
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: October 2, 2018
(Date of earliest event reported)

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 Number)

3301 Agriculture Drive, Madison, Wisconsin 53716
(Address of principal executive offices)

(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 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 ☐

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

On September 27, 2018, we issued a press release announcing that James Caruso, our President and Chief Executive Officer, will be presenting at the Ladenburg Thalmann 2018 Healthcare Conference, on Tuesday, October 2 at 3:00 p.m. Eastern time. A copy of the Corporate Presentation to be used is furnished as Exhibits 99.1, and is incorporated by reference herein.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Number	Title
<u>99.1</u>	<u>Collectar Biosciences, Inc. October 2018 Corporate Presentation</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: October 2, 2018

CELLECTAR BIOSCIENCES, INC.

By: /s/ Brian M. Posner

Name: Brian M. Posner

Title: Chief Financial Officer

Corporate Presentation

October 2018



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. 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 required to complete the development programs described herein, uncertainties related to the disruptions at our sole supplier of CLR 131, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, the completion of clinical trials, the FDA review process and other government regulation, the ability of our pharmaceutical collaborators to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement. This presentation includes industry and market data that we obtained from industry publications and journals, third-party studies and surveys, internal company studies and surveys, and other publicly available information. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. Although we believe the industry and market data to be reliable as of the date of this presentation, this information could prove to be inaccurate. Industry and market data could be wrong because of the method by which sources obtained their data and because information cannot always be verified with complete certainty due to the limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties. In addition, we do not know all of the assumptions that were used in preparing the forecasts from the sources relied upon or cited herein. 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, 2017 and our Form 10-Q for the quarterly period ended June 30, 2018.

Company Highlights

Developing orphan and rare pediatric oncology pipeline with multibillion-dollar¹ sales potential

Advancing multiple clinical programs; demonstrated activity in hematologic malignancies

9 clinical data readouts planned through 2019

PDC tumor targeting platform validated through clinical trials and corporate partnerships

Efficient capital allocation and low fixed-cost corporate structure allows for ~\$10M - \$12M annual cash burn

Multiple, Value-Creative, Near Term Milestone Potential

1. ResearchAndMarkets.com's offering, Neuroblastoma - Market Insights, Epidemiology and Market Forecast-2027 The market of Neuroblastoma in 7MM was found to be USD 733.58 million in 2016, and is expected to increase at from 2016-2027. Market Research Future Jan 2018 The osteosarcoma market has been on the rise over the past few years. Based on the MRFR analysis, the market is projected to reach USD 136.76 million by 2023 at a healthy CAGR of around 6.40%. Market Research Future July 2018 - The global pediatric brain tumor market is expected to reach US\$ 1659.4 million by 2023.

Collectar Accomplishments in the Past 3 Years

Robust Pipeline Focused on Unmet Need in Cancer



1

Mid-stage
Clinical
Compound



9

FDA Special
Designated
Programs
5 ODD¹
4 RPDD²



9.8

Million
Dollars in
non-dilutive
funding



6

Preclinical
Phospholipid
Drug Conjugate
(PDC) Programs



5

Corporate
PDC
Partnerships

Creating the Next Generation of Targeted Cancer Therapies

Pipeline

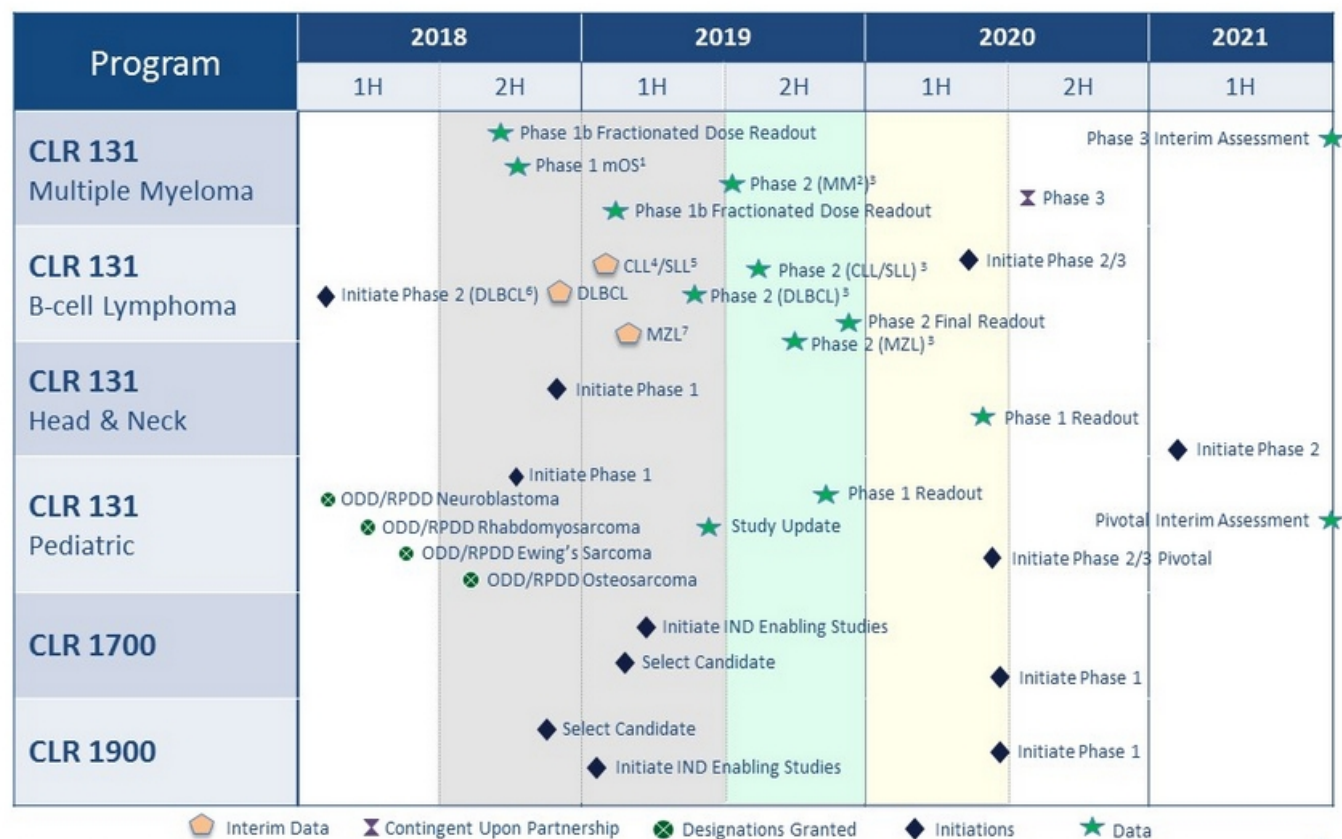
Focus on Niche Oncology Indications with Accelerated Commercial Timelines to Scalable Markets

