

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 15, 2022

Cellectar Biosciences, Inc.
(Exact name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

1-36598
(Commission
File Number)

04-3321804
(IRS. Employer
Identification No.)

100 Campus Drive, Florham Park, NJ, 07932
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (608) 441-8120

N/A
(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 (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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.00001 per share	CLRB	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 2.02. Results of Operations and Financial Condition.

As of December 31, 2021, Cellectar Biosciences, Inc., (the "Company") had cash and cash equivalents of approximately \$35.7 million (unaudited).

Because the Company's consolidated financial statements for the year ended December 31, 2021 have not yet been finalized or audited, the preliminary statement of the Company's cash and cash equivalents as of December 31, 2021 in this Item 2.02 is subject to change, and the Company's actual cash and cash equivalents as of December 31, 2021 may differ materially from this preliminary estimate. Accordingly, you should not place undue reliance on this preliminary estimate.

Item 7.01. Regulation FD Disclosure.

On March 16, 2022, the Company intends to make a presentation at the Oppenheimer 32nd Annual Healthcare Conference. This presentation would provide a Company overview, business update and progress on the Company's key initiatives. A form of the Company's slide presentation to be used at this conference is being furnished as Exhibit 99.1 to this Current Report on Form 8-K, and a copy is available on the Company's website at investor.cellectar.com.

The information contained in Item 2.02 and Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is furnished pursuant to Item 2.02 and Item 7.01 of Form 8-K

and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly stated by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Number	Title
99.1	Company 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.

CELLECTAR BIOSCIENCES, INC.

Date: March 15, 2022

By: /s/ Chad J. Kolean

Name: Chad J. Kolean

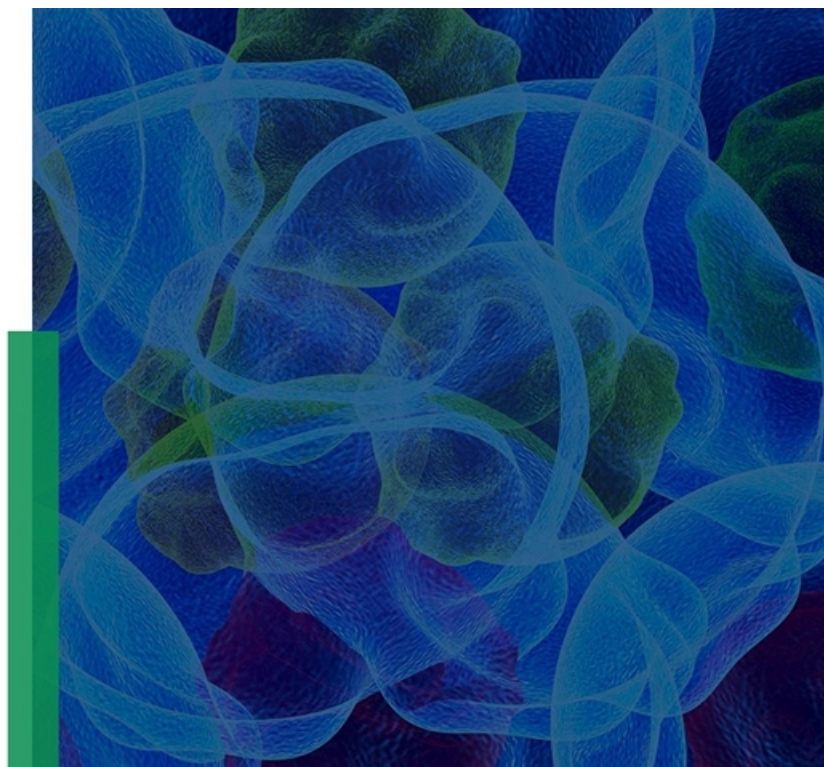
Title: Chief Financial Officer



Corporate Presentation

March 2022

NASDAQ: CLRB



Forward-Looking Statements

This presentation contains forward-looking statements. Such statements are valid only as of today and we disclaim any obligation to update this information. These statements are only estimates and predictions and are subject to known and unknown risks and uncertainties that may cause actual future experiences and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes including our expectations of the impact of the COVID-19 pandemic. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to raise additional capital, uncertainties related to the disruptions at our sole source supplier of iopofosine, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, patient enrollment and the completion of clinical studies, the FDA review process and other government regulation, our ability to maintain orphan drug designation in the United States for iopofosine, the volatile market for priority review vouchers, our pharmaceutical collaborators' ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement. A complete description of risks and uncertainties related to our business is contained in our periodic reports filed with the Securities and Exchange Commission including our Form 10-K for the year ended December 31, 2020 and our Form 10-Q for the quarter ended September 30, 2021.

