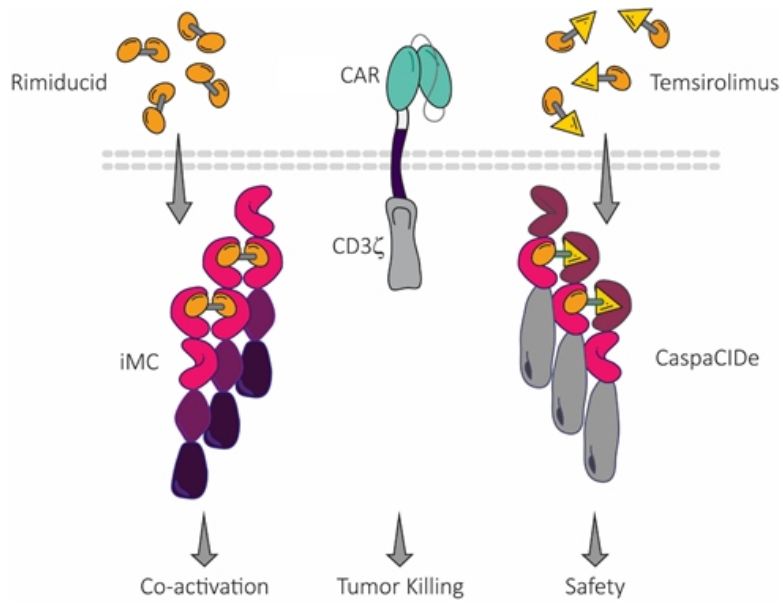
- >80% reduction in CAR-T transgene copies within 4 hours
- ICANS improvement to Grade 1 within 12 hours



1. Elkeky, et al, *Blood* (2018) 132 (Supplement 1): 2207.
 2. Matthew C. Foster, et al; Utility of a safety switch to abrogate CD19.CAR T-cell-associated neurotoxicity. *Blood* 2021; 137 (23): 3306–3309.

Dual-Switch GoCAR-T

A controllable system to manage CAR-T proliferation, persistence, and safety



Lead Program:
BPX-603
(HER2)



BPX-601 PSCA GoCAR-T

BPX-601 GoCAR-T Targets Solid Tumors Expressing PSCA

Product Profile Summary

- Attractive first-in-class solid tumor CAR-T opportunity
- First-in-human experience with iMC

Program Update

- Initial cell dose escalation, lymphodepletion optimization, and safety assessment of single and repeat-rimiducid dosing in pancreatic cancer complete
- Rimiducid dose escalation in metastatic castration-resistant prostate cancer (mCRPC) ongoing
- Planned presentation of initial mCRPC data in 1Q'22

Unmet Need

Unmet need in mCRPC remains, particularly in patients who have progressed after androgen deprivation therapy and chemotherapy

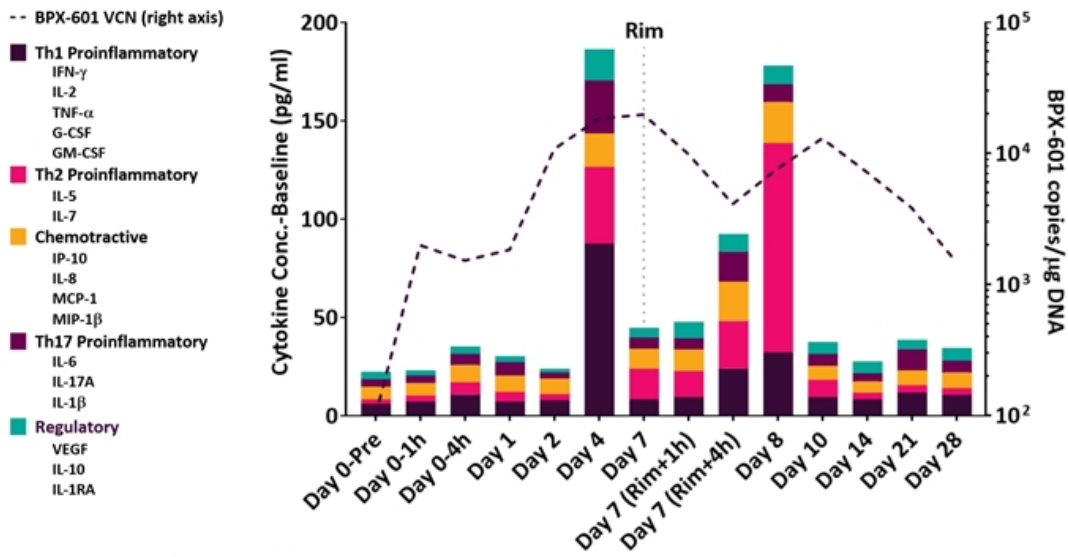
	Annual Incidence (U.S.)*	Annual Deaths (U.S.)	% Expressing PSCA
Prostate	249k	34k	75-90%

