
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: January 7, 2019
(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)

100 Campus Drive, Florham Park, New Jersey 07932
(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 January 3, 2019, we issued a press release announcing that James Caruso, our President and Chief Executive Officer, will be presenting at the Biotech Showcase, on Monday, January 7, 2019 at 10:00 a.m. Pacific Time. A copy of the Corporate Presentation to be used is furnished as Exhibit 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. January 2019 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: January 7, 2019

CELLECTAR BIOSCIENCES, INC.

By: /s/ Brian M. Posner

Name: Brian M. Posner

Title: Chief Financial Officer

Corporate Presentation

January 2019



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 September 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

8 clinical data readouts planned through 2019

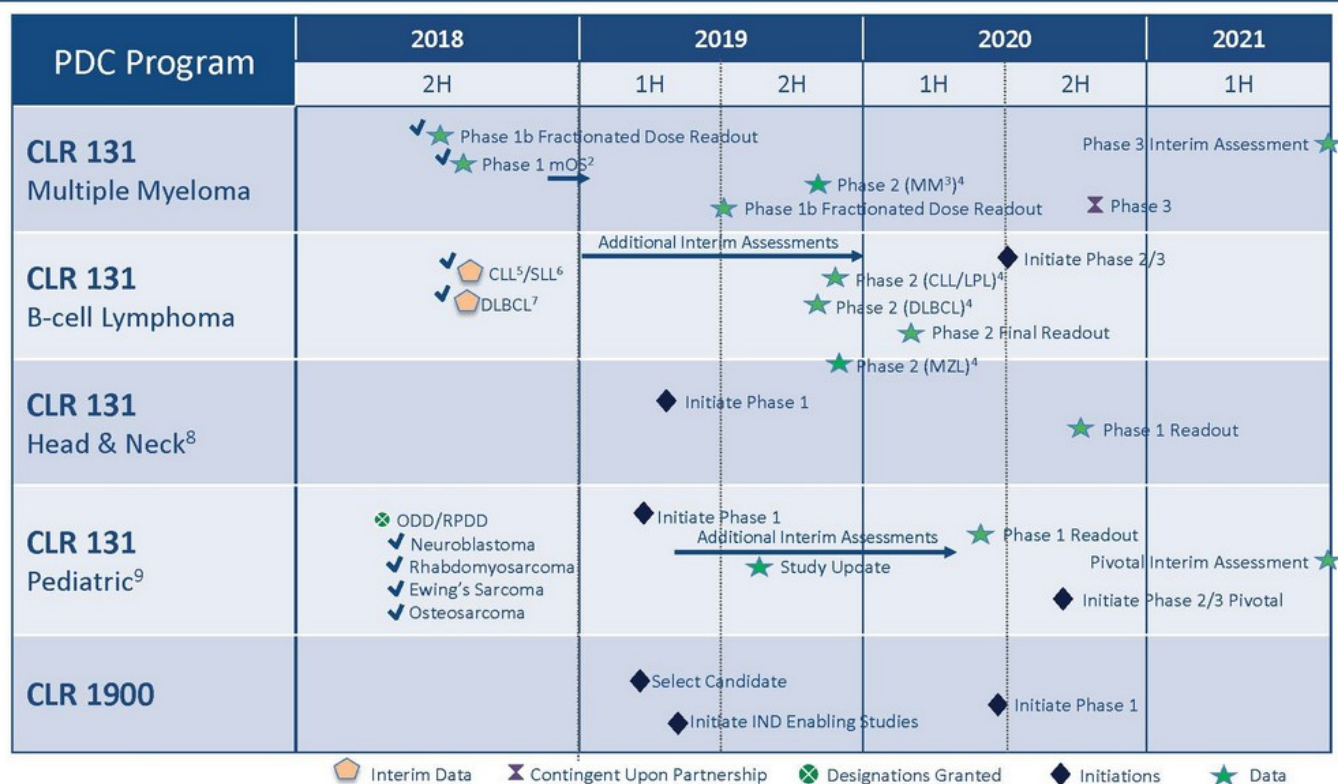
PDC² tumor targeting platform validated through clinical trials, corporate partnerships and academic collaborations

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. 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. 2. Phospholipid Drug Conjugate

Projected Pipeline Key Development Milestones¹



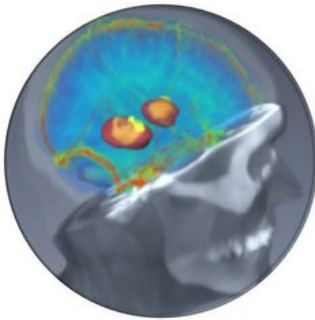
Cellctar to Announce Additional Developments and Events as They Occur

1. Reflects patient enrollment impact from Import Alert 2. Median Overall Survival Cohorts 1-4 3. Multiple Myeloma 4. Topline Data 5. Chronic Lymphocytic Leukemia