Company Highlights

Proprietary Versatile Drug Conjugate Platform to Target Cancer

Developing iopofosine I-131 (formerly known as CLR 131), a small-molecule radiotherapeutic in rare adult and pediatric cancer indications

Ongoing pivotal study of iopofosine in Waldenstrom's macroglobulinemia (WM), top-line data anticipated 2H 2022

Clear and defined regulatory pathway in WM; Granted U.S. Orphan Drug Designation and FDA Fast Track Designation

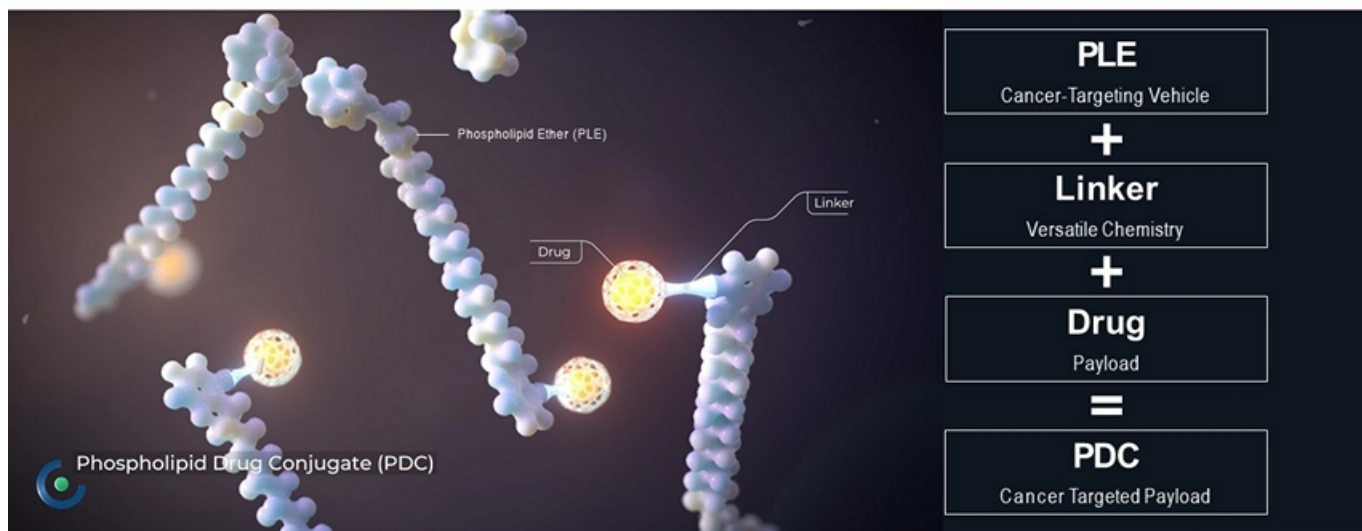
Additional clinical studies ongoing, including a Phase 2b study in highly refractory multiple myeloma; potential for near-term commercialization and route to approval

Cash balance of \$35.7 million as of December 31, 2021, supporting strategic plan beyond expected key data readouts



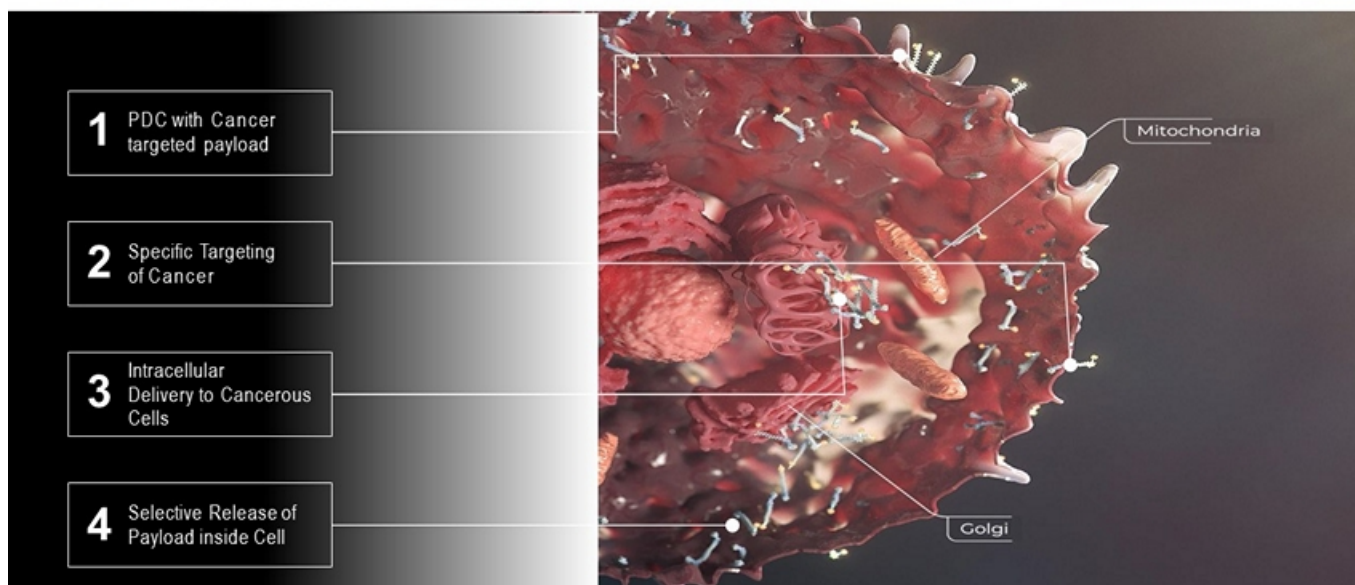
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PDC Platform Technology