* Incidence includes all newly diagnosed prostate cancer

Incidence and annual deaths: American Cancer Society projections for 2021 based on earlier reported SEER data. Source: seer.cancer.gov, August 2021
PSCA expression: Argani et al, Cancer Res 2001; Reiter et al., PNAS 1998; Abate-Daga et al, HGT 2014; Data on file

BPX-601: GoCAR-T Increased Immunomodulatory Cytokines

Infusion of BPX-601 and activation with rimiducid increased immunomodulatory cytokines



- Increases in Th1 and Th2 cytokines were observed with:
 - Administration of BPX-601 GoCAR-T cells
 - GoCAR-T activation with rimiducid

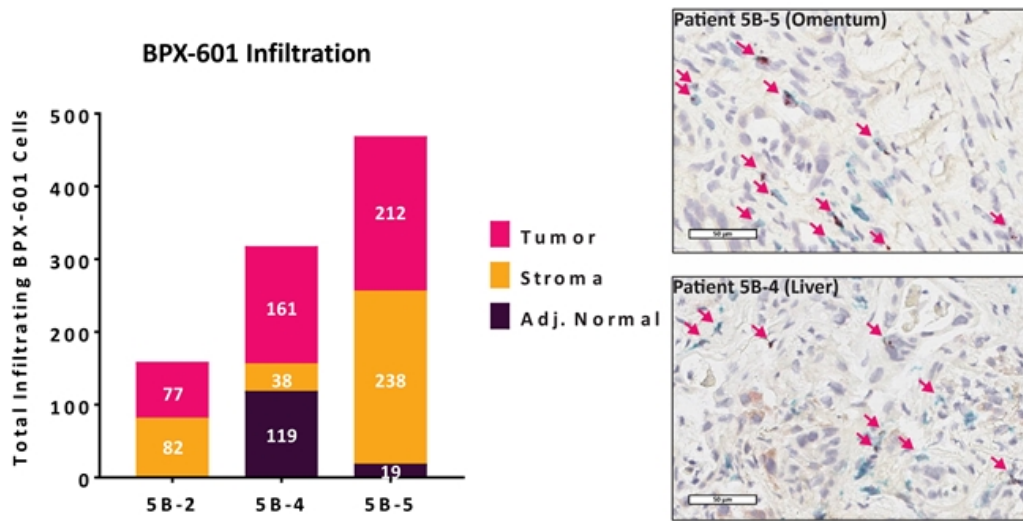


Shaw et al, ASCO GI 2020

Stacked bars represent the summed mean fold-change in concentration of cytokines in each category in patients from Cohort 5B (n=5). Black dotted line represents the mean VCN for Cohort 5B. Gray dotted line represented rimiducid administration on Day 7. Conc., concentration; Rim, rimiducid.

BPX-601: GoCAR-T Tumor Infiltration

On-treatment biopsies taken from metastatic lesions show BPX-601 tumor infiltration



- Analysis of tumor metastases from patients showed:
- Infiltration of BPX-601 GoCAR-T cells
- BPX-601 effectively localized to tumor