PDC ¹	Indications	Discovery	Pre-IND	Phase 1	Phase 2	Payload
CLR 131	Multiple Myeloma ²					Iodine-131
	B-Cell Lymphomas ²					
	Pediatric Cancer					
	Head & Neck ³					
CLR 1700	Hematologic Tumors					BTK ⁴
CLR 1900	Solid Tumors					Undisclosed
Current Partnerships						
CLR 1800	Solid Tumors					 Pierre Fabre
CLR 2000	Performance-based					 AVICENNA ONCOLOGY
CLR 2100	Solid Tumors					 ONCONOVA THERAPEUTICS
CLR 2200	Solid Tumors					 ONCONOVA THERAPEUTICS
CLR 12120	Solid Tumors					 oranomed

Leverage POC Data in Larger Opportunities to Attract Partners

1. Phospholipid Drug Conjugates 2. Phase 2 partially funded by \$2M NCI FastTrack Grant 3. Predominately funded by University of Wisconsin NCI SPORE Grant 4. Burton's Tyrosine Kinase

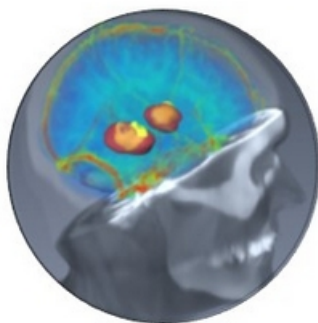
Projected Key Development Milestones



1. Median Overall Survival 2. Multiple Myeloma 3. Topline Data 4. Chronic Lymphocytic Leukemia 5. Small Lymphocytic Leukemia 6. Diffuse Large B-cell Lymphoma 7. Marginal Zone Lymphoma

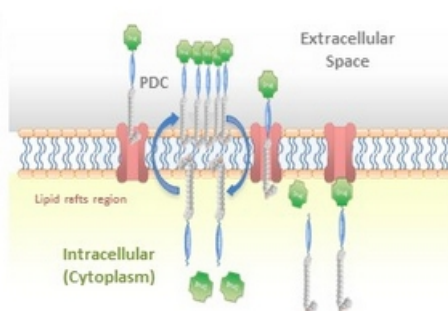
PDC Platform Technology

Precision Targeting



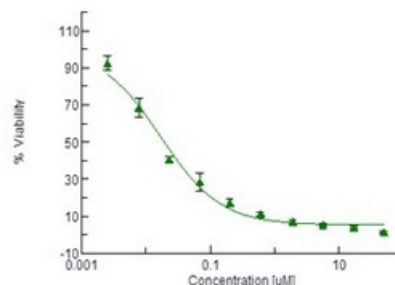
- Phospholipid ethers (PLEs) provide precise targeting even to the brain; crosses blood brain barrier (BBB)
- PLEs bind to specific membrane region (lipid rafts) rather than a single epitope
- Take advantage of the tumors' metabolic need

Optimized Entry



- Entry via lipid rafts and transmembrane flipping
- Delivery directly to cytosol
- PDCs will accumulate along the Golgi apparatus network and endoplasmic reticulum

Unique Linker Chemistry & Diversity of Payloads



- Custom-designed linkers
- Allows for control of rate, mechanism and localization of drug release
- Maximizes therapeutic benefit

***Based on Research in Phospholipids, Tumor Cell Membranes
and Cutting-edge Expertise in Protease Linker Design***

Our Pipeline

1 CLR 131

2 CLR 1700

3 CLR 1900

CLR 131: Manufacturing Update

- CLRB notified of FDA CPDC¹ Import Action on 8/07/18 which prevented shipment of CLR 131 into the U.S.
- The Import Alert stemmed from audit observations for a different product manufactured at a different building on the CPDC campus
- CPDC and the FDA completed a meeting September 11
 - CPDC presented their response and action plan to remedy inspection observations; CPDC has initiated all action items in their proposed plan
 - FDA provided CPDC with requirements to lift Import Alert
- FDA is now working directly with CLRB on pathway to exempt CLR 131 from the Import Alert
 - Multiple meetings completed; CLRB communicating requested information
 - Recent independent audit of CLR 131 process reconfirmed CGMP compliance