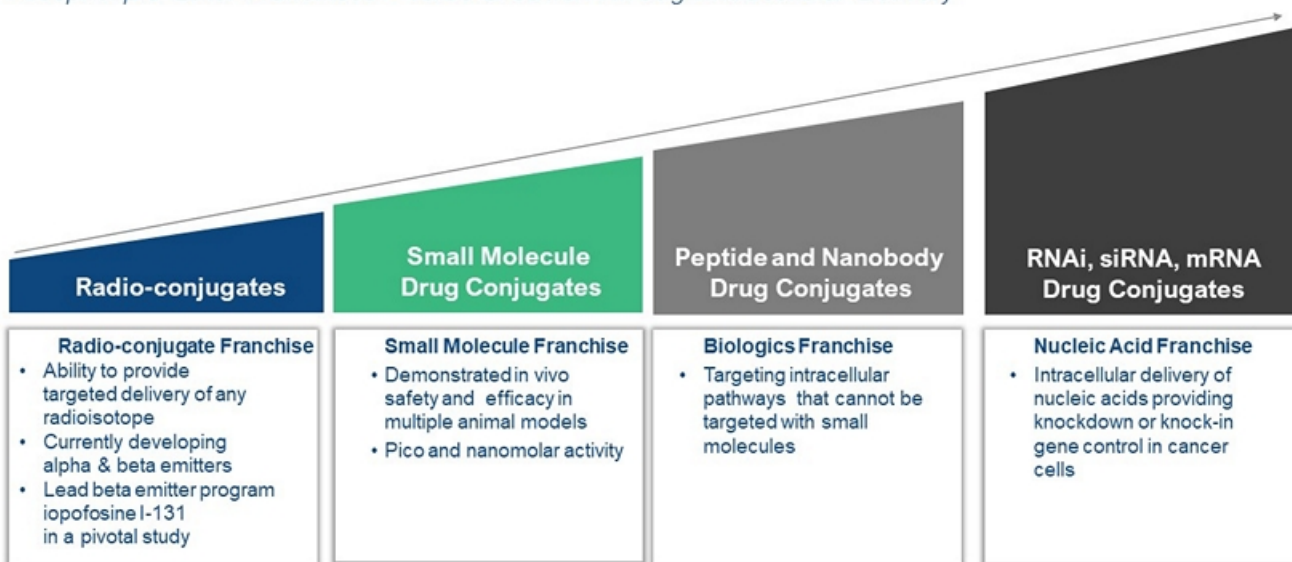
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Targeted Delivery to Tumor Cells



PDC Strategy

Phospholipid Ether Franchises - Value Creation Through Intracellular Delivery



Pipeline

PDC Program	Indication	Discovery	Preclinical	Phase 1	Phase 2	Pivotal	Collaboration Partner
Iopofosine I-131	Waldenström's macroglobulinemia						
	Highly Refractory Multiple Myeloma						
	Pediatric						
	Head and Neck (HNS)						WISCONSIN UNIVERSITY OF WISCONSIN-MADISON
CLR 1900	Solid Tumors						
Partnerships							
CLR 2000	Solid Tumors						
CLR 12120	Solid Tumors						oranomed
NewPDCs	Various targets						LCB LegoChemistria
NewPDC's	Various targets						Intocell into practice

Iopofosine I-131: Our Lead Product Candidate

A small-molecule PDC designed to provide targeted delivery of iodine-131 to cancer cells while limiting exposure to healthy cells

Currently being evaluated in:

