

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): **December 23, 2020**

CELLECTAR BIOSCIENCES, INC.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction
of incorporation)

1-36598
(Commission
File Number)

04-3321804
(I.R.S. Employer
Identification No.)

100 Campus Drive, Florham Park, New Jersey 07932
(Address of principal executive offices, and zip code)

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

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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication 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 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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.

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, par value \$0.00001	CLRB	NASDAQ Capital Market
Warrant to purchase common stock, expiring April 20, 2021	CLRBZ	NASDAQ Capital Market

ITEM 8.01 OTHER EVENTS

On December 23, 2020 we made available an updated Corporate Presentation on the Investor Relations page of our website, which will be used at investor and other meetings. A copy of the Corporate Presentation is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company does not undertake to update this presentation.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

<u>Number</u>	<u>Title</u>
<u>99.1</u>	<u>Cellestar Biosciences, Inc. Corporate Presentation, December 2020</u>

SIGNATURE

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.

Dated: December 23, 2020

CELLECTAR BIOSCIENCES, INC.

By: /s/ Dov Elefant

Name: Dov Elefant

Title: Chief Financial Officer

Corporate Presentation

December 2020



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 CLR 131, 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 CLR 131, 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, 2019 and our Form 10-Q for the quarters ended March 31, 2020, June 30, 2020 and September 30, 2020.

Presentation Topics

1 Company Overview

2 CLR 131 Clinical Development & Approval Pathway

3 Financials

4 Company Summary and Next Steps

Company Overview

Developing oncology therapies in rare adult and pediatric orphan and ultra orphan indications

Validated cancer-targeting platform with novel MOA¹; lead product is CLR 131, a small-molecule radiotherapeutic

Achieved Phase 2 endpoints; CLR 131 demonstrates broad range of efficacy & unique safety profile in B-cell malignancies

Initiated Waldenstrom's macroglobulinemia (WM) pivotal study in Q4 2020; first patient planned enrollment January 2021

Advancing Phase 1 pediatric study in malignant brain tumors, neuroblastoma, and sarcomas

WM Pivotal Study Cost ~\$18M; Incremental \$20M to Study Outcome, \$30M to NDA Submission and \$40M to Approval

CLR 131 Franchise Strategic Construction

Multiple Pathways to Value Creation

Waldenstrom's macroglobulinemia
Pivotal Phase 2b initiated 4Q20;
100% ORR² & 83% MRR

Multiple Myeloma (MM)
6th line of treatment ORR 47%;
Patient subset ORR at 40-62%

***Clear Registration Pathway in Waldenstrom's macroglobulinemia;
Enriching Triple Class Refractory Myeloma Data in Phase 2a Expansion***

Accelerated pediatric regulatory
pathway; Granted 4 Rare Pediatric
Drug designations & ODDs

Opportunity for
joint clinical development and
commercialization partnerships

***CLR 131 Maintains Multiple Clinical Development Pathways; Active
Radiotherapeutic Partnership Market Provides Strategic Options***

CLR 131 First to Market Indication

Waldenstrom's macroglobulinemia

- Excellent efficacy and safety profile; extended Treatment Free Survival (TFS)
- 1 WM approved drug & shifting treatment dynamics favor CLR 131
- Ultra-orphan status and CLR 131 Fast Track Designation accelerates registration pathway; study completion 15-18 months
- Clearly defined primary endpoint & achievable study objectives
- Limited clinical and market competitive investment; targeted commercial/medical team sufficient to drive CLR 131 adoption
- Significant topline revenue and favorable NPV in WM; 6% of total market achieves \$1B+ top-line revenue; additional upside likely via compendia listing & 3rd party reimbursement for MM

***WM Represents an Accelerated Registration Pathway for
CLR 131 with Limited Clinical & Commercial Market Competition***

Presentation Topics

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3 Financials

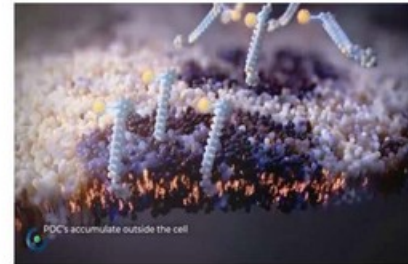
4 Company Summary and Next Steps

CLR 131 - A Phospholipid Ether (PLE) Radio-conjugate

Combination of a Validated Delivery Platform and Therapeutic Payload

- Tumor cells utilize lipids at significantly greater quantities than normal tissue
 - Energy source (β -oxidation)
 - Cell membrane production
 - Signaling molecules
- Collectar's PLEs exploit inherent tumor cell need for lipids to provide targeted delivery
 - Bind to specialized regions on tumor cells that provide uptake and internalization of lipids
 - Highly conserved across all tumor types
 - Target cancer stem cells, metastasis and primary tumor with same ligand
 - Deliver 20-40% of infused drug to tumor
- CLR 131 a phospholipid radio-conjugate
 - Provides targeted delivery of the radioisotope I-131
 - Phase 2 efficacy and safety in 4 hematologic cancers
 - Pivotal study initiated in WM