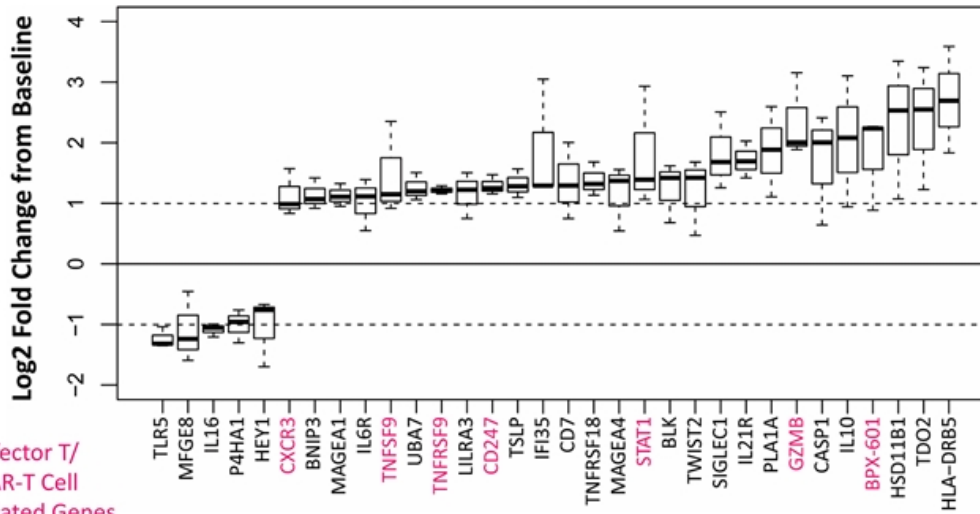
Shaw et al, ASCO GI 2020

(Left) Stacked bars represent the total number of BPX-601 cells quantified in ISH stained tissue sections of available (n=3) biopsies from metastatic lesions of Cohort 5B patients. White numbers in bars indicate the number of BPX-601 cells measured within each ROI.
(Right) Representative images of CD3 (IHC) and BPX-601 (ISH) stained tissue sections of available (n=3) biopsies from metastatic lesions of Cohort 5B patients. Red arrows indicate BPX-601 GoCAR-T cells.
Adj. normal, adjacent normal; ROI, region of interest.

BPX-601: Modulation of Tumor Microenvironment

Changes in gene expression consistent with productive T cell immune responses

Differentially Expressed Genes in Tumor Metastases After BPX-601 + Rim (Cohort 5B, n=3)



Effector T/
CAR-T Cell
Associated Genes



Shaw et al, ASCO GI 2020

Box and whisker plots indicate log2 fold change of genes with altered expression (upregulation or downregulation) while on-treatment (Day 14-21) from paired baseline sample (p-value < 10%). nCounter data using NanoString PanCan IO360 panel.

- Upregulation of T/CAR-T cell associated genes including:
 - GZMB – Target cell killing by cytotoxic T cells
 - CXCR3 – Activated T cell trafficking
 - 41BB(TNFSF9) / 41BBL(TNFRSF9) – T cell costimulation
 - CD3Z (CD247) – TCR Signaling
 - STAT1 – Interferon signaling
 - BPX-601 – Infiltrating GoCAR-T cells

BPX-601: BP-012 Phase 1/2 Study

Dose escalation in relapsed metastatic castration-resistant prostate cancer (mCRPC)

	Planned mCRPC Phase 1 – 3+3 Design*		
	Dose Level 1	Dose Level 2	Dose Levels 3+
Conditioning	Cytosan 0.5g/m ² Fludarabine 30mg/m ² @ Days -5, -4, -3		
BPX-601 @ Day 0	5 x 10 ⁶ cells/kg		
Rimiducid Beginning Day 7	Single Dose 0.4 mg/kg	Weekly 0.4 mg/kg	Escalating Dose

mCRPC Dose Escalation Rationale

- DL1 intended to establish safety in mCRPC at previously cleared dose/schedule in pancreatic cancer
- DL2 intended to establish safety of current rimiducid dose administered weekly
- DL3+ intended to increase rimiducid exposure
 - Non-clinical models demonstrate that increased rimiducid exposure enhances proliferation, persistence, and anti-tumor effect of GoCAR-T cells

Phase 2 Expansion

- Planned expansion of 10-40 patients once Phase 2 dose/schedule identified



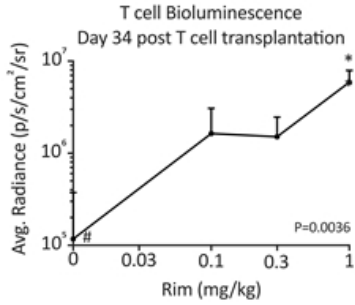
* Up to 4 additional cohorts (12-24 additional patients)

ClinicalTrials.gov Identifier: NCT02744287

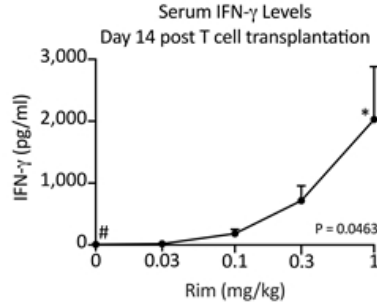
Rationale for Rimiducid Dose Escalation

In non-clinical models, increasing exposure to rimiducid leads to...