Pivotal Study
in Waldenstrom's
macroglobulinemia

Phase 2 CLOVER-1
study in highly
refractory MM

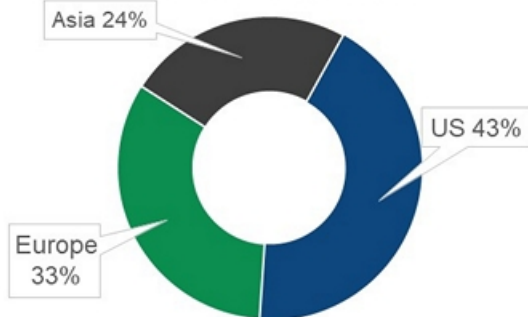
Phase 1 CLOVER-2 study in
relapsed pediatric cancers
(high grade glioma &
soft tissue sarcomas)

Phase 1 Investigator
Initiated Study
in relapsed
Head & Neck

Waldenstrom's Macroglobulinemia

Waldenstrom's macroglobulinemia is a rare cancer that begins in the white blood cells

Global Prevalence
Patient % Distribution¹



- The bone marrow produces too many abnormal white blood cells crowding out healthy blood cells
- The abnormal white blood cells produce a protein (IgM) that accumulates in the blood, impairs circulation and causes complications
- It is slow growing. Typical signs & symptoms include:
 - Easy bruising; bleeding from nose or gums; fatigue; weight loss; numbness in hands or feet; fever; headache; shortness of breath; changes in vision; confusion
- Ultra-rare orphan disease
 - ~8-year survival post-initial diagnosis^{2,3}
 - Median age 65
 - U.S. Annual incidence ~3,000; 30% annual growth rate through 2025
 - U.S. prevalence ~45,000⁴

WM Second Line Current Standard of Care

Ibrutinib Projected Revenues in WM Alone to Exceed \$1.2 Billion



Only 1 class (BTKi's) of approved drugs in WM (ibrutinib and zanubrutinib)

Prior to first line combination approval, ibrutinib projected peak year sales of >\$1.2B in 2024

Limited switching between ibrutinib and zanubrutinib

No monotherapy demonstrating major responses in dual WT patients (MYD88 & CXCR4 representing 20-40% of patients)

In addition to initial approval positioning; opportunity for iopofosine I-131 label expansion into early lines of therapy

"For a patient who has progression on ibrutinib, then acalabrutinib or zanubrutinib are not right answers in terms of the next line of therapy because they work the same way."

Iloprofosine I-131 Response Rates in WM

Only Monotherapy to Achieve an 83.3% MRR and 16.7% CRR

Iloprofosine I-131⁵

Administered in 4 x 20-minute doses
No requirement for continuous dosing

100% (6/6)

Overall Response Rate (ORR)

83.3% (5/6)

Major Response Rate (MRR)

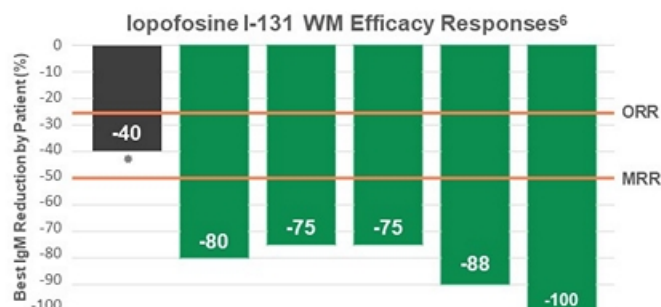
16.7% (1/6)

Complete Response Rate (CR)

100% ORR (2/2)

in Dual Wild Type Patients

Treatment Free Remission
Exceeding 1 Year



- Only treatment tested in BTKi failure patients
- Effective across all genotypes⁷
- 100% of high-risk patients achieved an MRR; including one Complete Response
- Deep and durable responses achieved in challenging relapsed or refractory patients
 - Total average ~72%
 - Median 45% reduction within 4 weeks of initial dose



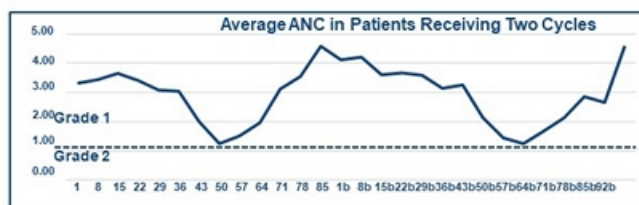
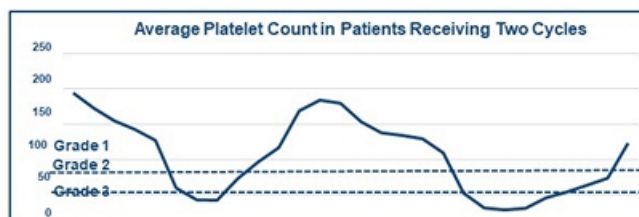
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Iloprofosine Safety Profile: Well-Tolerated in WM, MM and other NHLs