6. Small Lymphocytic Leukemia 7. Diffuse Large B-Cell Lymphoma 8. Funded through NCI SPORE Grant 9. Upon ex-U.S. regulatory authority approval to proceed or FDA allowance of CLR 131 drug supply to study sites

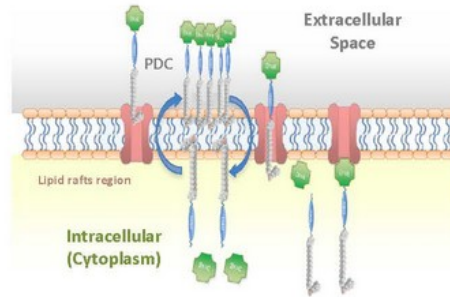
PDC Platform Technology

Precision Targeting



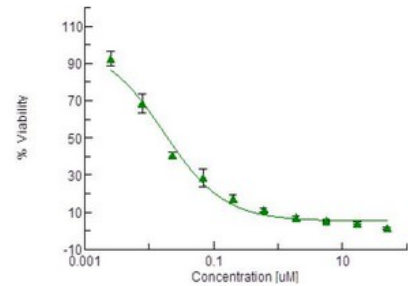
- Phospholipid ethers (PLEs) provide precise targeting even to the brain; crosses blood brain barrier (BBB)
- PLEs bind to specific membrane region (lipid rafts) rather than a single epitope
- Take advantage of the tumors' metabolic need

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***

- 1 Overview
- 2 Phase 2 R/R B-cell Lymphoma Study
- 3 R/R Multiple Myeloma Phase 1 Study
- 4 Pediatric Phase 1 Study

Radiotherapeutic Market

- Radiotherapeutic market forecast ~\$9.3 billion revenue in 2020¹
- Bayer's Xofigo® revenue ~\$500M in 2017²
- Y-mABs Therapeutics market cap of ~\$625M³
 - Direct injection of ADC⁴ (iodine 131 payload) into CNS⁵ for brain metastases
- Progenics Pharma market cap of ~\$350M³
 - Azedra™ (iobenguane I-131) for treatment of rare tumors of adrenal gland
- Recent acquisitions by Novartis
 - Advanced Accelerator Applications for \$3.9 billion
 - Radiotherapy Lutathera™ and imaging portfolio
 - Endocyte for \$2.1 billion
 - Radioligand therapy in mid-stage clinical trials

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. Bayer Annual Report 2017 3. 1/2/2019 - Yahoo Finance 4. Antibody Drug Conjugate 5. Central Nervous System

Strategic Positioning

- CLR 131 is a Targeted Radiotherapeutic
 - Cytotoxic radioisotope - iodine 131
 - Delivery platform provides novel mechanism of action
- Establish Phase 2 data for DLBCL & MM to drive potential partnerships
 - Potential for cost-effective & accelerated regulatory pathway for R/R¹ MM
- Advance R/R niche market opportunities to commercialization
 - R/R B-cell lymphomas (LPL, MZL, MCL²)
 - Few approved therapies; accelerated route to market
 - Potential revenues ~\$800M U.S. and ~\$1.8B worldwide³
 - R/R pediatric tumors
 - NB⁴, High Grade Glioma, RMS⁵, Ewing's & Osteosarcoma
 - Approximately 40 U.S. treatment centers; ~20 MIBG I-131 for NB
 - Potential revenues ~\$600M U.S. and ~\$1.5B worldwide⁶

Hematology Clinical Trials

- R/R Hematologic Phase 2 Study
 - DLBCL Interim Data
 - 33% Overall Response Rate (ORR) - 50% Clinical Benefit Rate (CBR)
 - Achieved pre-determined efficacy hurdle to expand cohort
 - Waldenstrom's (LPL) Case Study
 - Patient presenting with multiple large tumor nodules
 - Multiple Myeloma
 - Achieved pre-determined efficacy hurdle to expand cohort
- R/R Multiple Myeloma Phase 1 Study
 - Heavily pretreated patient population
 - Average of 5 lines of systemic therapy
 - All 5 cohorts deemed safe and tolerable
 - No peripheral neuropathy, DVT's, Cardio & GI toxicities
 - Median Overall Survival of 22 months

Pediatric Clinical Trial

- FDA approved Phase 1 protocol
 - Planned multicenter study (U.S. and International Sites)
 - Phase 1 ready to initiate¹
- Orphan drug designations (ODD) and rare pediatric designations (RPDD)
 - Neuroblastoma, Osteosarcoma, Rhabdomyosarcoma & Ewing's Sarcoma
 - All indications eligible for FDA breakthrough therapy designation
 - Any single approval results in Pediatric Voucher
- Neuroblastoma (NB) offers high clinical & commercial rationale
 - MIBG I-131 is considered SOC for second line treatment
 - CLR 131 provides same payload (I-131) with improved delivery and uptake
 - CLR 131 demonstrates ability to increase exposure, target primary NB tumors as well as metastatic sites in animal studies

1. Upon ex-U.S. regulatory authority approval to proceed or FDA allowance of CLR 131 drug supply to study sites

1 Overview

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3 R/R Multiple Myeloma Phase 1 Study