PLE Tumor Cell Targeting

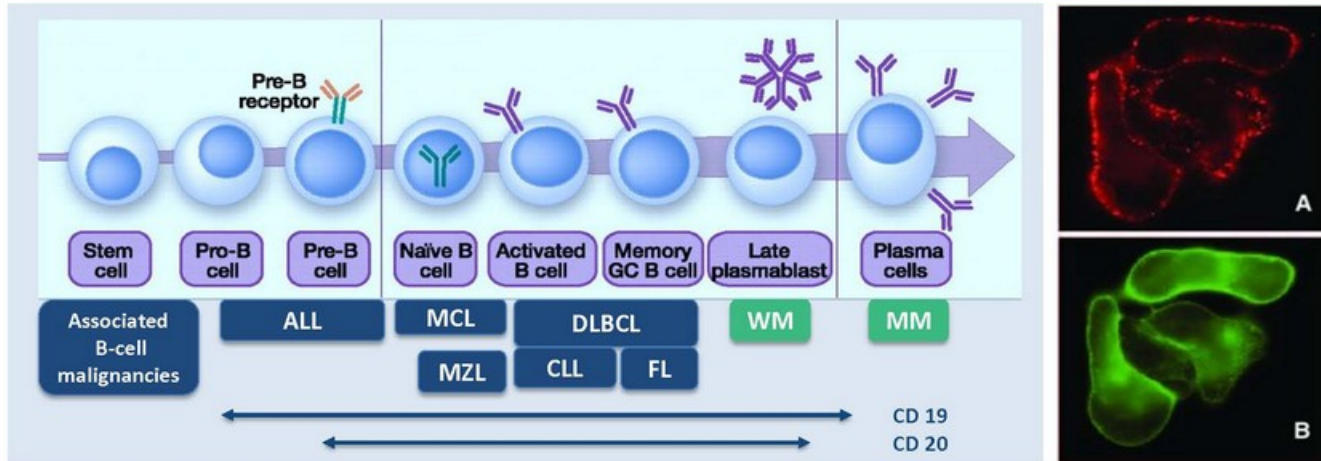


NSCLC SPECT Scan



Waldenstrom's macroglobulinemia Bridges Between NHL³ & MM

FGFR3 Overexpression in B-cell Malignancies and Lipid Rafts



- High level of tyrosine kinase receptors (TKR) = High presence of lipid rafts
- FGFR3 (a TKR) is over expressed in hematologic malignancies
 - 100% WM - 50% Multiple Myeloma - ~30% other NHLs
- Images A & B demonstrate a high level of co-localization of FGFR3 & lipid rafts; lipid rafts are not restricted to being only co-localized with FGFR3, in WM there is significant overlap

CLR 131 Response Rates Consistent with Correlation Between Lipid Rafts and Percent FGFR3 Overexpression in Hematologic Malignancies

Waldenstrom's macroglobulinemia Disease Overview

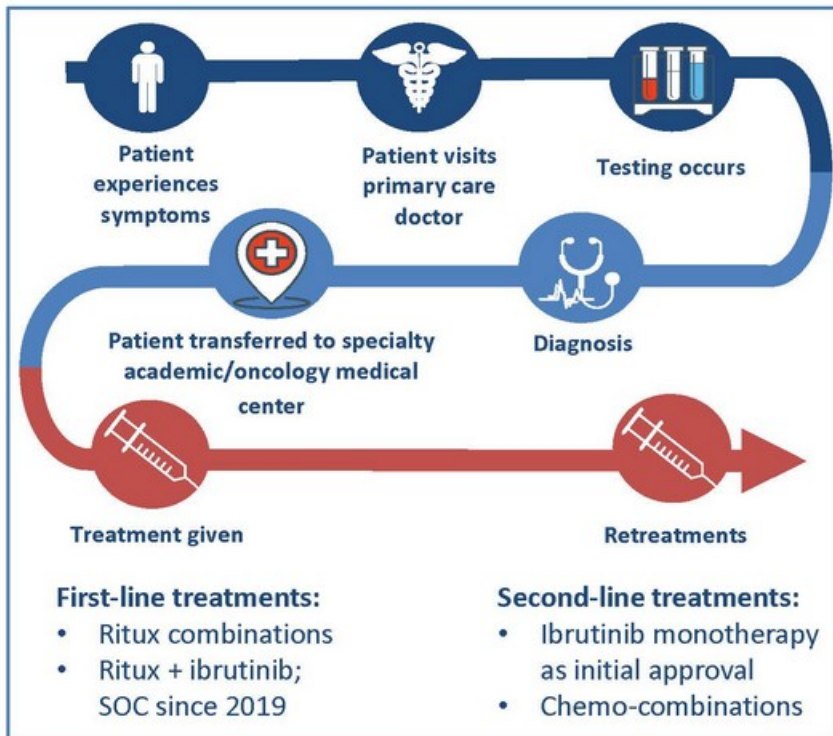
An Incurable Form of non-Hodgkin's Lymphoma