Predictable and Manageable AE-profile / Predictable Time to AE-Resolution

Treatment Emergent Adverse Events⁷ (≥25% of All Patients)

Preferred Term	All Doses	
	Total n=88	Phase 1 & 2 Pts
	Overall n (%)	≥ Grade 3 n (%)
Thrombocytopenia	73 (83)	64 (73)
Lymphocyte Count Decreased	40 (45)	35 (40)
Decreased White Blood Cell Count	52 (59)	41 (47)
Anemia	60 (68)	15 (17)
Neutropenia	49 (56)	45 (51)
Fatigue	51 (60)	12 (14)
Nausea	29 (33)	0



"Irrespective of the type of cytopenia, they were very predictable showing consistent timing to patients starting to experience cytopenias, the timing to nadir, and recovery."



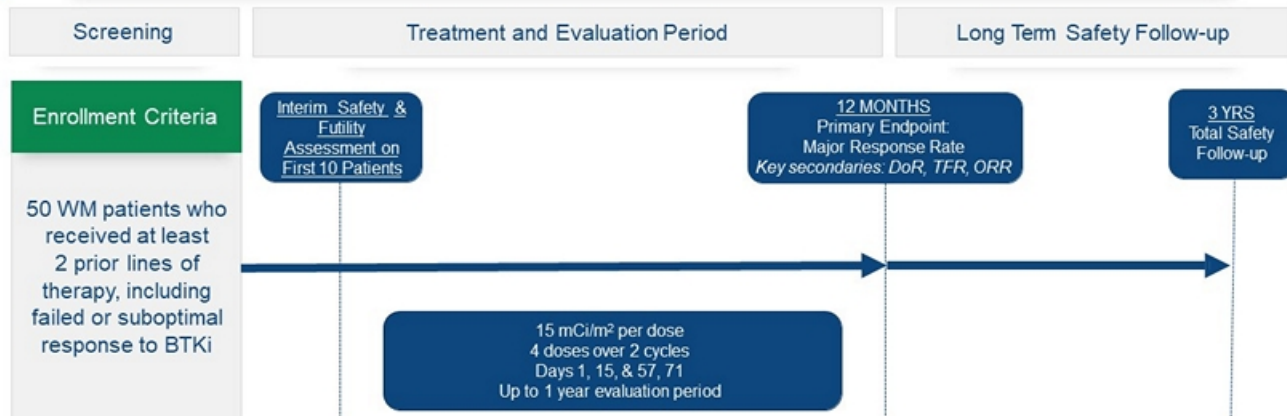
- Sikander Ailawadhi, MD
ASCO 2021

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Iopofosine I-131: Global WM Pivotal Study Design

FDA Agreed Upon Pathway to Approval

Single Arm Open-label Registration Study Enrolling; Fast Track Designation

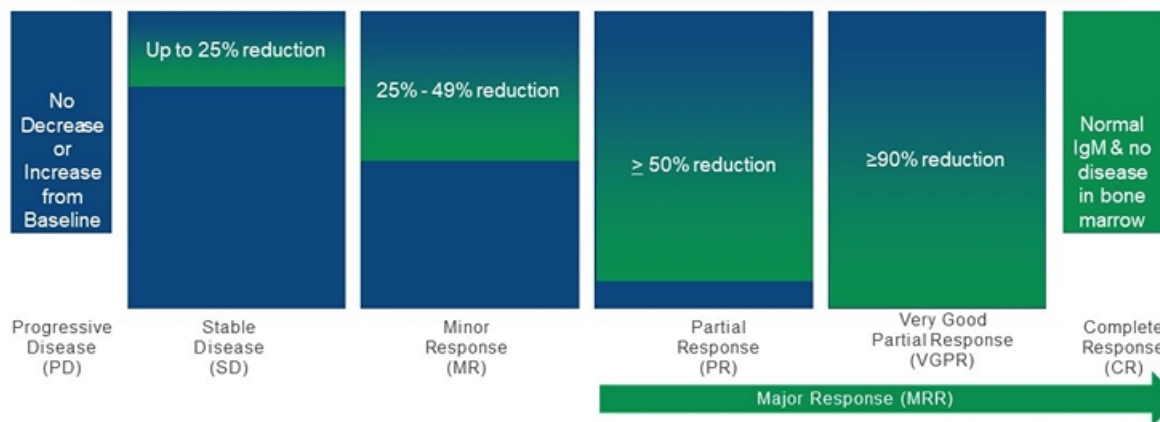


Primary Endpoint: Major Response Rate (MRR) of 20% (10 of 50 Patients) Achieves Statistical Significance