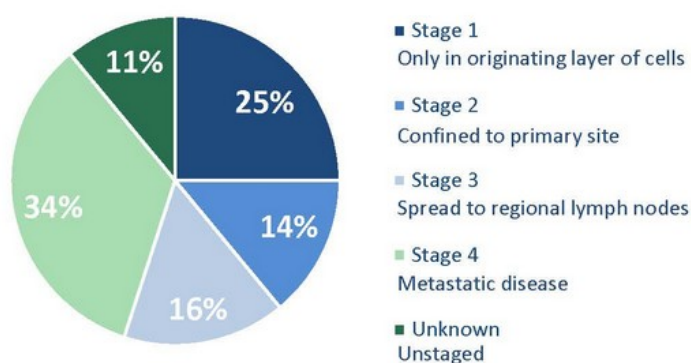
4 Pediatric Phase 1 Study

R/R B-cell Lymphoma Market Overview

Significant Unmet Needs Remain in Select B-cell Lymphomas

- B-cell Lymphomas
 - Represents cancers of lymphatic system
 - Indolent & aggressive tumors
 - Circulate in blood or form tumors in lymph nodes
- Demographic Background¹
 - Estimated 2018 U.S. incidence: 163,000
 - Median age at diagnosis: 67 years
 - Median age at death: 76 years

Percent Patients by Stage

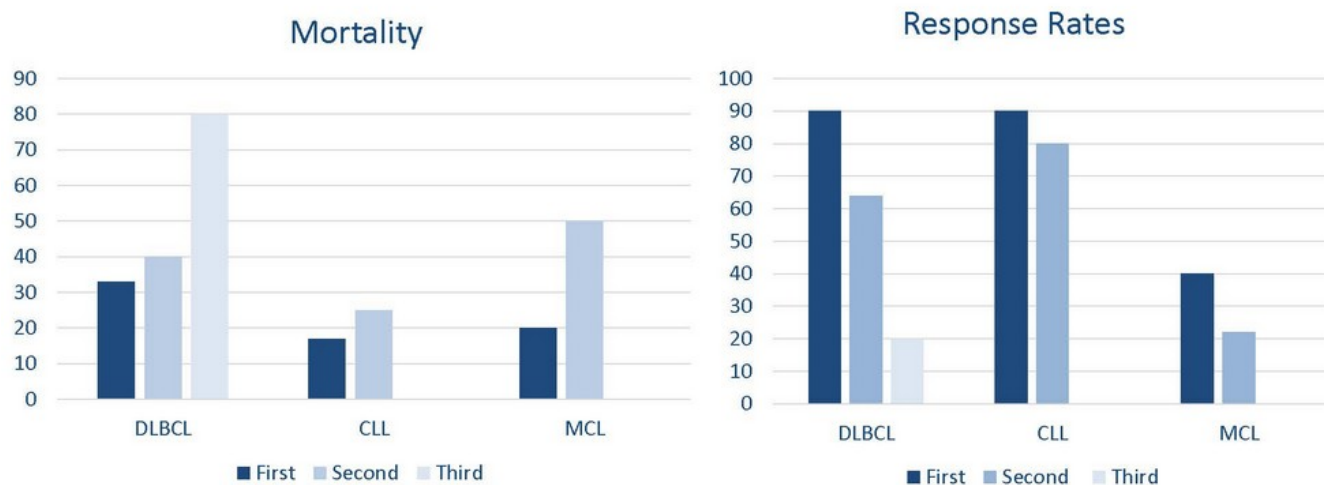


CLR 131 Targeting 75% of the Patients (Stage 3, 4 and Unstaged)