Radiotherapeutic Market & CLR 131 Positioning

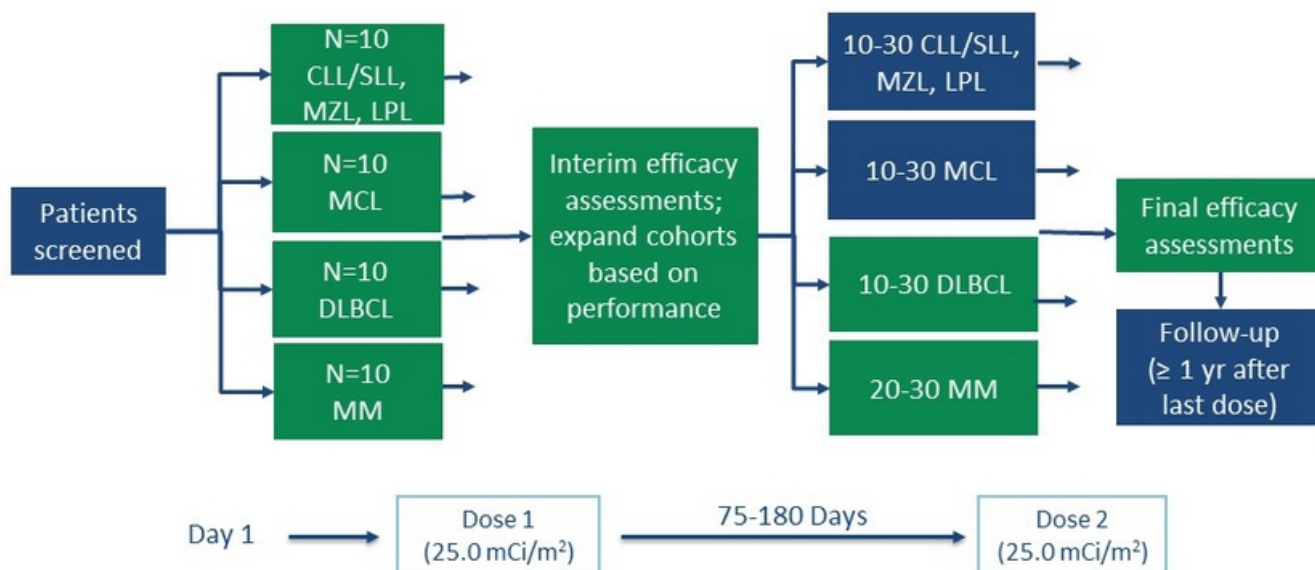
- Radiotherapeutic market forecast ~\$9.3 billion revenue in 2020¹
 - Novartis acquires Advanced Accelerator Applications for \$3.9 billion²
 - Lead product Lutathera - radioligand therapy
 - Bayer's Xofigo® radiotherapeutic generates \$473M in revenue³
 - Progenics Pharma Azedra™ (MIBG I-131) market cap of ~\$600M⁴
- CLR 131 Strategic Approach
 - Establish Phase 2 data for DLBCL & MM to drive potential partnerships
 - Advance R/R⁵ niche market opportunities to commercialization
 - R/R B-cell lymphomas (LPL, MZL, MCL⁶)
 - Few approved therapies; accelerated route to market
 - Potential revenues ~\$800M U.S./~\$1.8B worldwide⁷
 - R/R pediatric tumors (NB⁸, High Grade Glioma, RMS⁹, Ewing's & Osteosarcoma)
 - Approximately 40 U.S. treatment centers; ~20 MIBG I-131 for NB
 - Target indications represent ~30% of pediatric oncology market¹⁰
 - Potential revenues ~\$600M U.S./~\$1.5B worldwide¹¹

1. Seeking Alpha Report - Change to Research & Markets, "Global Radiotherapy Market Analysis, Companies Profiles, Size, Share, Growth, Trends and Forecast to 2024" Feb 2017 2. 2017 - <https://bit.ly/2ut9KZl>

3. Bayer Annual Report 2017 4. 7/17/2018 - Yahoo Finance 5. Relapsed Refractory 6. Mantle Cell Lymphoma 7. Company Estimates 8. Neuroblastoma 9. Rhabdomyosarcoma 10. American Cancer Society, Cancer Facts & Figures 2016 11. Company Estimates.

CLR 131: RR Hematologic Phase 2 Study Overview

Supported with a \$2M NCI SBIR Grant

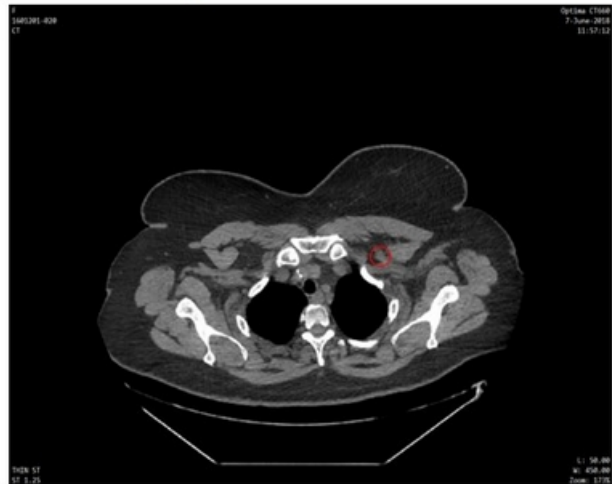
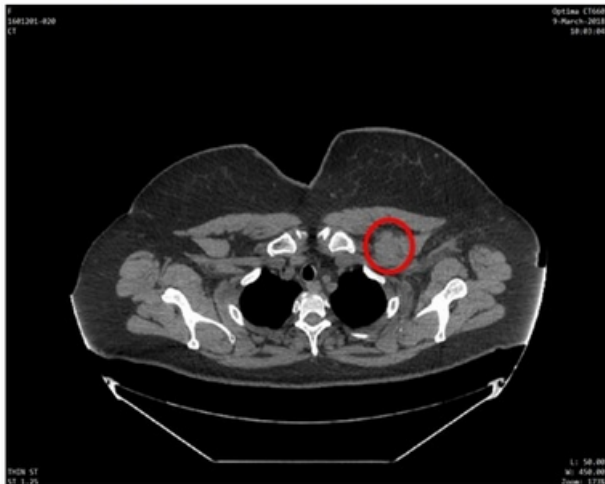