- Ultra-rare orphan disease
- Incurable disease with significant sequelae⁴
 - Hyperviscosity syndrome
 - Cryoglobulinemia/skin lesions
 - Cold agglutininemia
 - IgM induced peripheral neuropathy
 - Anemia/reduced iron levels
 - Organomegaly - lymph nodes, liver, spleen
 - Bing-Neel Syndrome (CNS infiltration)
- ~8-year survival post-initial diagnosis^{5,6}
- All patients eventually progress
 - 30-40% within 2 years of initial therapy
- Patients stratified by:
 - Risk levels: High, intermediate and low
 - Gene mutations: MYD88 and CXCR4



Waldenstrom's macroglobulinemia Patient Journey

No Post-ibrutinib Approved Therapies

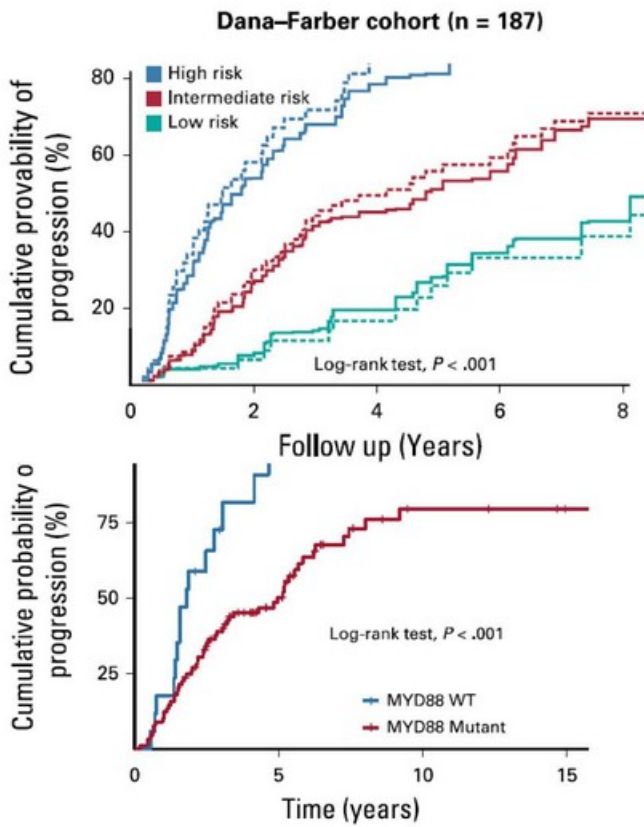


- Ibrutinib approved in 2015 2nd line monotherapy; only FDA approved agent
- Ibrutinib 2nd line market penetration 60-80%
- 10-30% of patients do not respond or have suboptimal response to ibrutinib
- 30% of patients discontinue ibrutinib treatment within one year due to toxicities
- Ibrutinib provides no post treatment duration of response (daily dosing required)

Ibrutinib Only FDA Approved Treatment for WM

WM Risk Profile Impact on Disease Progression

CLR 131 Has Demonstrated Activity in All Risk Profiles and Genotypes



Risk Group	Median Time to Progression
High Risk	1.9 years
Intermediate Risk	4.8 years
Low Risk	9.3 years

Four Criteria Determine Risk Profile

- Bone marrow involvement
- IgM level
- Beta2-microglobulin level
- Albumin level

MYD88 Status	Median Time to Progression
Wild type	1.3 years
Mutated	5.1 years

Waldenstrom's macroglobulinemia Unmet Patient Need

Clear Clinical and Market Opportunity for CLR 131

01 BTKi poor efficacy in key genotypes

- MYD88^{WT}/CXCR4^{WT}: No major responses
- MYD88^{WT}/CXCR4^{Mut}: 70% progress within 2 years
- MYD88^{Mut}/CXCR4^{Mut}: Greater major response rates, no complete responses

02 BTKi treated patients with sub-optimal response within 6 months

- Predicts relapse within 2 years
- No approved post-ibrutinib therapy

03 Treatment for BTKi intolerant patients

- Patient suffer atrial fibrillation (high risk of stroke) and significant bleeding events

04 Treatment for BTKi patient failures

- No approved post-ibrutinib therapy
- No monotherapy in relapse/refractory setting achieving complete responses