1. SEER data - <http://seer.cancer.gov/statfacts/html/nhl.html>

R/R B-cell Lymphoma Market Opportunity

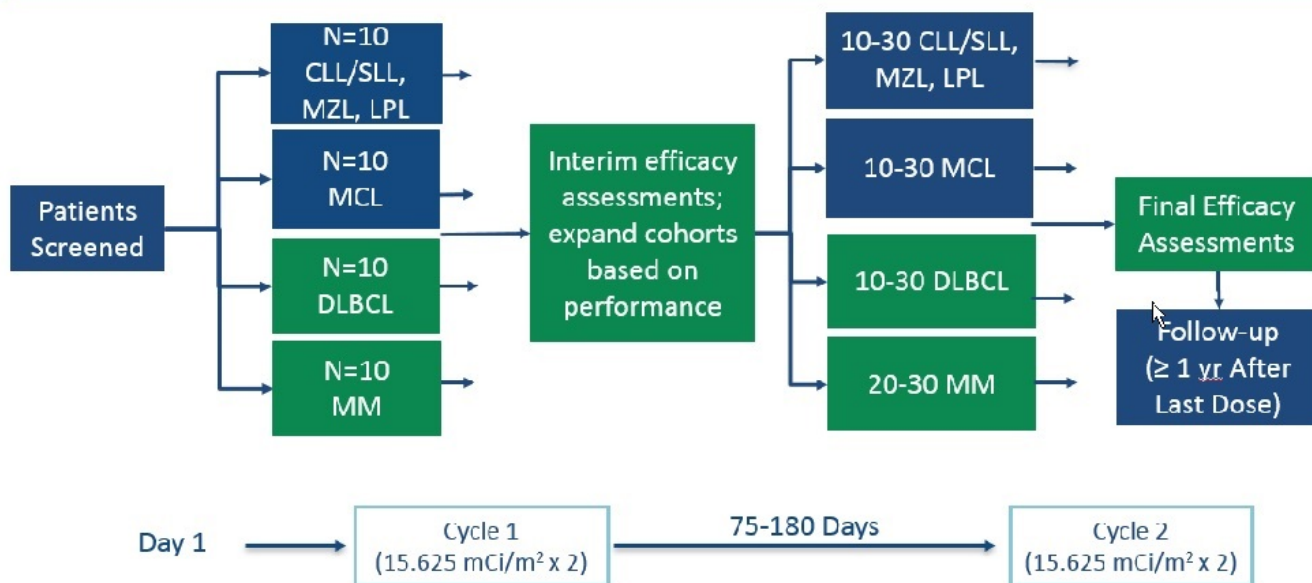
New Drugs Needed in Select B-cell Lymphomas



High Mortality and Poor Response Rates Remain in Second and Third Line Treatments Compounded by Limited Durability of Responses

Ongoing R/R Hematologic Phase 2 Study

Supported with a \$2M NCI SBIR Grant

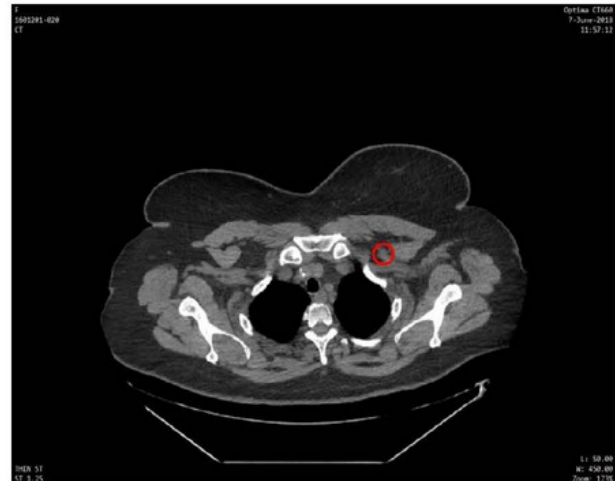
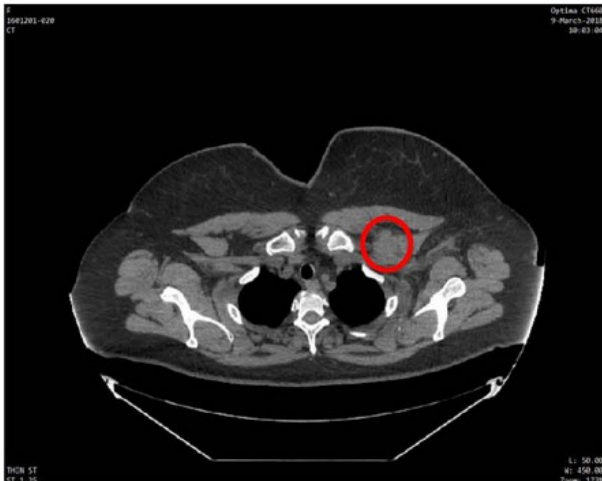


- Primary endpoint is efficacy as determined by response rate
- Upon study completion, individual cohorts may advance to a pivotal trial

