

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**

Xenetic Biosciences, Inc.

(Exact name of registrant as specified in charter)

Nevada
(State or other jurisdiction of incorporation)

001-37937
(Commission File Number)

45-2952962
(IRS Employer Identification No.)

40 Speen Street, Suite 102
Framingham, Massachusetts
(Address of principal executive offices)

01701
(Zip Code)

(781) 778-7720
(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 is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions see General Instruction A.2. below):

- ☐ 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.001 par value per share	XBIO	The Nasdaq Stock Market LLC
Purchase Warrants	XBIOW	The Nasdaq Stock Market LLC

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.

Attached to this report as Exhibit 99.1 is the current corporate presentation of Xenetic Biosciences, Inc. (the "Company"), which the Company has prepared in anticipation of potential upcoming investor meetings. The presentation is furnished pursuant to this Item 7.01 and shall not be deemed filed in this or any other filing of the Company with the Securities and Exchange Commission, unless expressly incorporated by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Updated 2021 Corporate Presentation</u>
104	Cover Page Interactive Data File (formatted as inline XBRL).

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.

XENETIC BIOSCIENCES, INC.

Date: September 13, 2021

By: /s/ James Parslow
Name: James Parslow
Title: Chief Financial Officer



Expanding the Potential of CAR T Cell Therapy

Investor Presentation

September
2021

Forward-Looking Statements

This presentation contains forward-looking statements that we intend to be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation other than statements of historical facts may constitute forward-looking statements within the meaning of the federal securities laws. These statements can be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including, but not limited to, all statements regarding: the CAR T focus and potential upside with PolyXen technology set forth under the "Investment Highlights" section of this presentation; XCART opportunities, including targeting tumor-specific antigens that are independent of CD19 or other antigens common to all B-Cells and advancing towards a Phase 1 study; plans to leverage outsourced relationships; potential for XCART to result in increased efficacy, safety and tolerability over currently approved CAR T therapies; the potential to conduct a Phase 1 trial with academic collaborators; potential utilities of PolyXen; and expectations regarding cash runway funding the Company through an IND filing; as well as all statements set forth under the "Driving Development Through Outsourced Relationships" section of this presentation, including those related to upcoming potential milestones, all statements set forth under the "Investment Summary" section of this presentation; all statements regarding expectations that the CAR T therapies will hold significant revenue share by 2026, including anticipations that there will be a significant drop in Rituxan use. Any forward-looking statements contained herein are based on current expectations and are subject to a number of risks and uncertainties. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. Important factors that could cause actual results to differ materially from such plans, estimates or expectations include, among others, (1) unexpected costs, charges or expenses resulting from the acquisition of the CAR T technology; (2) uncertainty of the expected financial performance of the Company; (3) failure to realize the anticipated potential of the XCART technology; (4) the ability of the Company to implement its business strategy; (5) failure of Scripps Research and/or Pharmsynthez or the other academic institutions in Belarus and Russia (as applicable) to perform their obligations under their respective agreements; (6) failure of the Company and Pharmsynthez to reach agreements with the contract sites on terms favorable to the Company, or at all; (7) failure of our licensees to successfully utilize the PolyXen technology and generate royalties for the Company; and (8) other risk factors as detailed from time to time in the Company's reports filed with the SEC, including its annual report on Form 10-K, periodic quarterly reports on Form 10-Q, periodic current reports on Form 8-K and other documents filed with the SEC. The foregoing list of important factors is not exclusive. In addition, forward-looking statements may also be adversely affected by general market factors, general business and economic conditions, including potential adverse effects of public health issues such as the COVID-19 pandemic, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new product candidates and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this presentation speak only as of the date the statements were made, and the Company does not undertake any obligation to update forward-looking statements, except as required by law.

Disclaimer

The information contained in this presentation is provided for informational and discussion purposes only and is not, and may not be relied on in any manner as legal, business, financial, tax or investment advice or as an offer to sell or a solicitation of an offer to buy an interest in Xenetic Biosciences, Inc. or to participate in any trading strategy.