- Primary endpoint is efficacy as determined by response rate (can occur on either dose)
- All cohorts currently enrolling; expect to complete study in 1H-19
- Upon study completion, individual cohorts may advance to a pivotal trial

All Patients Eligible for a Second 25.0 mCi/m² Dose at Day 75-180

CLR 131: Phase 2 DLBCL Interim Data

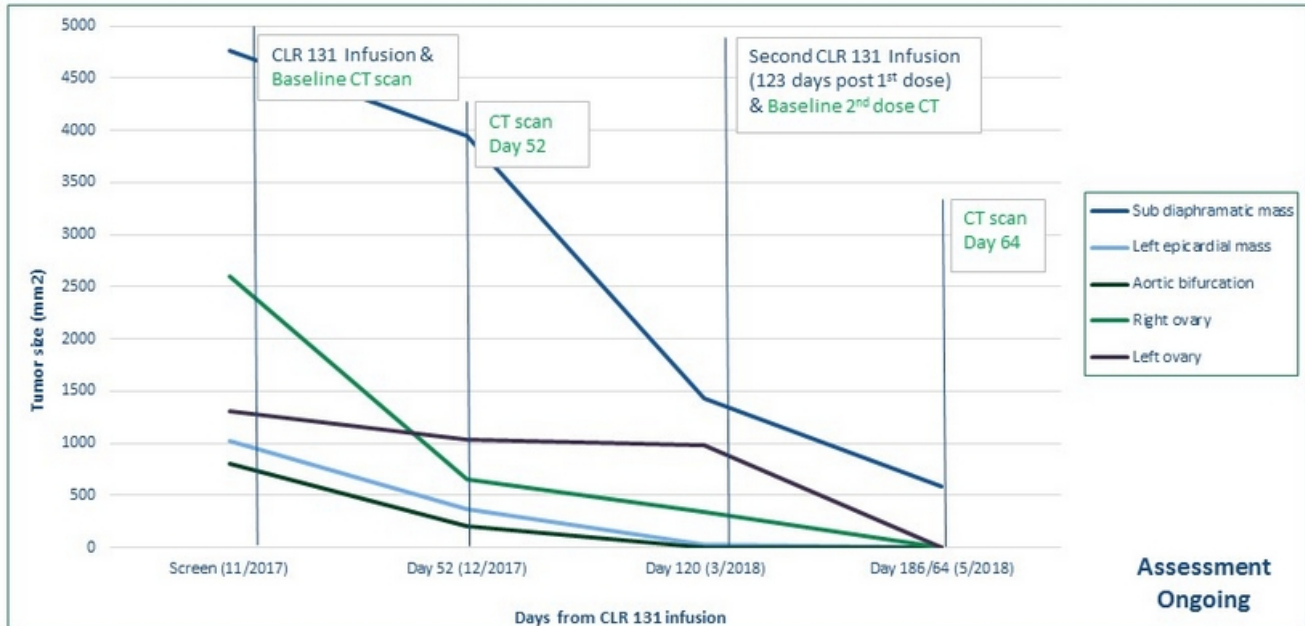
- Diffuse Large B-cell Lymphoma (DLBCL) is an aggressive form of lymphoma, accounting for ~30% of newly diagnosed cases in the U.S.¹
- DLBCL cohort opened 1Q-18
- 33% Overall Response Rate (ORR) to date
- 50% Clinical Benefit Rate (CBR) to date
- Of responses observed, overall tumor reduction ranged from 60-90%



1. According to the Lymphoma Research Foundation.

CLR 131: Phase 2 LPL Patient Case Study (Waldenstrom's)

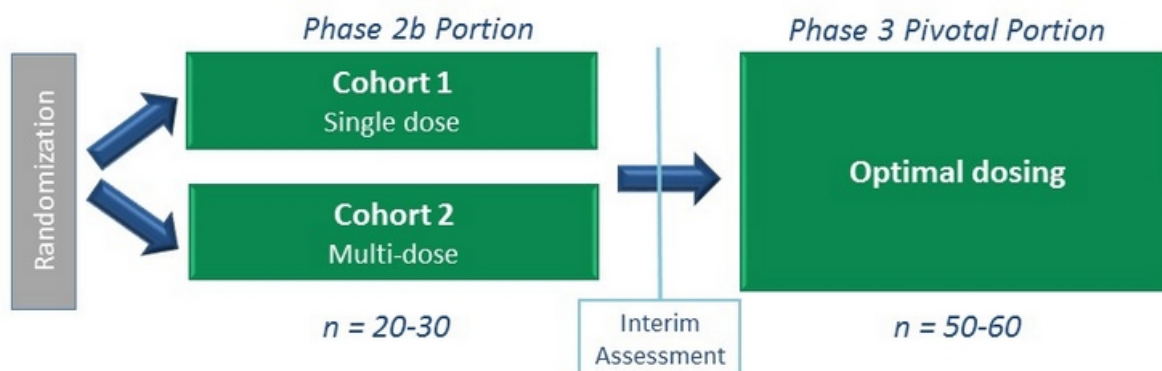
- Baseline: Pleural effusion & multiple large tumor nodules; symptomatic with cough
- Following 1st infusion: Dramatic improvements in cough and no significant cytopenias



- CT day 64 (Post 2nd Infusion) showed 94% reduction in overall tumor burden as well as complete resolution of 4/5 tumors