05 BTKi offers no TFS

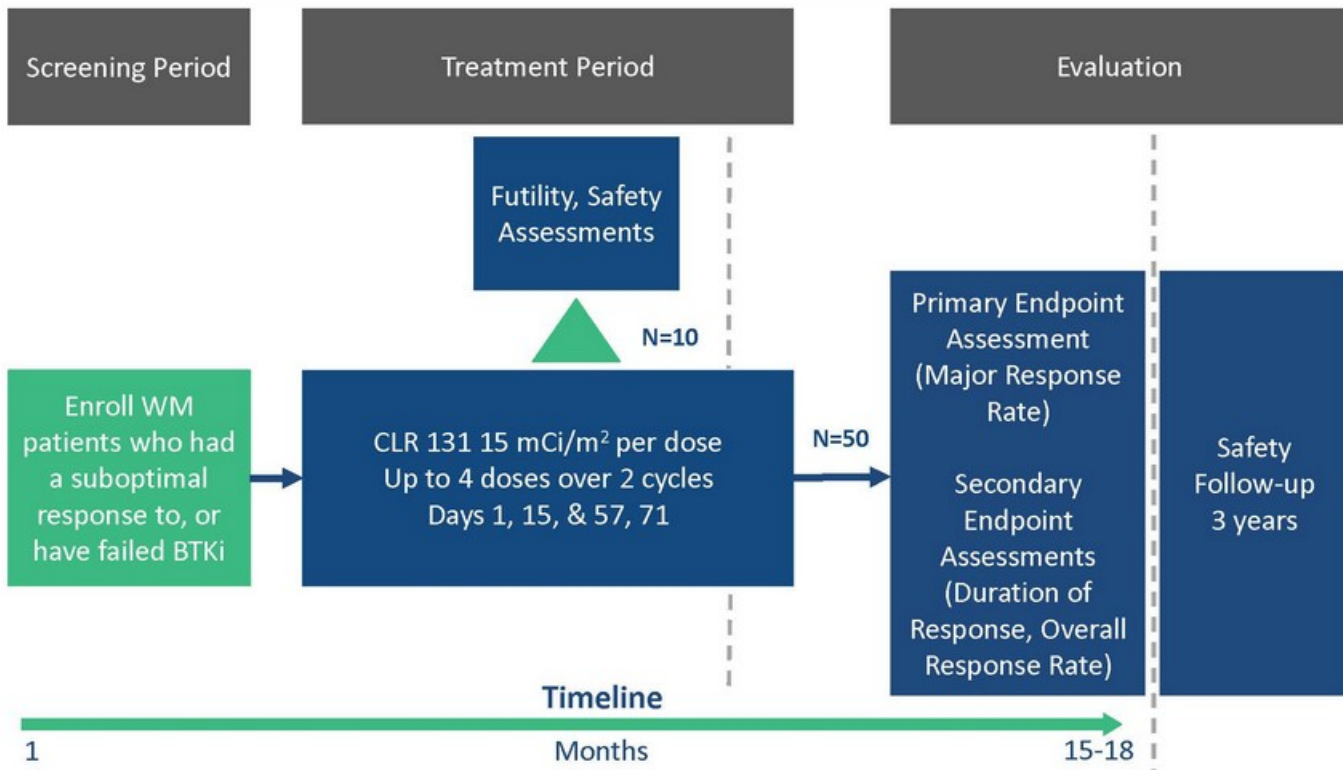
- BTKi therapy requires treatment until progression - no treatment free survival (TFS)
- All current therapies provide no TFS - no long-term duration of response