Investment Highlights

CAR T Focus:

Advancing XCART™, a personalized CAR T platform targeting cancers with a patient- and tumor-specific approach

Building on the proven success of CAR T therapy

Following established roadmap for significant early-stage value creation

Potential Upside with PolyXen® Technology:

Ongoing royalty stream through license arrangement

Platform for partnerships

XCART™ Opportunity

- ✓ Targeting tumor-specific antigens that are independent of CD19 or other antigens common to all B-Cells
- ✓ Advancing towards Phase 1 study
- ✓ Lead program targeting \$7 billion B-Cell malignancy market¹

**Leveraging
Outsourced Relationships**

Team with Proven Expertise



Jeffrey F. Eisenberg
Chief Executive Officer & Director

Life Sciences executive with over 20 years of successful track record in value creation in both private and public companies; former CEO of Noven Pharmaceuticals, responsible for leading 2 product launches and Noven's Novogyne Women's Health joint venture with Novartis



Curtis Lockshin, Ph.D.
Chief Scientific Officer

20 years Biotech/Pharma management experience, including discovery, preclinical and clinical development and commercial manufacturing; former CEO of SciVac Therapeutics, CTO of VBI Vaccines and VP of Corporate R&D Initiatives for OPKO Health



James F. Parslow, MBA, CPA
Chief Financial Officer

Over 30 years of experience providing financial and business leadership to biotech, manufacturing, technology, business-to-business e-commerce and cleantech industries

Scientific Advisory Board with Extensive Cell Therapy Development Experience

Dr. Matthew Frigault

Medical Oncologist in the Hematologic Malignancy Program at the Massachusetts General Hospital Cancer Center, as well as Assistant Director of the Cellular Immunotherapy Program; serves as Instructor at Harvard Medical School

Dr. Alexander Gabibov

Head of the Shemyakin & Ovchinnikov Institute of Bioorganic Chemistry at the Russian Academy of Science

Dr. Guenther Koehne

Internationally recognized cancer specialist and current Chief of Blood & Marrow Transplant and Hematologic Oncology at the Miami Cancer Institute

Dr. Greg MacMichael

President and Founder of CMC BioServices, LLC; Previously served as the Senior VP of Technical Operations at Axovant Gene Therapies; VP of Development, Manufacturing and Quality Control at NantKwest Therapeutics; and Senior VP of Process, Development, Manufacturing and Quality Assurance at RocketPharma

Dr. Maksim Mamonkin

Assistant Professor, Pathology and Immunology and an independent faculty member at the Center for Cell and Gene Therapy at Baylor College of Medicine

Dr. Jia Xie

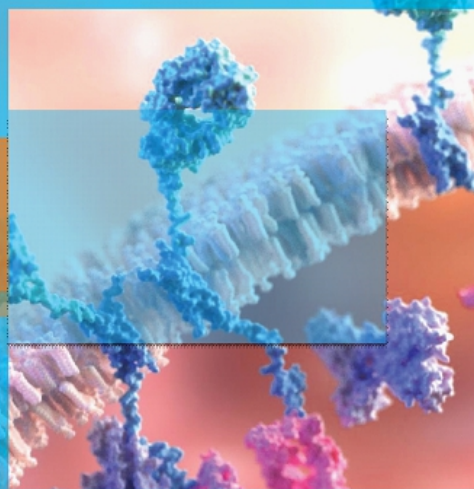
Assistant professor at University of Miami Department of Chemistry, assistant professor of Psychiatry and Behavior Science at University of Miami Miller School of Medicine; and visiting investigator at the Department of Chemistry at Scripps Research Institute

Dr. Alexey V. Stepanov

Senior Staff Scientist in the Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry; Senior Staff Scientist position in the Dmitry Rogachev National Medical Research Center of Pediatric Hematology, Oncology and Immunology in Russia; Professional scientific collaborator of Dr. Richard Lerner's laboratory in The Scripps Research Institute