CLR 131: B-cell Lymphoma Clinical Development Strategy

Proposed Phase 2/3 Adaptive Design Pivotal Study (for LPL, MZL or MCL)



Proposed Phase 2/3 Pivotal Study Design

- Relapsed/refractory niche lymphoma indication
- Phase 2b enrollment of ~20 patients
- Phase 3 pivotal, single-arm
 - Primary endpoint: Overall Response Rate (ORR)
 - Secondary endpoints: Overall Survival (OS), Progression Free Survival (PFS)

Program Timing¹

- Phase 2a to complete 1H-19
- Phase 2b/3 initiation 1H-20
- NDA submission 2023

Clinical Costs¹

- Phase 2b = \$4 - \$8 million
- Phase 3 pivotal trial = \$15 - \$20 million
- Eligible for pivotal trial SBIR Grant up to \$4M per indication²

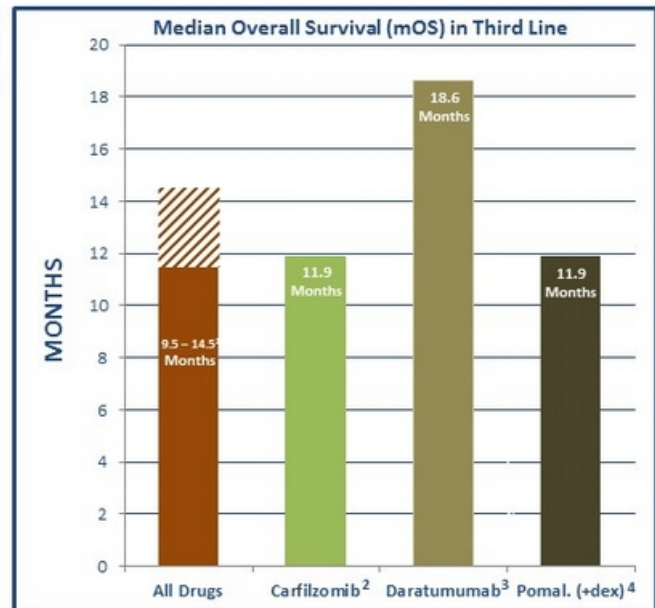
1. Estimated 2. <https://www.grants.gov/web/grants/learn-grants.htm>

CLR 131: Relapsed/Refractory Multiple Myeloma

New Treatments are Needed

Key Unmet Need: Improved Survival Rates and Tolerability

- Most approved drugs for R/R MM in third line or later average 11.9 months of survival, including several recent additions
- Darzalex™ for third-line treatment averages 18.6 months of survival
- Most treatments are now given in combination for use in earlier lines of therapy; most frequent is triplet combination
- More patient-friendly dosing regimens required, fewer infusions, less pills
- Common adverse events include peripheral neuropathy, infection, deep vein thrombosis, severe cytopenia, fatigue



Opportunity to Capture Significant Market Share in Third Line or Later Based on an Improved Efficacy, Safety and Tolerability Profile

¹Traditional monotherapy chemotherapy, protease inhibitor, and immunomodulating agents

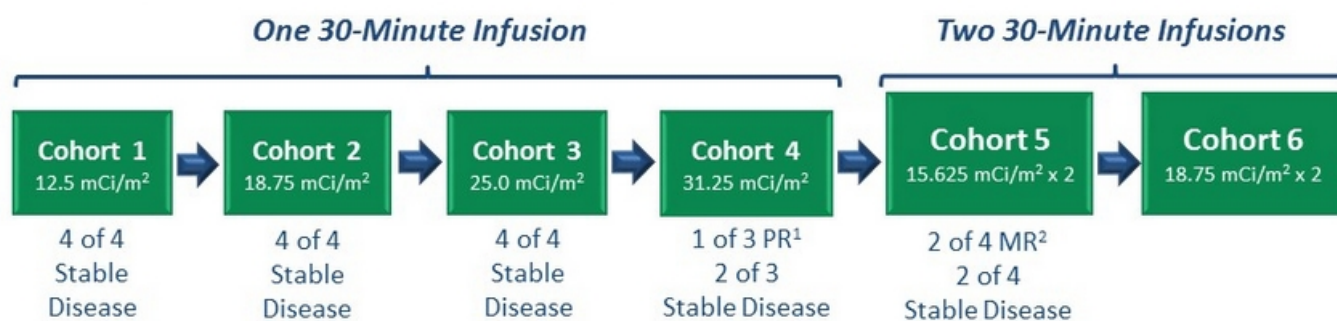
²Jurczyszyn et al (2014). New drugs in multiple myeloma – role of carfilzomib and pomalidomide. *Contemp Oncol*.

³Usmani, et al (2016). Clinical efficacy of daratumumab monotherapy in patients with heavily pretreated relapsed or refractory multiple myeloma. *Blood Journal*.

⁴Dimopoulos et al (2016). Safety and efficacy of pomalidomide plus low-dose dexamethasone in STRATUS (MM-010): a phase 3b study in refractory multiple myeloma. *Blood Rev*.