06 Treatment for high-risk patients

- 60% progress within 2 years of treatment
- Reduced 5-year survival rate

CLR 131 WM Global Pivotal Study Design

Open Label, Single Arm Registration Clinical Study; Rolling Submission

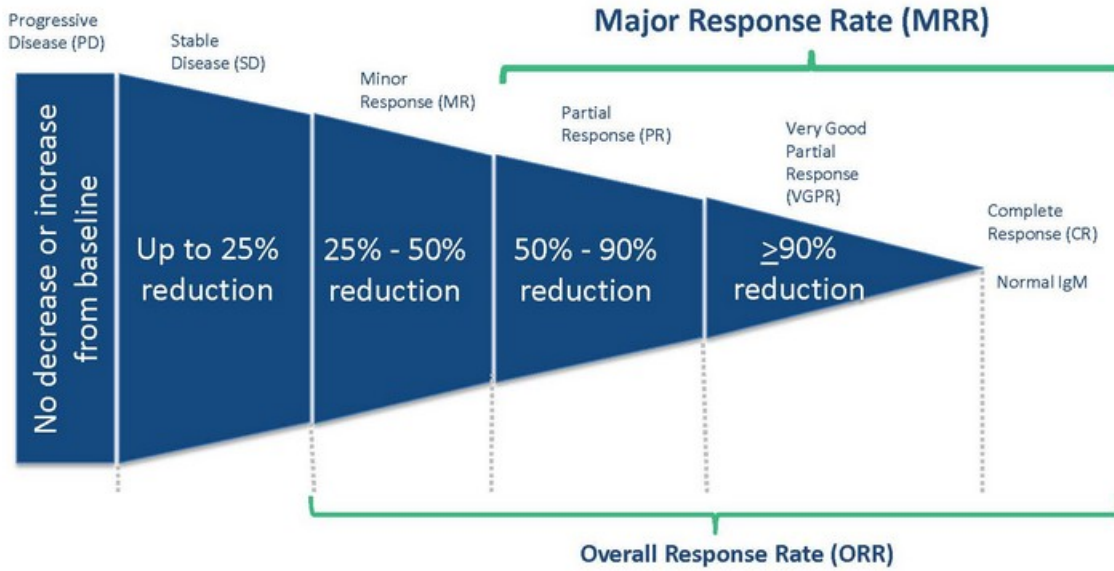


CLR 131 Major Response Rate of 20% Achieves Statistical Significance

Waldenstrom's macroglobulinemia Disease Assessment

Serum IgM is Primary Biomarker for Response Rate

Decreasing Serum IgM Levels and Clinical Symptoms/Extramedullary Disease

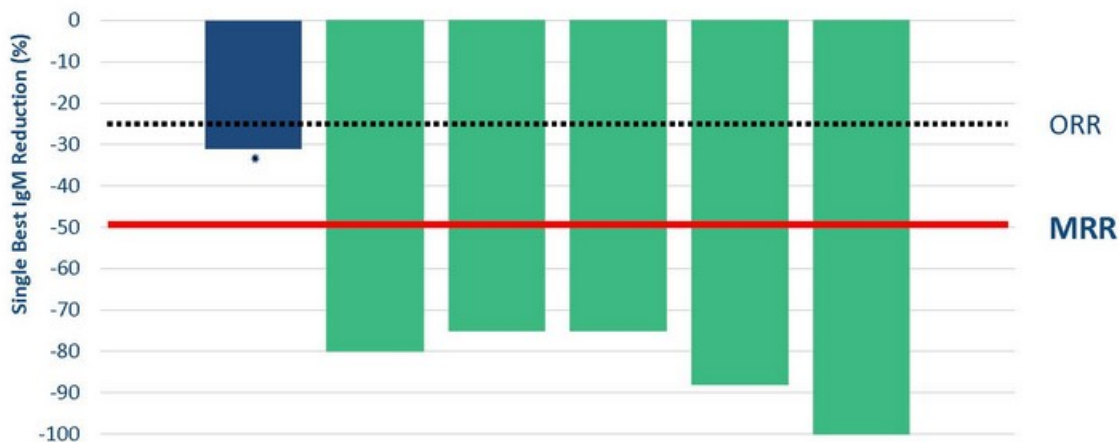


CLR 131 MRR in 10 of 50 Patients Achieves Pivotal Study Statistical Significance

CLR 131 Response Rates in WM BTKi Failed¹³ Patients

Demonstrates Activity in All Key Genotypes

CLR 131 Responses in BTKi *Sub-optimal Response* or *Failed* Patients



- 83% MRR in BTKi *sub-optimal response* or *failed* patients
- First & only monotherapy to achieve a CR in BTKi failed patient population
- Only treatment tested in BTKi failure patients

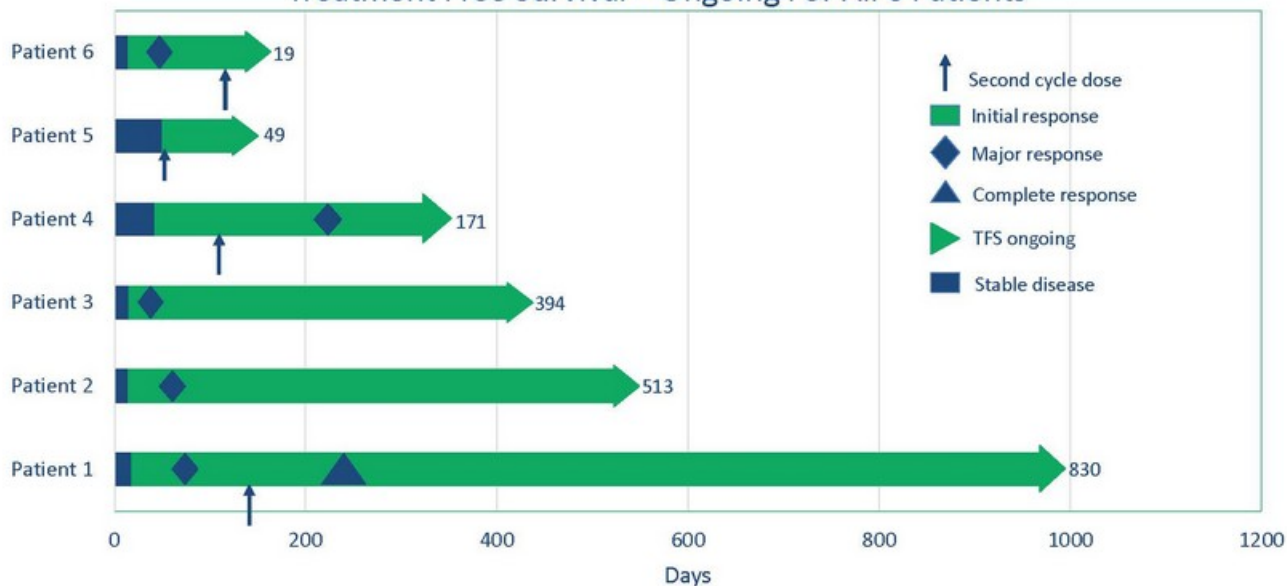
CLR 131 Only Monotherapy to Achieve 83% MRR and a CR in BTKi Failed or Sub-optimal Response Patients