All Patients Eligible for a Second Cycle at Day 75-180

Phase 2 DLBCL Interim Data

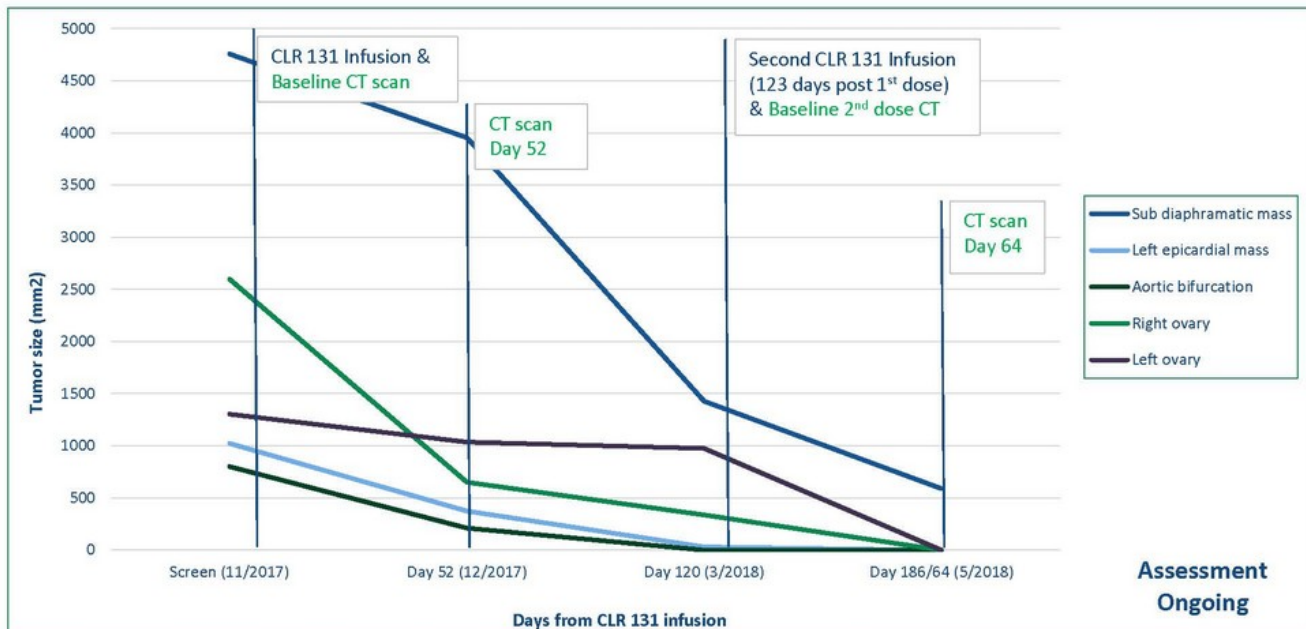
- Diffuse Large B-cell Lymphoma (DLBCL) is an aggressive form of Lymphoma, accounting for ~30% of newly diagnosed cases in the U.S.¹
- DLBCL cohort opened 1Q18
- 33% Overall Response Rate (ORR) - 50% Clinical Benefit Rate (CBR)
- Of responses observed, overall tumor reduction ranged from 60-99%



1. According to the Lymphoma Research Foundation

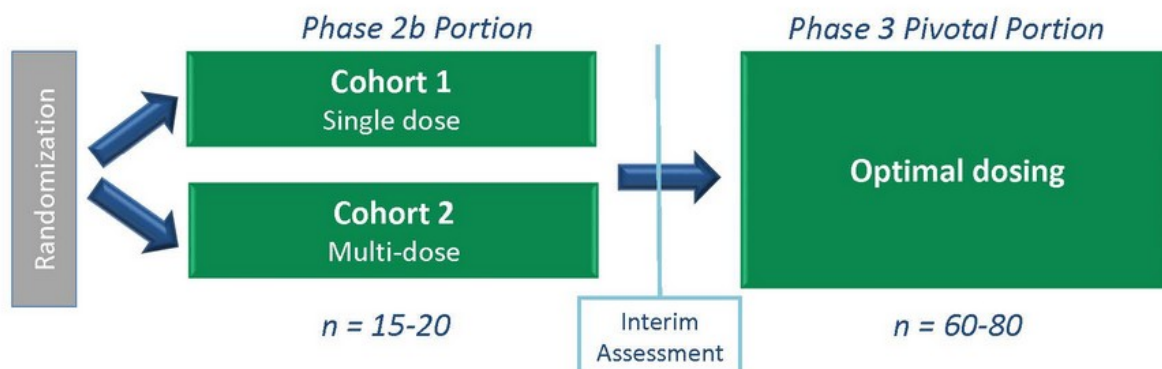
Phase 2 LPL Patient Case Study (Waldenstrom's)

- Baseline: Pleural effusion & multiple large tumor nodules; symptomatic with cough
- Following 1st infusion: Dramatic improvements in cough and no significant cytopenias
- CT day 187 (64 days post-2nd infusion) showed >95% reduction in overall tumor burden as well as complete resolution of 4/5 tumors



Proposed B-cell Lymphoma Pivotal Study

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 2H19
- Phase 2b/3 initiation 2H20
- NDA submission 2022

Clinical Costs¹

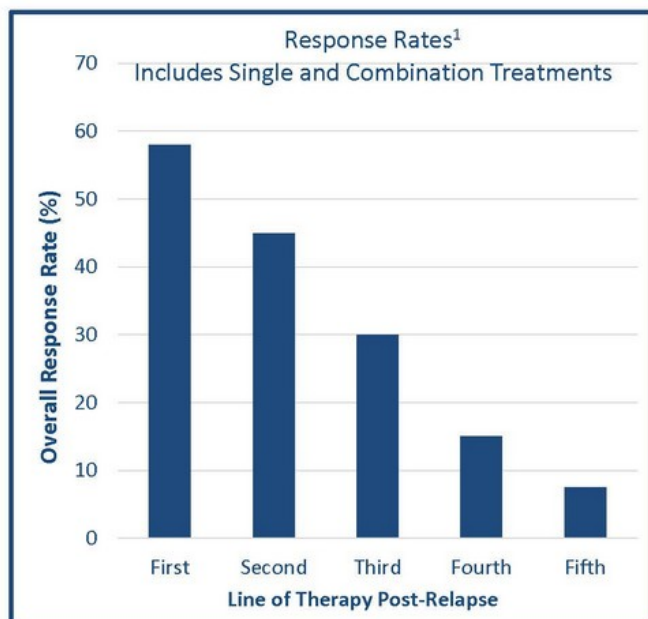
- Phase 2b = \$2 - \$3 million
- Phase 3 pivotal trial = \$9 - \$12 million
- Eligible for pivotal trial SBIR Grant up to \$4M per indication²