Waldenstrom's Macroglobulinemia Disease Assessment

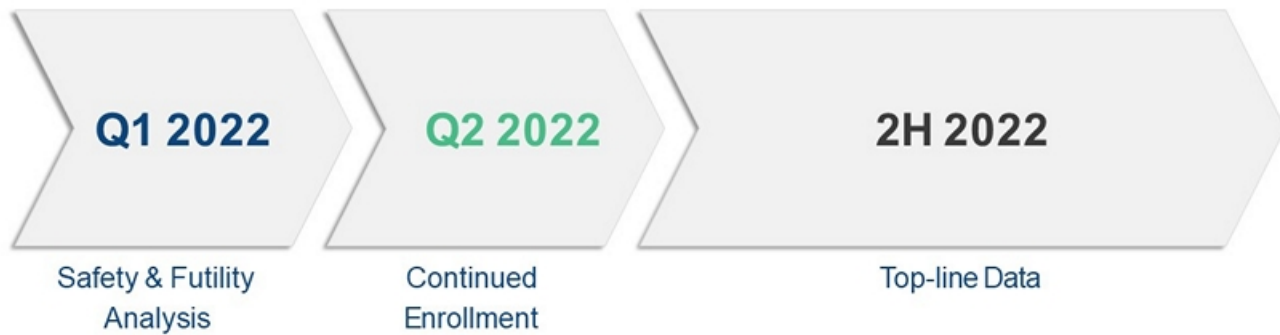
Serum IgM is Primary Biomarker for Response Rate

Decreasing Serum IgM Levels and Clinical Symptoms/Extramedullary Disease



Iopofosine I-131 Achieved an 83.3% MRR in Phase 2a Surpassing Pivotal Study Primary Statistical Endpoint of 20%

WM Pivotal Study Expected Milestones



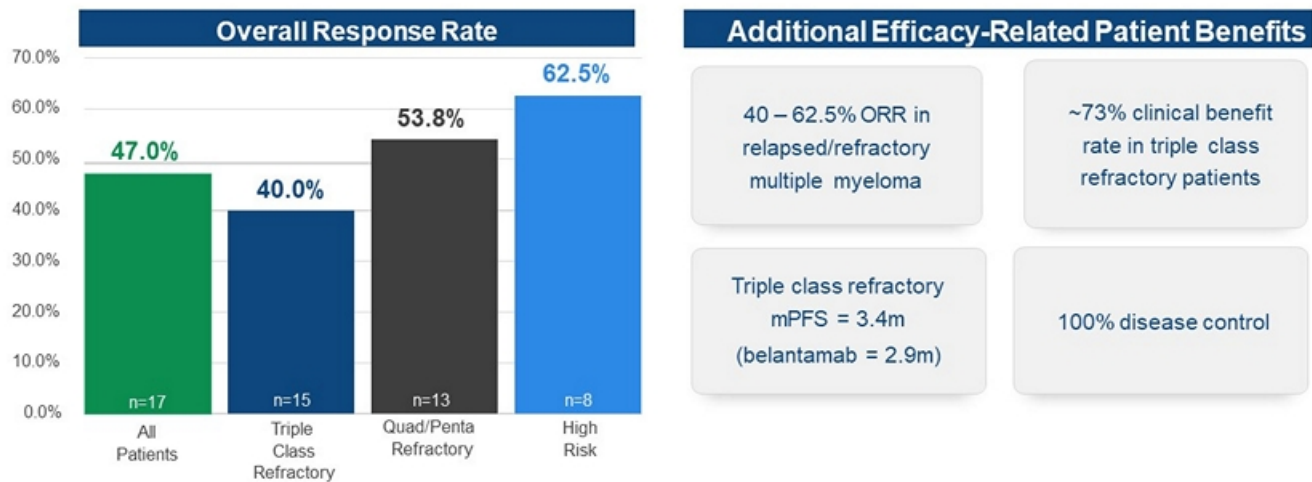
U.S. Breakthrough and EU Prime Designation Submissions Planned for 2022



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Iopofosine I-131 in Multiple Myeloma