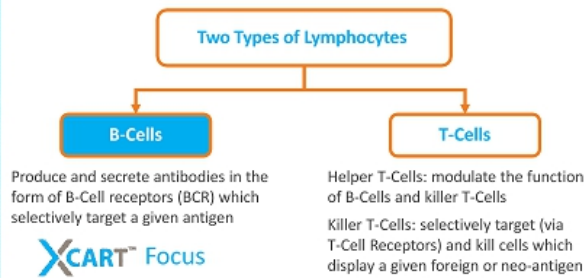
X^CART™ Platform

Personalized CAR T platform targeting cancers with a patient- and tumor-specific approach



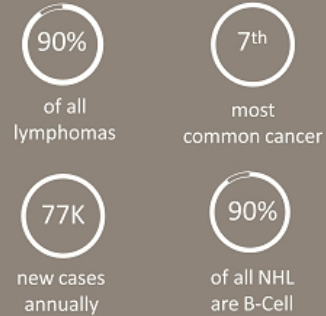
Lymphoma

Group of blood cancers that develop from lymphocytes located in the lymph system



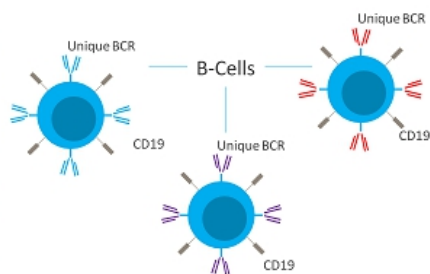
Non-Hodgkin Lymphoma (NHL)¹

US Market Overview



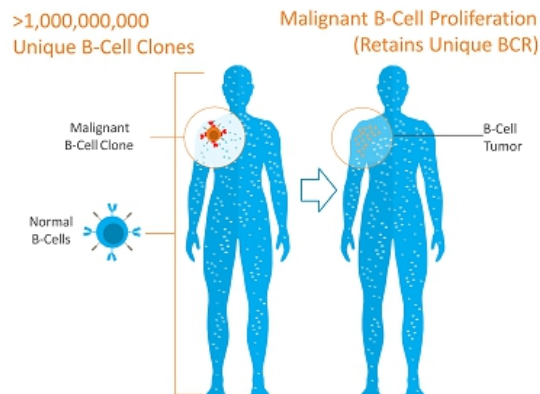
B-Cells and Tumor Growth

B-Cell receptor (BCR) vs CD19



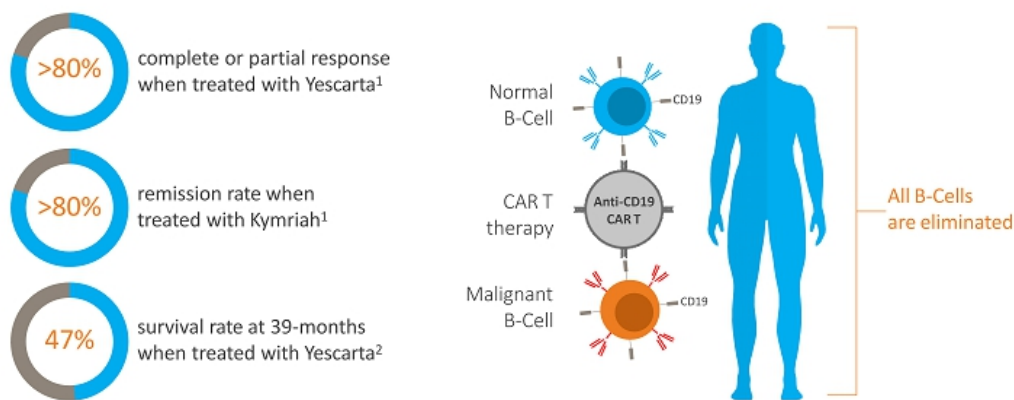
Current commercial therapies target the common **CD19** receptor that is present on all B-Cells

Tumor develops with the unique BCR clone



Anti-CD19 CAR T Therapies Work...