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

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R/R Multiple Myeloma Market Opportunity

New Treatments are Needed



Response Rates for Fourth and Fifth Line TRx are 15% & 8%

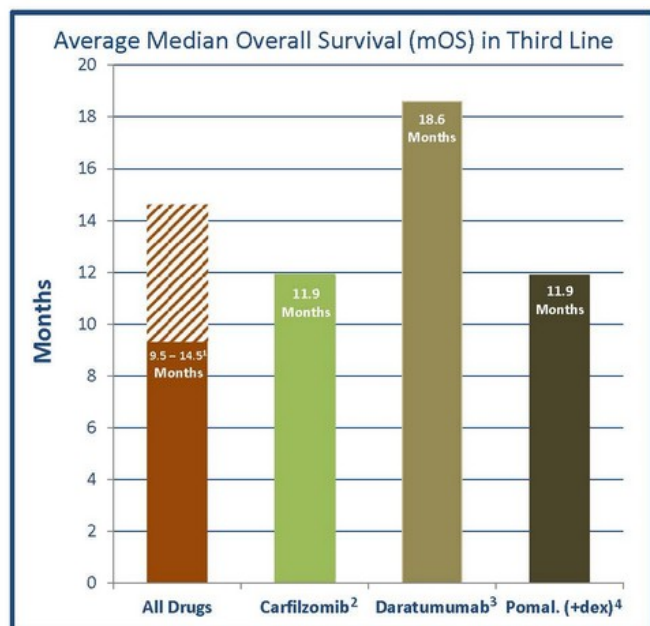
2018 Estimated MM Patient Population¹

	Diagnosed	% Treated	Treated Total
First Line	25,063	90%	22,557
Second Line R/R	16,900	75%	12,675
Third Line R/R	10,800	65%	7,020
Fourth Line R/R	5,600	55%	3,080
Fifth Line & Later R/R	3,210	45%	1,445

Approximately 40% of TRx Eligible Patients in Third Line or Greater Elect Not to Receive Further TRx

R/R Multiple Myeloma Market Opportunity

New Treatments are Needed



- Average mOS for 3rd line therapies is ~12 months¹
- Average mOS for dual refractory⁵ is ~9 months, irrespective of prior lines of therapy
- Average mOS for penta-refractory⁶ is ~9 months, irrespective of prior lines of therapy
- CLR 131 Phase 1 single dose patient population
 - 100% third line or later
 - Average prior lines of therapy = 5
 - ~33% dual refractory
 - ~13% penta-refractory

CLR 131 Achieved mOS of 22 Months in Single Dose Cohorts

¹Traditional monotherapy chemotherapy, protease inhibitor, and immunomodulating agents

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

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

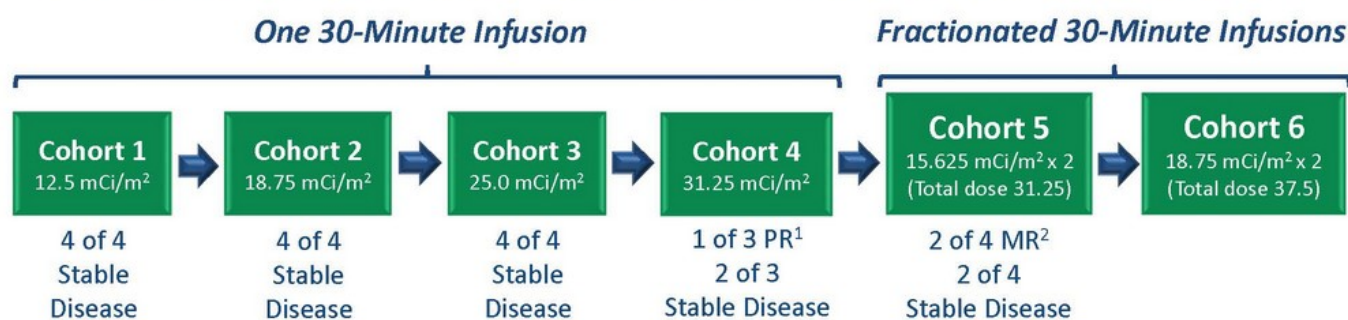
⁴Dimopoulos et al (2016). *Safety and efficacy of pomalidomide plus low-dose dexamethasone in STRATUS (MM-010): a phase 3b study in refractory multiple myeloma*. Blood Review.