CLR 131: RR MM Phase 1 Study Overview

Primary endpoints are safety, tolerability and determination of maximum tolerated dose



Patient Demographics					
Metric	Cohort 1 (12.5 mCi/m ²)	Cohort 2 (18.75 mCi/m ²)	Cohort 3 (25.0 mCi/m ²)	Cohort 4 (31.25 mCi/m ²)	Cohort 5 (31.25 mCi/m ²)
Average Age	68	70	71	65	71
Prior # of Treatment Lines	5.8	4	5	5	5
Tumor Burden	2.71	2.86	4.19	4.36	2.69
≥ 1 Triple Combination Treatment	4/4	4/4	4/4	3/3	3/4
Stem Cell Transplant	1/4	3/4	4/4	2/3	1/4

All Patients Have Advanced Disease and are Heavily Pre-treated

1. Partial Response 2. Minimal Response 3. Based on baseline B2 Microglobulin

CLR 131: RR MM Tolerability & Overall Survival (OS)

Key Results To Date ¹	Adverse Events	Avg. Number ²	Avg. Grade ²	Median Grade
- All cohorts determined to be safe and well-tolerated by independent DMC - No patients experiencing peripheral neuropathy, deep vein thrombosis, cardiotoxicities, embolisms or GI toxicities - Cytopenias most common adverse events - All viewed as predictable & manageable ≥ Grade 3 fatigue and fever = 7% - No change in liver enzymes or renal function	Cohort 1 (12.50)	4.75	2.05 ± 0.91	2.0
	Cohort 2 (18.75)	4.75	2.74 ± 0.93	2.0
	Cohort 3 (25.00)	6.75	2.52 ± 1.22	3.0
	Cohort 4 (31.25)	4.25	3.23 ± 0.93	3.0
	Cohort 5 (15.625 x 2)	5	2.95 ± 1.10	3.0

Pooled Phase 1 Study³: Overall Survival (n=15)



Survival Data Updated 10/02/18; mOS Not Reached to Date

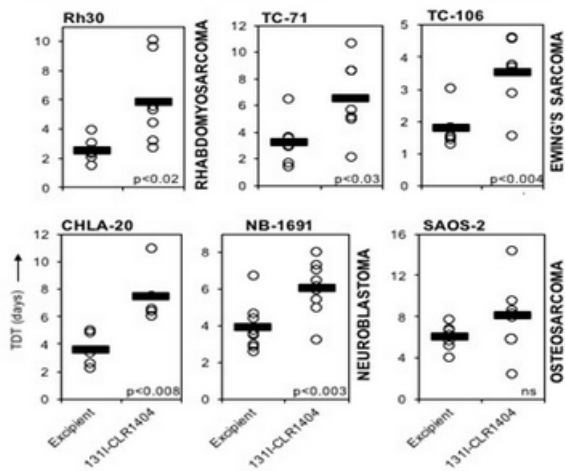
1. Study ongoing n=19 - Final results may differ from data presented 2. Per patient 3. Single dose cohorts 1-4

CLR 131: Efficacy in Pediatric Preclinical Models

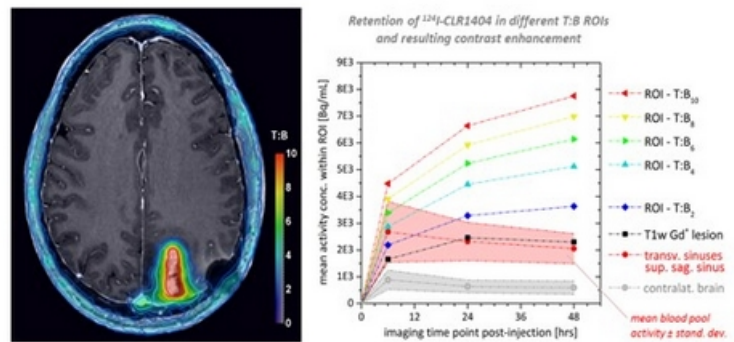
Preclinical Results

- Various mouse models demonstrate significant uptake of CLR 131
 - Neuroblastoma, Rhabdomyosarcoma, Ewing's Sarcoma, Osteosarcoma
- Uptake correlated to reduction in tumor volume and ~50% slowing of tumor growth
- Minimal adverse effects were seen on hematologic parameters

Efficacy in Mouse Models

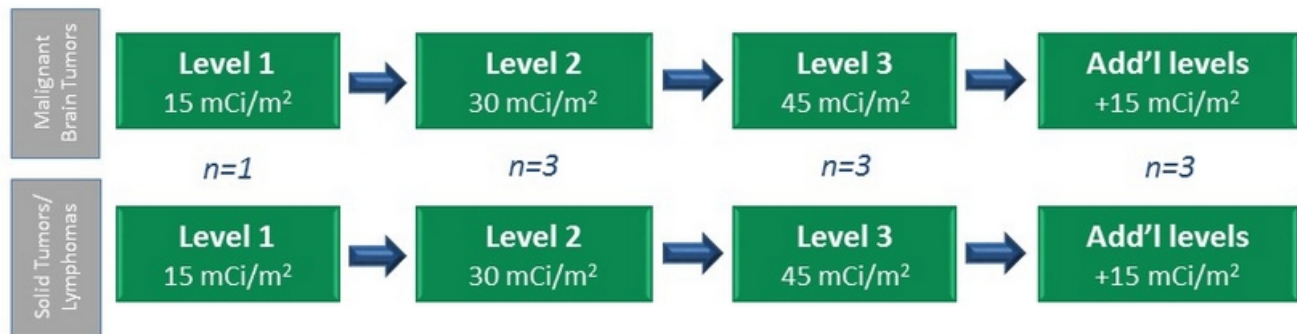


Uptake in the Brain (Crossing BBB)



CLR 131: Pediatric Clinical Development Strategy

FDA Agreement on Phase 1 Accelerated Study Design



Proposed Phase 2/3 Pivotal Study Design¹

- Granted ODD & RPDD for NB, RMS, and Ewing's Sarcoma
- Eligible for Fast Track, Breakthrough and SPA submissions
- Initial enrollment of 10 - 15 patients to confirm dose; upon appropriate efficacy expand into Phase 3
- Phase 3 pivotal trial single arm ~65 patients
 - Primary endpoint: Overall Response Rate
 - Secondary endpoints: EFS³, CBR⁴, PFS

Program Timing²

- Phase 1 to complete 4Q-19
- Phase 2/3 pivotal initiation 2020
- NDA submission 2022