Current CAR T therapies target both normal and malignant B-Cells



...But There Is Need For Improvement

Significant shortcomings with currently approved CAR T therapies

Lack of Initial Efficacy of Anti-CD19 CAR T Due To:

- CD19^{low}:** low initial levels of CD19 receptors on tumor cells
- CD19⁻:** initial lack of CD19 receptors on some or all tumor cells

CAR T Relapse: lack of durable response

T-Cell Exhaustion: progressive loss of CAR T effector function

Toxicity Problems:

- Cytokine Release Syndrome (CRS)
- Neurotoxicity
- B-Cell Aplasia: elimination of all B-Cells

CD19 Escape: Emergence of CD19⁻ Tumor Cells Resulting from Anti-CD19 Treatments, including CAR T

~50% of CAR T treated patients relapse within 12 months¹



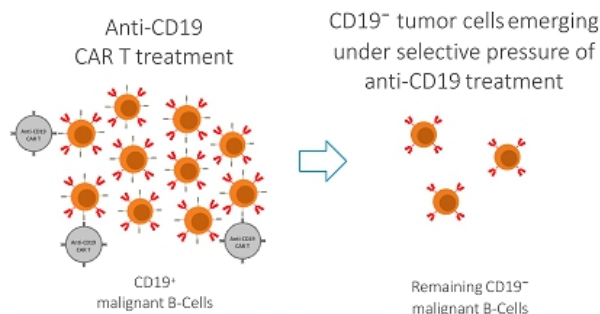
Estimated percentage of patients who relapse due to CD19 escape²



Of patients have a lower count of CD19-positive B-Cells due to prior therapies²

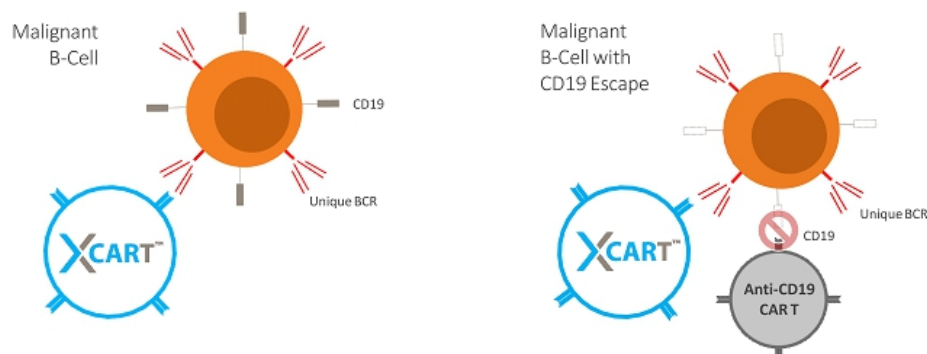
Incidence of CD19 escape is expected to increase with growing number of anti-CD19 treatments

Significant problem in treating B-Cell cancers, affecting the efficacy of currently approved therapies



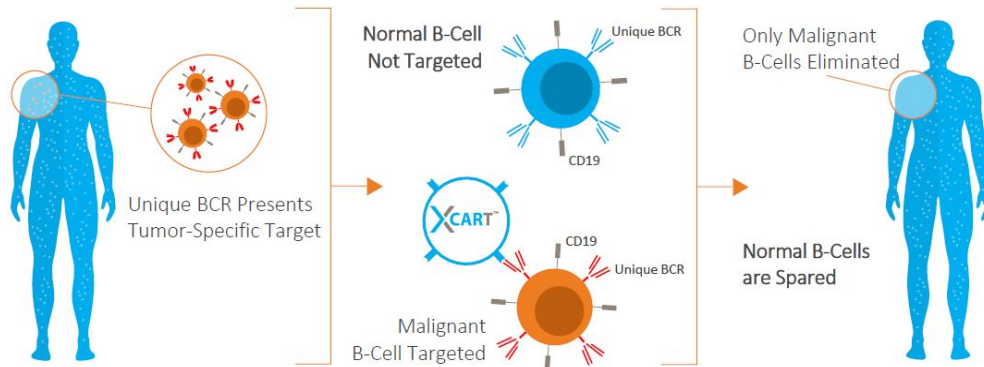
X^{CART}™ Targets the Tumor's Unique BCR