Demonstrates Profound Activity in Late Line Difficult to Treat MM Patients



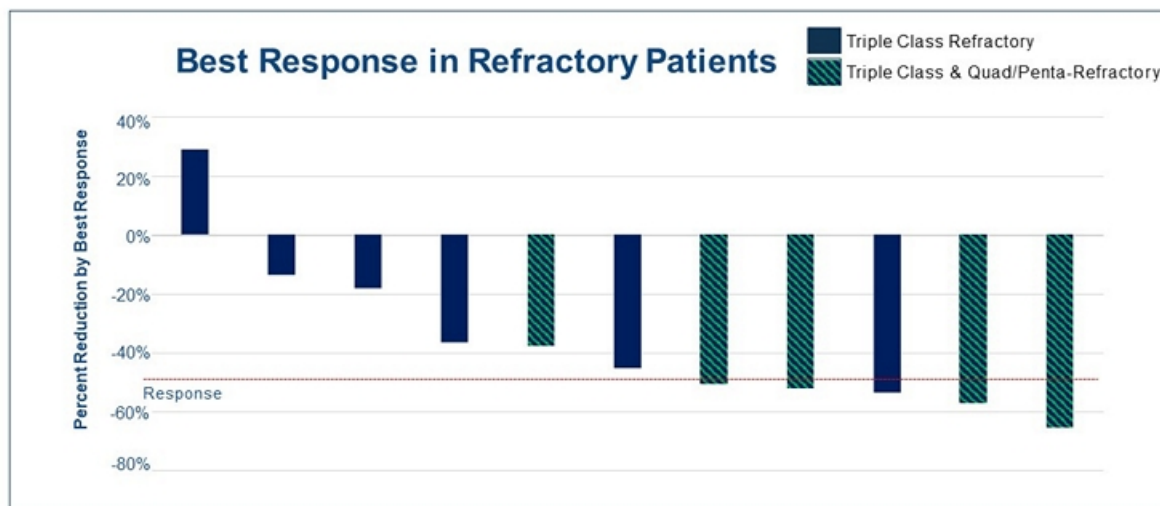
Enrichment of Highly Refractory MM Patient Data Provides Strategic Route to NCCN Guideline Inclusion and Potential Third-party Reimbursement



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Iopofosine I-131 r/r Multiple Myeloma

Triple Class and Penta-drug Refractory

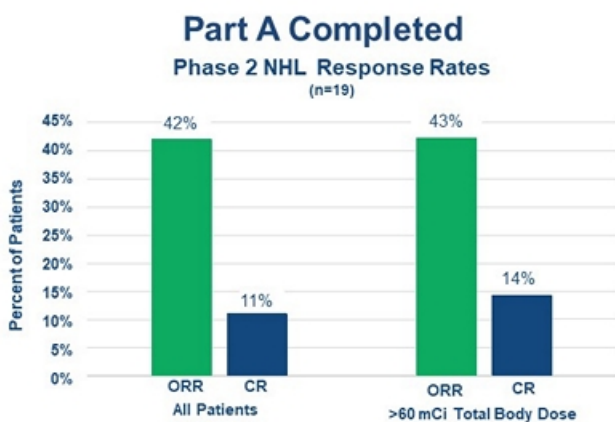


Iopofosine I-131 Demonstrates Strong Activity in Triple Class Refractory MM



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Iopofosine I-131 Phase 2 CLOVER-1 Study in B-cell Lymphomas



- Median age = 70
- Median third line patients
- Highly refractory DLBCL, CLL/SLL, MZL and MCL
 - ~60% of patients were multi-drug refractory

Non-Hodgkin's Lymphoma

Key Efficacy Measures

43% ORR in NHL

>14% Complete Response Rate

71.4% Clinical Benefit Rate

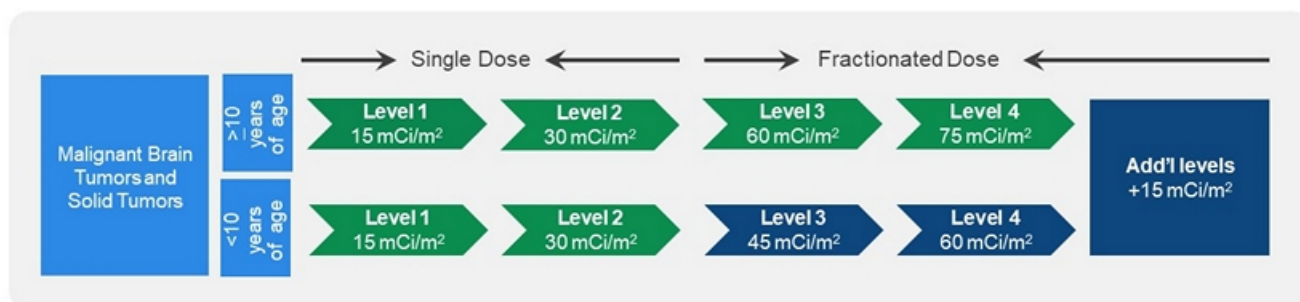
Median tumor volume reduction of ~25%



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Iopofosine I-131 in Pediatric

Phase 1 Global Study – Accelerated Development Approach



Primary objective

- Part A to determine the safety, tolerability, and initial efficacy of iopofosine I-131 in children with relapsed/refractory malignancies (ongoing)
- Part B efficacy confirmation and potential pivotal study

Data Highlights:

- Demonstration of crossing blood brain barrier and uptake into brain tumors
- Therapeutic responses, evidenced by changes in tumor parameters observed in high grade glioma and soft tissue sarcomas
- Patients experiencing extended progression free survival