Clinical Costs²

- Phase 1 = ~\$4 million
- Phase 2/3 pivotal trial = ~\$15 million
- Potential for SBIR contract of ~\$2.3M for Phase 1 & up to \$4M per indication⁵ for a pivotal trial

***Approval in Any Indication May Provide Priority Review Voucher
and Potential for NCCN Compendium Listing for Other Tumor Types***

1. Relapsed/Refractory 2. Estimated 3. Event Free Survival 4. Clinical Benefit Response Rate 5. <https://www.grants.gov/web/grants/learn-grants.html>

CLR 131 & MIBG Product Profile Comparison

MIBG I-131 Currently Second Line Standard of Care for Neuroblastoma

Profile	CLR 131	MIBG I-131
Delivery Vehicle/Payload	Phospholipid Ether (PLE)/ Iodine-131	Meta-iodobenzylguanidine/ Iodine-131
Therapeutic Regimen	Single 30 minute mCi infusion Total dose ~45 - 80 mCi	3-5 cycles, ~300 mCi per cycle, 90-120 minute infusion Total dose ~1000 - 1500 mCi
Hospitalization	TBD ¹	4-8 days
Capable to Cross the Blood Brain Barrier		
Ability to Target Metastasis		
Stem Cell Transplant Support		
NB Response Rate	TBD	20-60% (~30%)
Indicated for NB	YES, upon approval	NO



FAVORABLE/POSSESSES



NOT YET KNOWN



DEFICIENT/LACKS

1. To Be Determined

Our Preclinical Pipeline

1 CLR 131

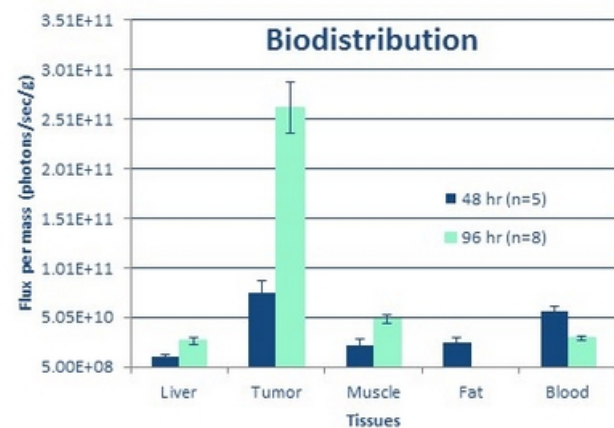
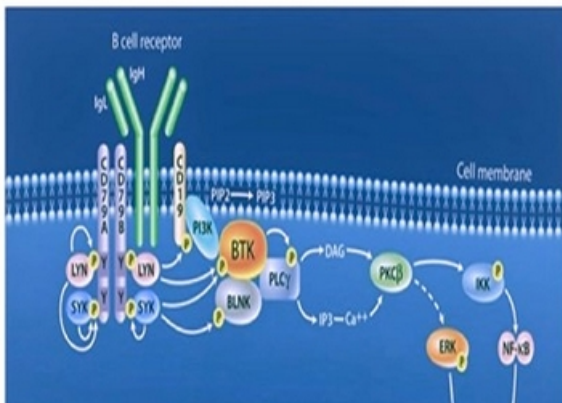
2 CLR 1700

3 CLR 1900

CLR 1700: Proprietary Chemotherapeutic PDC Program

CLR 1700 Mechanism of Action

- CLR 1700 payload inhibits Burton's Tyrosine Kinase (BTK)
- BTK inhibitors work only in hematologic cancers
- Induces tumor cell apoptosis
- Currently approved BTK inhibitors generate annual revenue of ~\$4 billion¹
- Program is currently in lead optimization

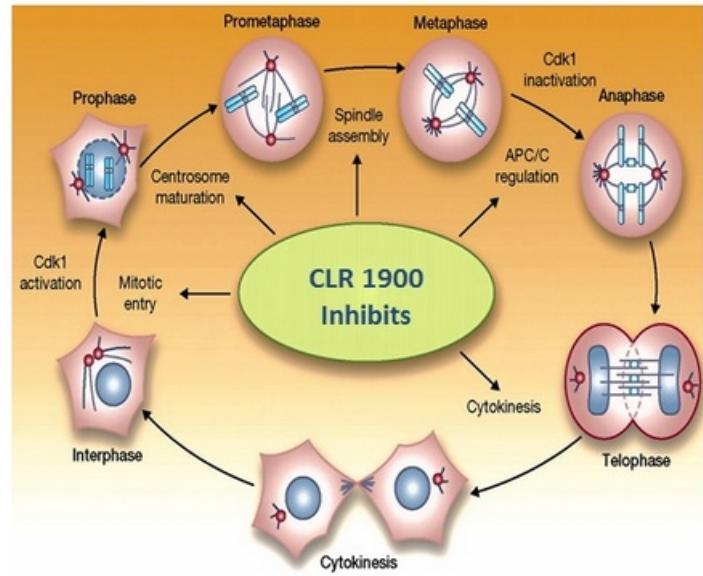


1. Walker, Joseph (1 January 2016). "Patients Struggle With High Drug Prices: Out-of-pocket costs for pricey new drugs leave even some insured and relatively affluent patients with hard choices on how to afford them". Belleville, Illinois Wall Street Journal. Retrieved 1 January 2016. States potential for \$5B in sales for one BTK inhibitor.