Ability to address the CD19 escape phenomenon



X^{CART}™ Only Targets Malignant B-Cells

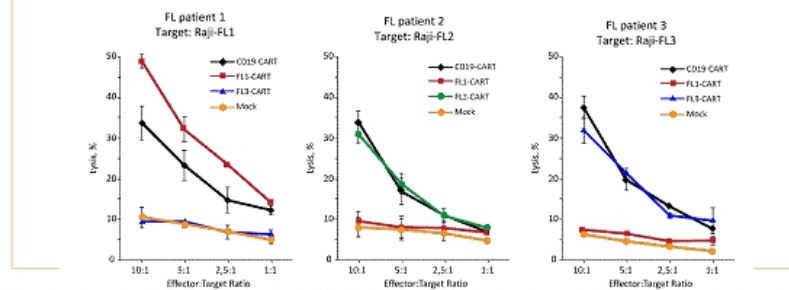
Potential for increased efficacy, safety and tolerability over currently approved CAR T therapies



X^{CART}™ Selectively Kill Raji B-Cell Lines Expressing Target BCRs

Human CD8+ T cells were transduced with Lentiviral vectors coding for one of pepFL1-CAR, pepFL2-CAR, pepFL3-CAR or CD19-CAR constructs

Raji B-cells (Raji-FL1, Raji-FL2 and Raji-FL3) expressing BCRs from the respective FL lymphomas were lysed by activated human CD8+ T cells bearing a corresponding cyclopeptide-CAR construct¹



XCART Addresses Need in Current Lymphoma Treatment Paradigm

Follicular Lymphoma (FL)
~14,000/year US Incidence¹

1st Line Therapy:
~11,000 Patients

2nd Line Treatment:
~5,000 Patients

**XCART Opportunity:
3rd Line Treatment
~3,000 Patients**

Diffuse Large B-Cell Lymphoma (DLBCL)
~26,000/year US Incidence¹

1st Line Therapy:
~21,000 Patients

2nd Line Treatment:
~6,000 Patients

**XCART Opportunity:
3rd Line Treatment
~4,000 Patients**

Leveraging Outsourced Relationships

Expediting Development Pipeline with Proven Expertise and Capabilities



Driving Development Through Outsourced Relationships



Upcoming Potential Milestones



Exploratory Patient Biopsy Study

Evaluating XCART platform in biopsy and blood samples from B-Cell NHL patients

①

Validate upstream workflow for isolating and screening tumor-specific neoantigens

②

Identify and characterize potential tumor-specific CAR constructs

③

Study has provided materials and methods needed to proceed with IND-enabling studies

Collaborators

Additional collaborations advancing XCART toward IND-enabling studies

Academic Collaborators

Working with world-renowned academic institutions, researchers and clinical investigators

Access to methods and materials, including clinical samples, for optimizing the overall XCART workflow

Scripps Research

(One of the original developers of the XCART platform)

Design and implementation of the preclinical development program

Method development activities supporting process development for clinical manufacturing

Outsourced Relationships

Leveraging additional vendors to expedite commercial development

Developing cost-effective clinical manufacturing process for patient-specific cell therapy products

Academic Collaborator

PHARMSYNTHEZ

Research organization coordinating activities with partnered academic institutions in Eastern Europe



Supports optimization of overall XCART workflow



Access to clinical centers and B-Cell non-Hodgkin lymphoma (NHL) patients



Potential to conduct Phase 1 trial

PolyXen® PSA Technology Platform

Enables Next Generation Biologic Drugs

PolyXen: Next Generation Half-Life Extension Platform Technology

Polysialylation employs the biological polymer polysialic acid (PSA) to modulate the PK and PD profiles of protein drugs

Generating Royalty Stream

Platform for Partnerships

Extensive IP protection



Clinically demonstrated to extend half-life of therapeutic proteins



Applicable to franchise extensions as well as candidates in development



Potential utility in other molecule classes such as peptides and small molecules

Receiving royalties on net sales through licensing arrangement in the field of blood coagulation disorders