* Patient's efficacy assessment ongoing

CLR 131 Treatment Free Survival in WM BTKi Failed Patients

Meaningful TFS Exhibited

Treatment Free Survival – Ongoing For All 6 Patients



- Initial response for most patients occurs within 22 days of first cycle
- Time to major response is typically less than 45 days
- Ibrutinib provides no TFS; progression within 4 weeks after treatment discontinuation

***CLR 131 Treatment Free Survival 330 Days on Average and Ongoing For All Patients;
No Patients Have Initiated New Therapy***

WM Major Response Rates

CLR 131 Exceeds All Reported MRRs (Overall and by Subtype)

Drug	Overall	Prior BTKi exposure	MYD88 ^{MUT} / CXCR4 ^{WT}	MYD88 ^{MUT} / CXCR4 ^{MUT}	MYD88 ^{WT} / CXCR4 ^{MUT}	MYD88 ^{WT} / CXCR4 ^{WT}
Ibrutinib ^{11,12} (n=63)	78%	N/A	91.2%	61.9%	NR	0%
Acalabrutinib (n=92)	78%	NT	NR	NR	NR	NR
Zanubrutinib (n=73)	78%	NT	59%	27.3%	NT	11%
Venetoclax (n=30)	73%	30% (n=10)	86%	63%	NT	NT

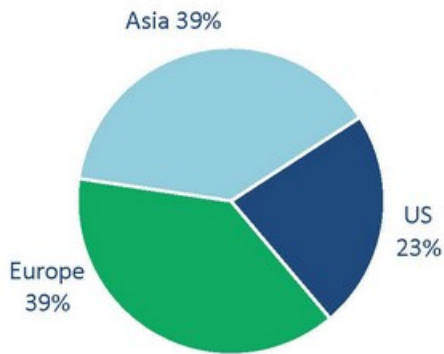
- All BTKi's evaluated in treatment **naïve and post first line** relapsed patients
 - Non-reversible and reversible BTKi behave the same in WM
 - Neither provide meaningful responses in the difficult to treat MYD88 wild type patients
- Venetoclax evaluated in treatment **naïve and post first line** relapsed patients
 - 10 patients were **BTKi previously treated**; demonstrated **30% response rate**
 - Based upon genotypes, most patients expected to be BTKi intolerant
 - Based upon intolerant rates to ibrutinib, 50% (n=5) of patients likely intolerant

Currently MRR in BTKi Failures or Sub-optimal Response 15-24%

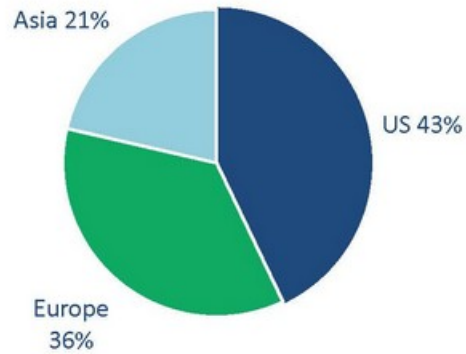
Waldenstrom's macroglobulinemia Global Market

Epidemiology and Treatment Centers by Region

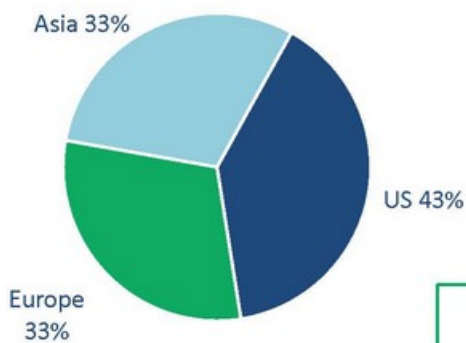
Annual Incidence 6,500⁷



Key Treatment Centers 70



Annual Prevalence ~60,000⁷



- Median age at diagnosis is 65
- 5-year survival for high-risk patients @ 36%
- U.S. represents a slightly larger market opportunity with a higher prevalence
- More common in males of European descent
- Growth rate driven by aging population

Incidence Growth Rate of ~30% Through 2025

Waldenstrom's macroglobulinemia Global Market

CLR 131 Forecasted Revenue in 2nd & 3rd Line Patient Population



Assumptions	Factor
2 nd /3 rd Line Population	6,008
Annual Growth Rate	2.33%
Revenue Per Dose	\$75,000
Avg. Revenue Per Patient	\$262,500
Market Ramp to Peak Penetration	6 Years