⁵Defined as refractory to at least one proteasome inhibitor and one immunomodulator

⁶Defined as refractory to Revlimid, Pomalyst, Velcade, Kyprolis, and Darzalex

R/R 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	6	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

R/R MM Tolerability & Median Overall Survival (mOS)

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: mOS n=15 - Average Prior Lines of Therapy = 5



Single 30 Minute Infusion Achieves Median Overall Survival of 22 Months

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

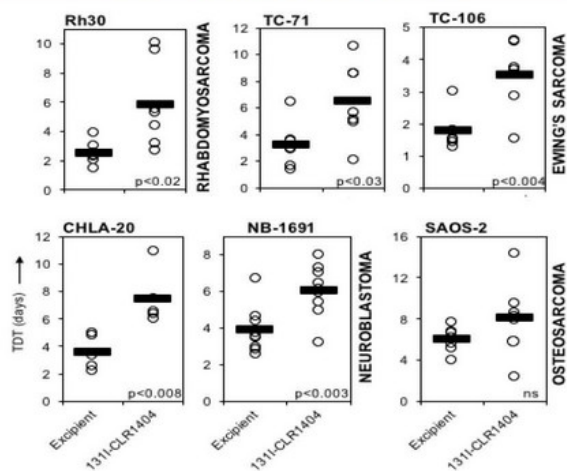
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Efficacy in Pediatric Preclinical Models

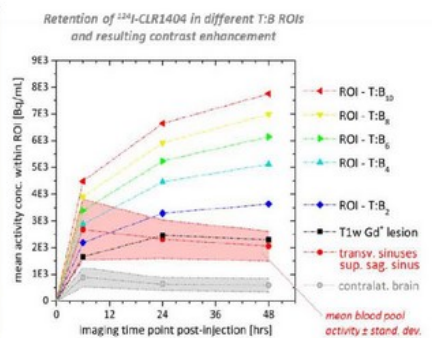
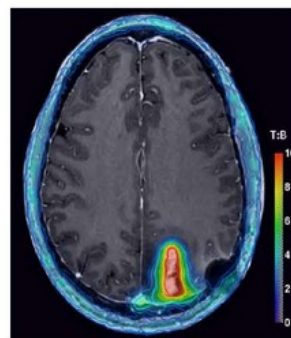
Preclinical Results

- 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

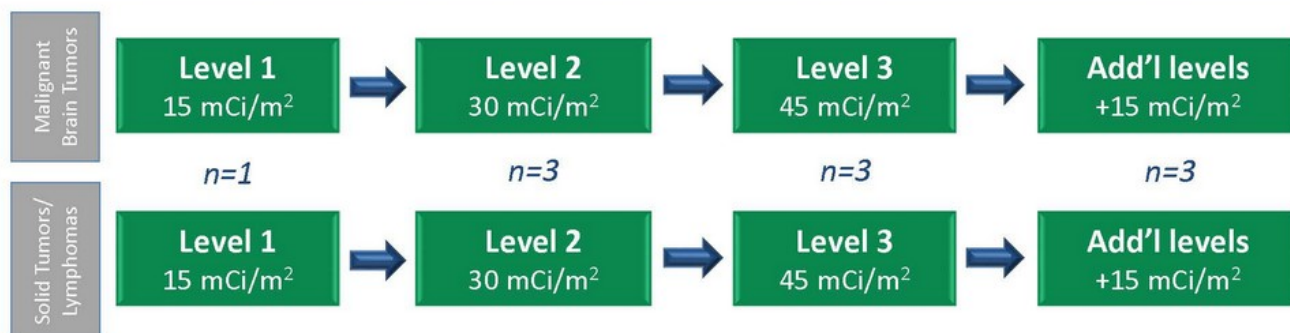


Uptake in the Brain (Crossing BBB)



Pediatric Clinical Development Strategy¹

FDA Agreement on Phase 1 Accelerated Study Design



Proposed Phase 2/3 Pivotal Study Design²

- 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: EFS⁴, CBR⁵, PFS

Program Timing³

- Phase 1 to complete 2Q20
- Phase 2/3 pivotal initiation 4Q20
- NDA submission 2022

Clinical Costs³

- Phase 1 = ~\$4 million
- Phase 2/3 pivotal trial = ~\$11 - \$12 million

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

1. Upon ex-U.S. regulatory authority approval to proceed or FDA allowance of CLR 131 drug supply to study sites 2. Relapsed/Refractory 3. Estimated 4. Event Free Survival 5. Clinical Benefit Response Rate