Pharmsynthez filed registration dossier in Russia for Epolong, a polysialylated form of recombinant human erythropoietin as a treatment for anemia in patients with chronic kidney disease

Financial Snapshot

NASDAQ: XBIO

Cash runway expected to fund Company through XCART IND filing

Market Cap¹
~\$26M

Shares Outstanding²
~9.7M

Average Volume¹
~10.1M

Cash Balance
\$9.3M
as of June 30, 2021

Does not include net proceeds from
\$12.5 million private placement
which closed on July 28, 2021

Investment Summary

Advancing XCART program through preclinical
development into the clinic as quickly as possible



Truly differentiated
CAR T technology



Lead program targeting
growing \$7 billion B-Cell
malignancy market¹



Strong balance sheet
expected to fund Company
through IND filing

PolyXen

Upside through
licensing arrangements

Positioning to have a transformative impact in the CAR T space

Xenetic

BIOSCIENCES

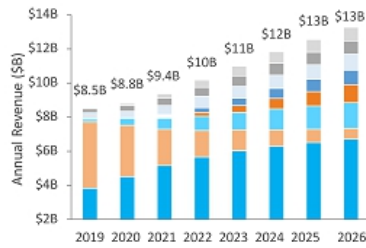
Expanding the Potential of CAR T Cell Therapy

JTC Team, LLC.
T: 833-475-8247
xbio@jtcir.com

Appendix

CAR T Therapies Expected to Hold Significant Revenue Share by 2026

US revenue for top products* targeting key B-Cell malignancies



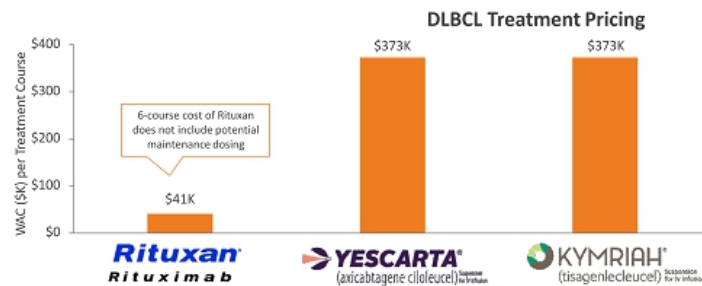
* Top 7 products based on 2026 analyst revenue forecasts, plus Kymriah, are selected here
 ** CAGR from 2020-2026
 ^ First Approval relates to first approval among DLBCL, CLL, FL, or MCL; Source: EvaluatePharma, BMT, Accessed August 2020
 ** Potential launch for DLBCL in 2021

Product	Company	Mechanism	First Approval [^]	Relevant Indications	2026 Revenue	CAGR (2019-2026)
Polivy		CD79B antibody	06/2019DLBCL	DLBCL	\$805M	48%
Kymriah			08/2017ALL	DLBCL	\$774M	18%
Yescarta		CD19 CART	10/2017DLBCL	LBCL (including DLBCL patients)	\$946M	14%
Uso-cel			Expected 2020		\$849M	135%**
Tazverik		EZH2 inhibitor	06/2020FL	FL	\$1.05B	91%**
Calquence		BTX inhibitor	11/2019CLL	MCL, CLL	\$1.50B	37%
Rituxan		CD20 antibody	12/1997FL	FL, DLBCL, CLL	\$643M	-23%
Imbruvica		BTX inhibitor	02/2014CLL	MCL, CLL, DLBCL**	\$6.71B	8%

Significant drop in Rituxan use anticipated due to the availability of alternate monoclonal antibody and small molecule treatment options (limited revenue attributed to biosimilar – 3 anticipated to be available in 2026)

Current CAR T Therapies Are Priced Over \$300,000

Novel CAR-T therapy use in earlier lines of treatment may be limited by comparative treatment costs and are likely to face challenges gaining market access



Type of Therapy	Monoclonal Antibody	Cell Therapy	
Approved Indications	NHL (including CLL and DLBCL)	LBCL (including DLBCL patients)	ALL, LBCL (including DLBCL patients)
Ex-US Pricing	\$10-15K	\$300-355K	\$300-310K