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 26, 2014

CYCLACEL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-50626**	**91-1707622**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

200 Connell Drive, Suite 1500
Berkeley Heights, NJ 07922
(Address of principal executive offices and zip code)
Registrant's telephone number, including area code: (908) 517-7330

(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):

- o **Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)**
- o **Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)**
- o **Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))**
- o **Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))**

Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 and incorporated by reference herein is an investor presentation of Cyclacel Pharmaceuticals, Inc.

The information set forth under this "Item 7.01. Regulation FD Disclosure," including the exhibit attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Investor Presentation of Cyclacel Pharmaceuticals, Inc., dated September 26, 2014.

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 thereunto duly authorized.

CYCLACEL PHARMACEUTICALS, INC.

By: /s/ Paul McBarron
Name: Paul McBarron
Title: Executive Vice President—Finance,
Chief Financial Officer and Chief Operating Officer

Date: September 26, 2014

EXHIBIT INDEX

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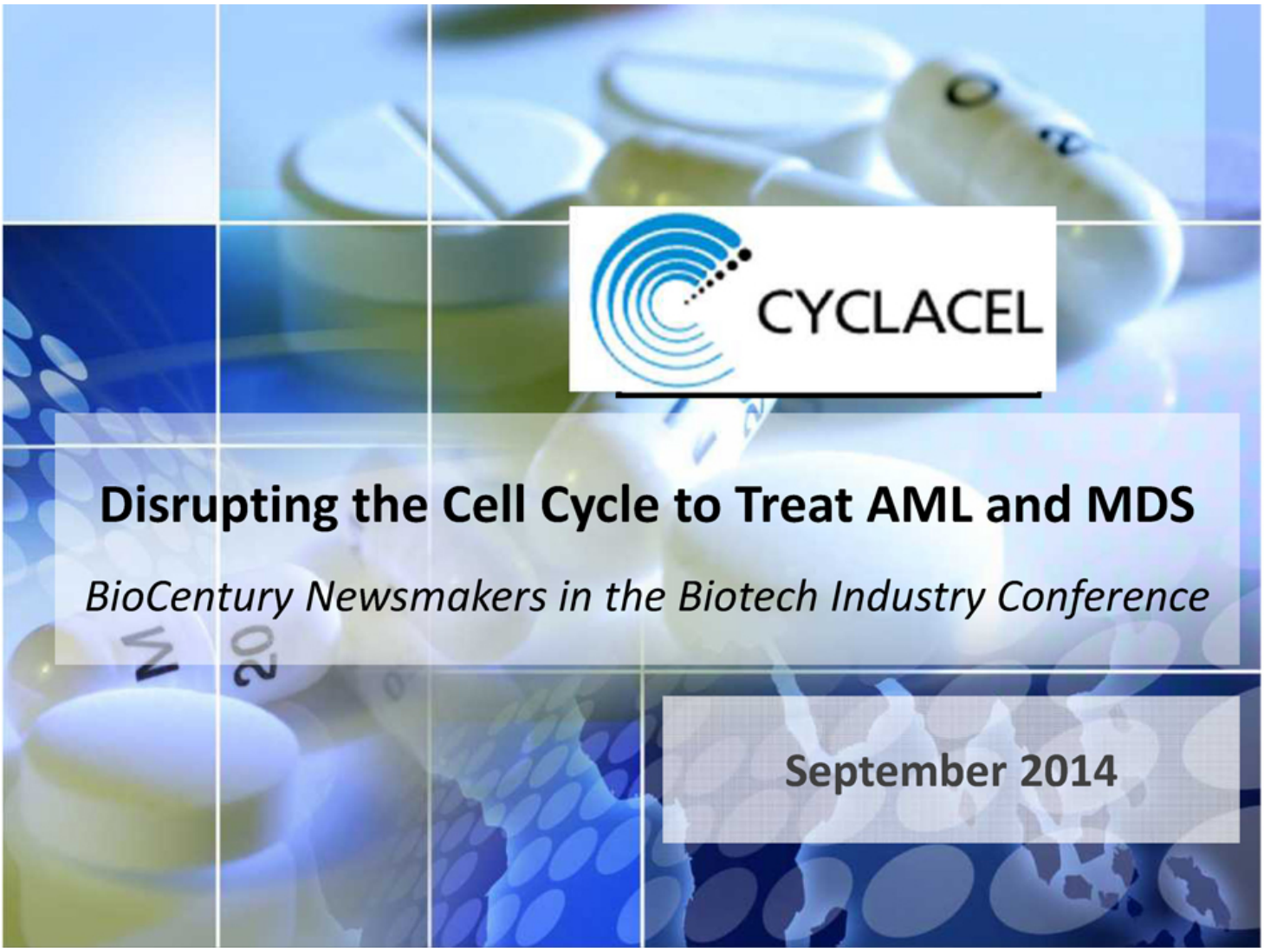
Exhibit 99.1