- Global WM prevalence ~60,000; forecasted 2nd/3rd line market shares of 30%, 55% & 80% represent ~ 3%, 6% & 8% of overall prevalence market
- Projection are global revenues (U.S. represents ~60% of global market)
- Patent protection and regulatory exclusivity until 2032/2033

Forecasted WM Peak Revenue ~\$670M - >\$1.8B

CLR 131 For The Treatment Of Multiple Myeloma

Challenging Patient Population - Characteristics¹⁴

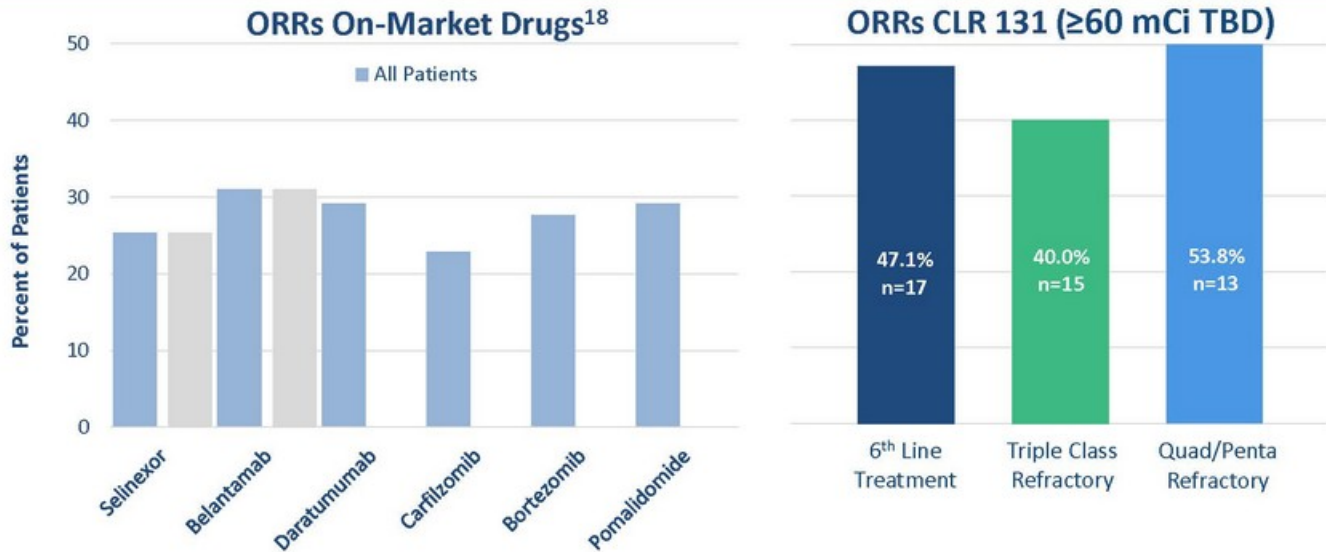
Criteria	Total Body Dose <50 mCi (n=11)	Total Body Dose ~50 mCi (n=22)	Total Body Dose ≥60 mCi (n=20)	Total (n=53)
Median Age (Min-Max)	68.5 (55-85)	70 (51-82)	70 (59-83)	70 (51-85)
Male (%)	50	60	71	62
Median Prior Lines of Therapy (Min-Max)	4 (3-12)	5 (2-13)	5 (3-17)	5 (2-17)
Cytogenetics at Diagnosis				
High Risk [n (%)]	3 (27.2)	8 (36.4)	8 (40)	19 (35.8)
Unknown [n (%)]	0	3 (15)	4 (18)	7 (13.2)
Median Beta-2 Macroglobulin (Range)	2.62 (2.09,4.4)	3.9 (1.98,9.49)	2.65 (1.1,4.4)	2.83 (1.1, 9.49)

Total Evaluable Patients n=49 (%)	
Refractory to Immediate Prior Therapy	44 (89.8)
Quad ¹⁵ /penta-refractory ¹⁶	31 (63.3)
Triple Class Refractory ¹⁷	26 (53.1) 25 (96.2)

Patient Population Mirrors Real World Utilization

Multiple Myeloma Competitive Landscape

Approved Products and CLR 131 Response Rate Summary



- ORR for on-market drugs 22.9% to 31%
- Only two approved drugs with triple class refractory response data
 - Selinexor (25.4%) and belantamab (31%)

CLR 131 Demonstrates Activity in Key Refractory Patient Populations

CLR 131 All B-cell Malignancies Patients

Well Tolerated Safety Profile in WM, MM and Other NHL's

Treatment Emergent Adverse Events¹⁴ (≥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

- Most frequent TEAEs¹⁹ are cytopenias; very predictable and manageable
 - Nadir occurs ~34 days post initial dose; recovery occurs within ~21 days post nadir
- No deaths, cardiotoxicities, liver, renal or neurologic toxicities, keratopathy, etc.