U.S. ODD and RPDD Granted for NB, RMS, OS and ES⁸

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Financial Summary

Cash position as of December 31, 2021 (millions)	\$	35.7 M
Cash anticipated to support strategic plan into Q3 2023		

Capitalization as of November 8, 2021		
Common Stock Outstanding		61,101,263
Reserved for issuance:		
Convertible Preferred Stock		1,111,111
Warrants		15,633,825
Employee/Director Stock Options		6,097,200
Fully Diluted Shares Outstanding:		83,943,400



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Company Summary

Developing iopofosine I-131, a small-molecule radiotherapeutic in rare adult and pediatric hematologic and solid tumor indications

Anticipate top-line WM pivotal study data in 2H 2022; lead indication represents an underserved patient population and significant market opportunity

Clear and defined regulatory pathway in WM; Granted U.S. Orphan Drug Designation and FDA Fast Track Designation

Efficacy demonstrated in multiple r/r cancer types including highly refractory MM - 47% ORR in hexa-line, 40% triple class and 54% quad/penta refractory

Cash balance of \$35.7 million as of December 31, 2021, supporting strategic plan beyond expected key data readouts

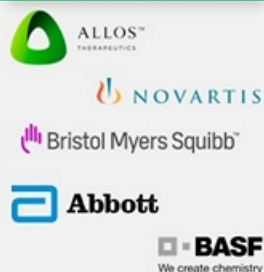


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Experienced Management



James Caruso
President, CEO and Director



Chad Kolean
Chief Financial Officer



Laurence Reilly, MD, LL.M
Interim Chief Medical Officer



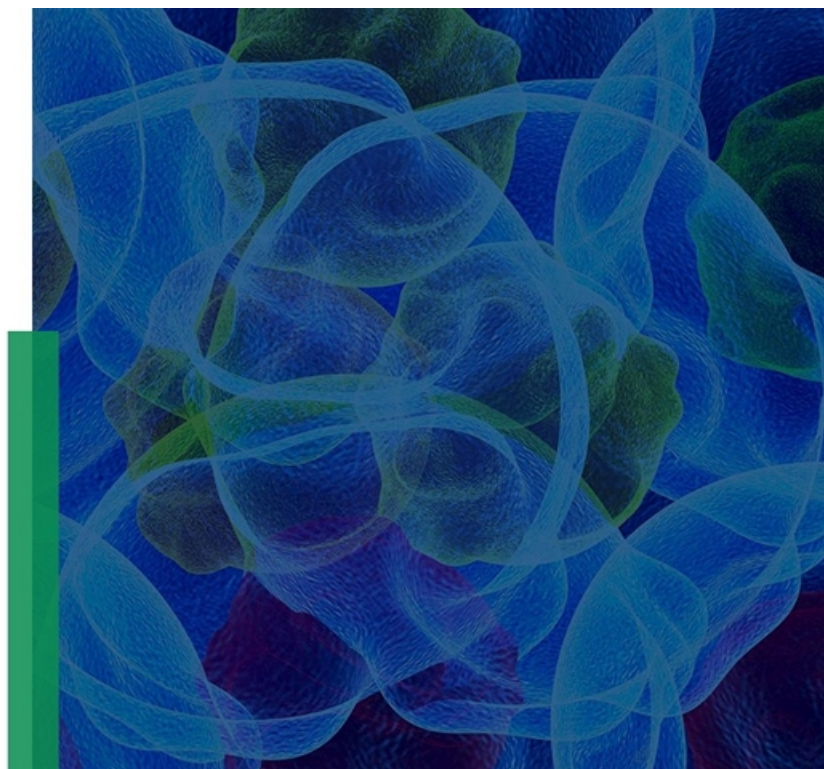
Jarrod Longcor
Chief Business Officer



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THANK YOU

NASDAQ: CLRB



Footnotes

1. Datamonitor Healthcare; Centers for Disease Control and Prevention, 2017; Ferlay et al., 2018; National Cancer Institute, 2017; Steingrímsson et al., 2017; United Nations, 2017
2. Non-Hodgkin's Lymphoma
3. www.iwmlf.com/about-wm/signs-and-symptoms
4. October 2021 IWMF Torch: Newton Guerin; Morie Gertz, MD, Mayo Clinic, Rochester, MN
5. Iopofosine I-131 Phase 2 CLOVER-1 Study in B-cell Lymphomas
6. Data as of Nov 2020
7. As of April 2021
8. U.S. Orphan Drug Designation and Rare Pediatric Disease Designation Granted for Neuroblastoma, Rhabdomyosarcoma, Osteosarcoma and Ewing's Sarcoma