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

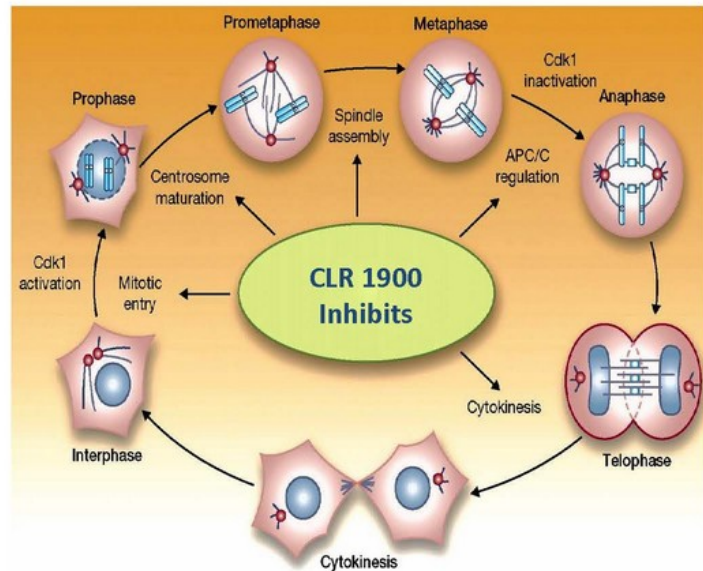
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CLR 1900

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 November 9, 2018

Common Stock Outstanding	4,757,786
Reserved for issuance:	
Convertible Preferred Stock	1,182,500
Warrants	5,318,747
Employee Options	<u>256,304</u>
Fully Diluted	<u>11,515,337</u>
Cash / Equivalents as of September 30, 2018	~\$16.4 million

Cash Believed to Be Adequate to Fund Operations into 2020

Executive Leadership

Jim Caruso
President, CEO and Director

HIP Innovation Technology - EVP &
COO, Allos Therapeutics - EVP & CCO,
BCI, Novartis, BASF, Bristol-Myers
Squibb

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 Extensive Healthcare Leadership and a
Proven Track Record of Development and Commercialization***

Company Highlights

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

Advancing multiple clinical programs; demonstrated activity in hematologic malignancies

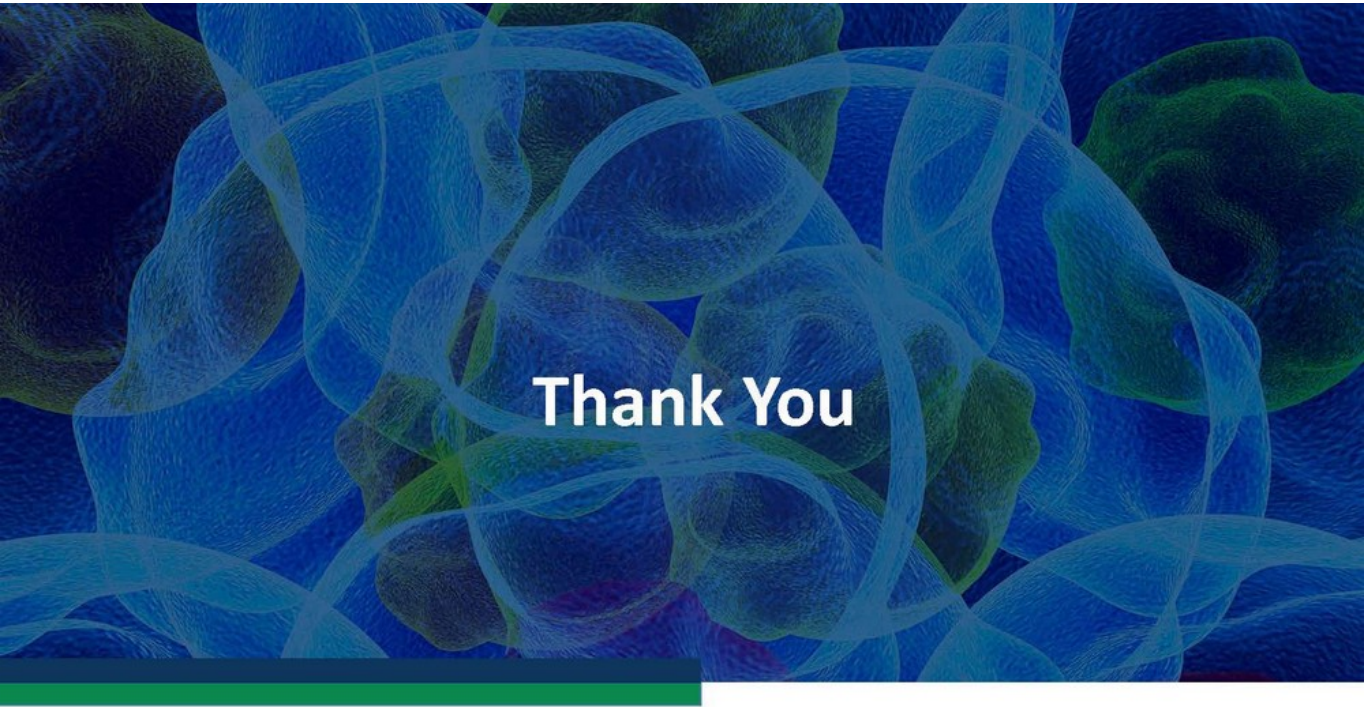
8 clinical data readouts planned through 2019

PDC² tumor targeting platform validated through clinical trials, corporate partnerships and academic collaborations

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

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Thank You



NASDAQ: CLRB