CLR 1900: Chemotherapeutic PDC Program

CLR 1900 Mechanism of Action

- CLR 1900 payload inhibits mitosis (cell division)
- Targets a key element in the pathway required for mitosis
- Payload represents a novel class of molecules and a novel target
- Pathway inhibition has been validated with other classes of molecules; results in apoptosis of tumor cells
- Select solid tumor focus
- Program is currently in lead optimization



PDC Demonstrates Preclinically Improved Therapeutic Index vs. Parent¹



Corporate Information



Financial Summary

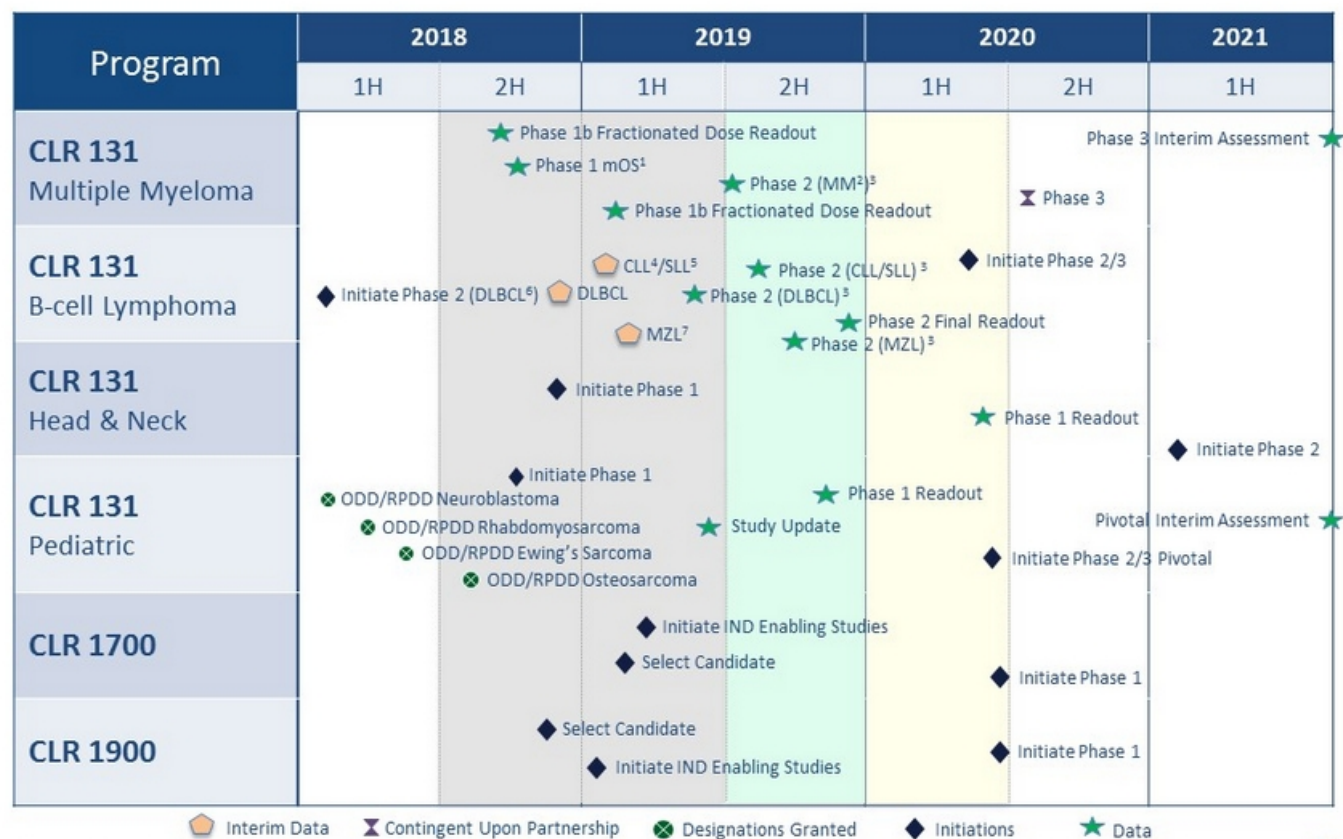
Capitalization as of September 4, 2018

Common Stock Outstanding	3,797,825
Reserved for issuance:	
Convertible Preferred Stock	2,142,500
Warrants	5,318,747
Employee Options	<u>56,919</u>
Fully Diluted	<u>11,315,991</u>
Cash / Equivalents as of June 30, 2018	~\$4.2 million
Pro Forma Cash / Equivalents as of June 30, 2018	~\$19.1 million ¹

Cash Believed to Be Adequate to Fund Operations into 2020

1. Company closed an underwritten public offering on July 31, 2018. Pro forma balance reflects company's cash/equivalents balance as if the underwritten public offering closed on June 30, 2018.

Projected Key Development Milestones



1. Median Overall Survival 2. Multiple Myeloma 3. Topline Data 4. Chronic Lymphocytic Leukemia 5. Small Lymphocytic Leukemia 6. Diffuse Large B-cell Lymphoma 7. Marginal Zone Lymphoma

Executive Leadership

Jim Caruso President, CEO and Director	HIP Innovation Technology - EVP & COO, Allos Therapeutics - EVP & CCO, BCI, Novartis, BASF, Bristol-Myers Squibb
John Friend, MD Chief Medical Officer	Helsinn Therapeutics - SVP & Head of R&D, Akros Pharma, Actavis, AlphaPharma, Hospira, Abbott
Jarrold Longcor Chief Business Officer	Avillion LLP - CBO Melinta Therapeutics, Inc. (formerly Rib-X Pharmaceuticals, Inc). - VP Corp Development and Operations
Brian Posner Chief Financial Officer	Alliqua BioMedical, Ocean Power Technologies, Power Medical Interventions, PharmacoPeia - CFO



Executive Team With ~100 Years of Healthcare Leadership and a Proven Track Record of Development and Commercialization

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Thank You



NASDAQ: CLRB