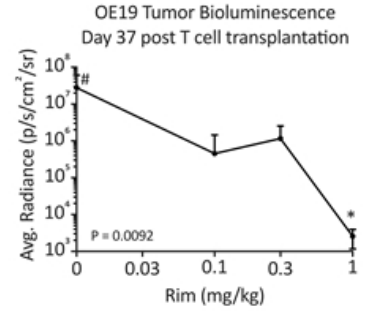
Increased GoCAR-T Cell Persistence



Enhanced Cytokine Production



Improved Anti-Tumor Efficacy



N = 5 mice per group
- Reference group
* - Comparator
P values calculated by one-way ANOVA



BPX-603
HER-2 Dual-Switch GoCAR-T

BPX-603 Dual Switch GoCAR-T Targeting HER2

Product Profile Summary

- HER2 is a validated tumor antigen expressed on numerous solid tumors with high unmet need
- BPX-603 designed to potentially address limitations of previous CAR-T efforts targeting HER2
 - Moderate affinity scFv to enhance target engagement and activity
 - MC signaling to increase cell proliferation & persistence, modulate the TME, and enhance host immunity
 - Bellicum switch technology designed to time and manage CAR-T activation and enable mitigation of acute toxicities

Program Update

- Enrolling Dose Level 1
- Planned presentation of initial data in 4Q'21

Unmet Need

Indication	Incidence ¹	HER2 ⁺	5-year OS (Stage IV) ¹
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%
Breast	271,000	16% ⁷	90%
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, (7) Cronin et al, Cancer Invest. 2010

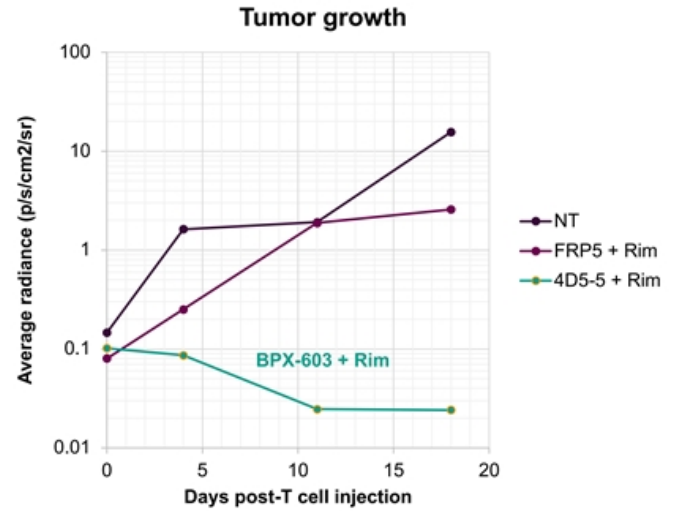
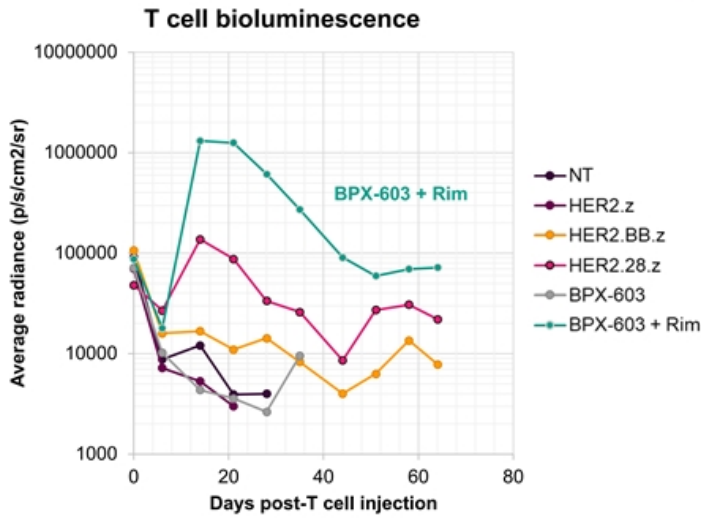
Historical HER2 Studies: Modest Clinical Outcomes

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: Compelling Preclinical Evidence