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Financials

Capitalization as of November 9, 2020

Common Stock Outstanding **26,813,593**

Reserved for issuance:

Convertible Preferred Stock²⁰ 537,500

Warrants 17,937,766

Employee/Director Stock Options 1,184,464

Fully Diluted **46,473,323**

Cash/Equivalents as of September 30 **~\$18.8 million**

WM Pivotal Study Cost ~\$18M; Incremental \$20M to Study Outcome, \$30M to NDA Submission and \$40M to Approval

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Company Summary

CLR 131 Clinical Development Next Steps

- High unmet medical need and significant market opportunity in Waldenstrom's macroglobulinemia and Multiple Myeloma
 - WM: BTKi (ibrutinib) failed patients
 - MM: Subset populations: Later line, triple class & quad/penta refractory
- CLR 131 impressive product profile in B-cell malignancies
 - WM: 100% ORR & 83.3% MRR in BTKi failed patients; extended TFS
 - MM: 47% ORR 6th line, 40% triple class and 54% quad/penta refractory
- Near-term clinical development plan
 - WM: Phase 2b pivotal study initiated 4Q20
 - MM: Phase 2a to enroll additional ~15 triple class refractory patients
 - Pediatric: Phase 1 malignant brain tumors, neuroblastoma & sarcomas

***CLR 131 is an Effective Drug in Multiple Indications; Lead Indication
WM represents an Underserved and Addressable Market***



Thank You



NASDAQ: CLRB

Footnotes

1. Mechanism of Action
2. Overall Response Rate
3. Non-Hodgkin's Lymphoma
4. <https://www.iwmf.com/about-wm/signs-and-symptoms>
5. Sekhar J, et.al. Waldenström macroglobulinemia: a SEER database review from 1988 to 2005. *Leuk Lymphoma* 2012;53(8):1625-1626;
6. https://www.orpha.net/consor/cgi-bin/OC_Exp.php?Expert=33226
7. Datamonitor Healthcare; Centers for Disease Control and Prevention, 2017; Ferlay et al., 2018; National Cancer Institute, 2017; Steingrimsson et al., 2017; United Nations, 2017
8. Treon et al. 2012. *New England Journal of Medicine*. 367, 826-833.
9. Hunter et al. 2014. *Blood*. 123, 1637-1646.
10. Castillo and Treon, *Leukemia*, 2019.
11. Treon et al, EHA 2018
12. Treon et al, EHA 2018
13. Failed = patient achieving less than a partial response including disease progression
14. Data as of 31Jan2020
15. When patients are refractory to 4 therapeutic agents
16. When patients are refractory to 5 therapeutic agents
17. When patients are class refractory to proteasome inhibitor, Immunomodulatory drug, and CD38 antibodies
18. ODAC Briefing Document, Selinexor Feb. 26, 2019. ; Usmani, et al (2016). *Clinical efficacy of daratumumab monotherapy in patients with heavily pretreated relapsed or refractory multiple myeloma*. *Blood Journal*. ; Dimopolous et al (2016). *Safety and efficacy of pomalidomide plus low-dose dexamethasone in STRATUS (MM-010): a phase 3b study in refractory [MM]*. *Blood Review*. ; Jurczynsyn et al (2014). *New drugs in multiple myeloma - role of carfilzomib and pomalidomide*. *Contemporary Oncology*; *Lancet Oncology DREAMM-2 Study - 2.4 mg per kg; KarMMa-2 Study - Dose group 300x106*
19. Treatment Emergent Adverse Events
20. Convertible preferred stock is convertible at any time at the holder's option into a number of shares of common stock at a conversion rate of 1:2,500. There are currently 215 shares outstanding they do not contain any preferential rights over common stock

Executive Leadership

Jim Caruso President, CEO and Director	HIP Innovation Technology - Co-Founder, EVP & COO, Allos Therapeutics - EVP & CCO, BCI, Novartis, BASF, Bristol-Myers Squibb	 NOVARTIS	 Abbott
Dov Elefant Chief Financial Officer	Akari Therapeutics PLC - CFO, Celsus Therapeutics, Inc. - CFO Lev Pharmaceuticals - Corporate Controller	 Bristol-Myers Squibb	 BASF We create chemistry
John Friend, MD Chief Medical Officer	DRGT - CMO, Helsinn Therapeutics - SVP & Head of R&D, Akros Pharma, Actavis, Alpharma, Hospira, Abbott	 HELINN Building quality cancer care together	 ALLOS [®] THERAPEUTICS
Jarrold Longcor Chief Business Officer	Avillion LLP - CBO Melinta Therapeutics, Inc. (formerly Rib-X Pharmaceuticals, Inc). - VP Corp Development and Operations	 AVILLION	 Melinta THERAPEUTICS

Executive Team With Extensive Healthcare Leadership and a Proven Track Record of Product Development and Commercialization

Waldenstrom's macroglobulinemia Disease Manifestation

MYD88 and CXCR4 Genotypes Drive Disease and Outcomes