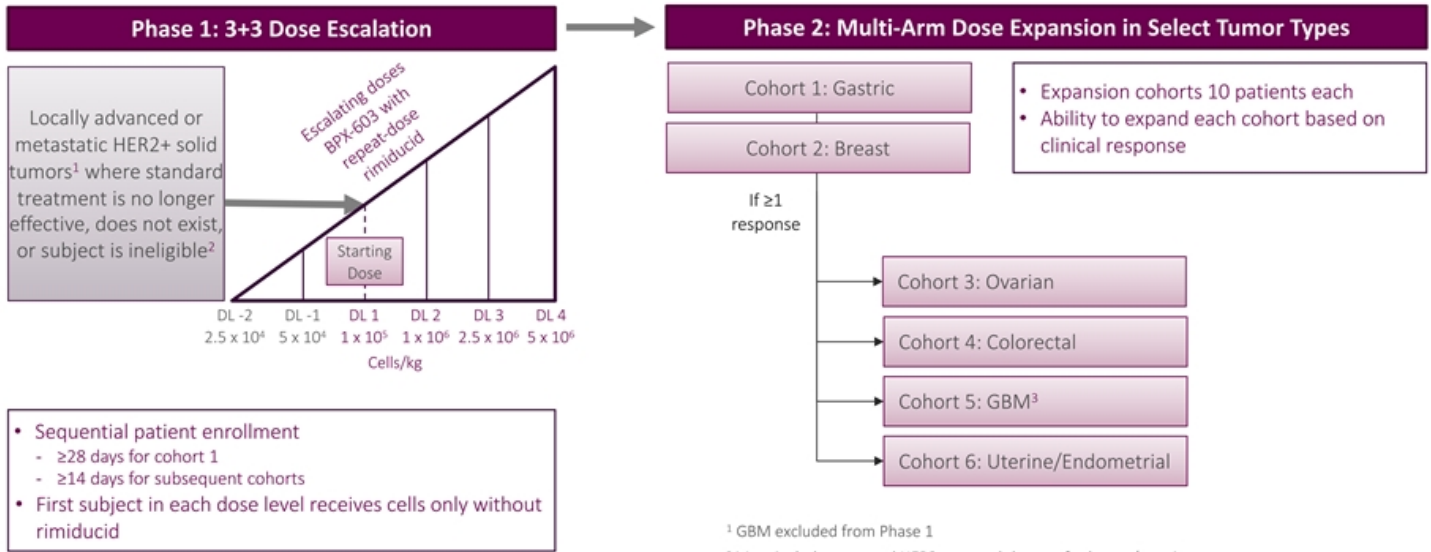
iMC co-activation enhances cell proliferation relative to current CAR-T standards

Moderate affinity scFv enhances anti-tumor effect relative to low affinity FRP5



BPX-603 Phase 1/2 Trial Design

Two-Part Safety/Activity Study of HER2-Targeted Dual Switch GoCAR-T Cells in Previously Treated HER2+ Solid Tumors



¹ GBM excluded from Phase 1

² Must include approved HER2-targeted therapy for breast/gastric cancers

³ Subjects with GBM will be dosed at recommended dose for expansion (RDE) -1





Expanding the Use of CaspaCIDe Through Licensing

Expanding the Use of CaspaCIDE Through Licensing

Summary

- CaspaCIDE is the most clinically-validated safety switch, offering the potential to improve the benefit/risk of cell therapies
- Bellicum has established option/license agreements with leading institutions for use of CaspaCIDE and rimiducid in cell therapies
 - Agreements currently cover seven CAR-T and CAR-NK programs with potential to add more over time
- Under these agreements, Bellicum is entitled to:
 - Sub-license execution fees upon out-license of program
 - % share of milestones and certain other sub-licensing revenue
 - Single digit % royalty on product net sales
- Agreements have generated over \$11m in revenue to date

New Licensing Agreements in 2021

- The University of Texas
MD Anderson Cancer Center
- University of North Carolina
Lineberger Comprehensive Cancer Center
- Massachusetts General Hospital Cancer Center



Summary

Anticipated Key Program Goals & Milestones

Product Candidate	Goals & Milestones	Planned Timing
BPX-601 PSCA GoCAR-T	Initial Phase 1 data in mCRPC	1Q'22
BPX-603 HER2 GoCAR-T (Dual-Switch)	Initial Phase 1 data	4Q'21

Investment Summary

Building a next generation cell therapy pipeline around the GoCAR platform

GoCAR Platform

Differentiated co-activation domain (MyD88/CD40) and switch technology drive greater proliferation, persistence, power, and performance

BPX-601

- Autologous GoCAR-T targeting PSCA
- Enrolling mCRPC patients in Phase 1/2 trial
- Data update planned 1Q'2022

BPX-603

- Autologous Dual-Switch GoCAR-T targeting HER2
- Enrolling HER2+ solid tumor patients in Phase 1/2 trial
- First data update planned 4Q'2021

CaspaCIDE Licensing

- Seven licensed programs to date
- Potential to expand use of switch technology

Cash runway extends into 2Q'22

- Cash balance of \$21.8M as of June 30, 2021