CYCLACEL
Disrupting the Cell Cycle to Treat AML and MDS
BioCentury Newsmakers in the Biotech Industry Conference
September 2014

Disclaimer

This presentation contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 about financial results and estimates, business strategy, clinical trial plans and research and development programs of Cyclacel Pharmaceuticals, Inc. By their nature, forward-looking statements and forecasts involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. For a further list and description of the risks and uncertainties the Company faces, please refer to our most recent Annual Report on Form 10-K and other periodic and current filings that have been filed with the Securities and Exchange Commission and are available at www.sec.gov. The information in this presentation is current as of this date. Cyclacel does not take any responsibility to update such information.

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Cyclacel Highlights

Sapacitabine in front-line AML in the elderly: SEAMLESS Phase 3

- Oral agent for elderly AML patients; minimal options today
- Interim analysis for futility expected late 2014/early 2015
- Complete enrollment 2014/15; top-line data 2H15

Sapacitabine in high-risk MDS after HMA failure

- "Impressive" Phase 2 survival data in 2nd/3rd Line MDS
- Phase 2b RCT planned to start in 2015

Strong financial position & earlier-stage pipeline

- Sufficient capital beyond SEAMLESS Phase 3 data readout
- Sapacitabine in solid tumors; CDK and PLK inhibitors

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Sapacitabine for AML

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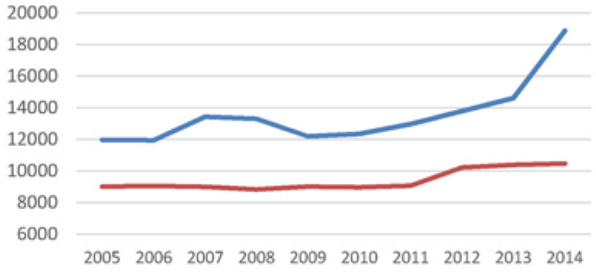
AML Unmet Medical Need since 1969*



16,000 US prevalence '13E

14,590 US incidence '13E

Treatment	*Fit for Intensive Chemo (20%)*	*Unfit/Refused Intensive Chemo (80%)*
Front line	7 + 3	*Clinical trial* Sapacitabine
Relapsed/ Refractory	*Clinical trial*	*Clinical trial*

** **AML: elderly disease: 50% ≥ 70 yrs.**; median age: ~ 67. Source: American Cancer Society and Cyclacel-commissioned primary market research. Sapacitabine data on file.*

Predicament of 70+ year old AML Patient

- Newly diagnosed AML: multigenetic, heterogeneous disease

- Old age, frailty and comorbid conditions

Options:

- 45-year old intensive chemotherapy regimen
- Investigational agent(s) in a clinical trial
- Hospice or terminal care at home

- Expected median survival of 3 - 6 months
- Mortality in first 2 months of ~ 20 - 36%
- Drug development goal: overall survival (OS)

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Elderly AML Benchmark Data

Most elderly patients unable to sustain intensive chemotherapy

Treatment mortality ↑ and survival ↓ with age over 60 years

Treatment	*Patients*	*4-week death rate*	*8-week death rate*	*m OS (months)*
Intensive Chemotherapy	≥70 yrs.	26%	36%	~ 5 *
Best Supportive Care	≥70 yrs.	17%	30% ∓	~ 4 ◊
Low-intensity (LoDac or decitabine)	≥60 yrs.	9%	20%	~ 5 - 8 † ‡
Sapacitabine Pilot Lead-in for SEAMLESS	≥70 yrs.	5%	**13%**	~ 8 @

** Kantarjian, et al, Blood, 2010. † Burnett, et al, Cancer, 2007, Kantarjian, et al, Blood , 2012 ◊ Harousseau, et al, Blood 2009. ‡ Cashen, et al, JCO, 2010, Kantarjian, et al, JCO, 2012. ∓ Est. from survival curves. @ Ravandi F, et al, American Soc. of Hematology Ann. Mtg. 2012, Abs. 2630.*

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Rationale for Sapacitabine in AML

- Elderly AML patients are very frail
- How to control leukemia cell growth but not worsen the patient's immunity & quality of life?
- Sapacitabine-based Phase 3 "low-intensity" regimen balances those needs, resulting in ~ half the 60-day mortality vs. that reported with control regimen
- Hypothesis tested in SEAMLESS Phase 3 study under SPA:
  - Can the use of a sapacitabine-based less-intensive treatment regimen ↑ OS vs. active control

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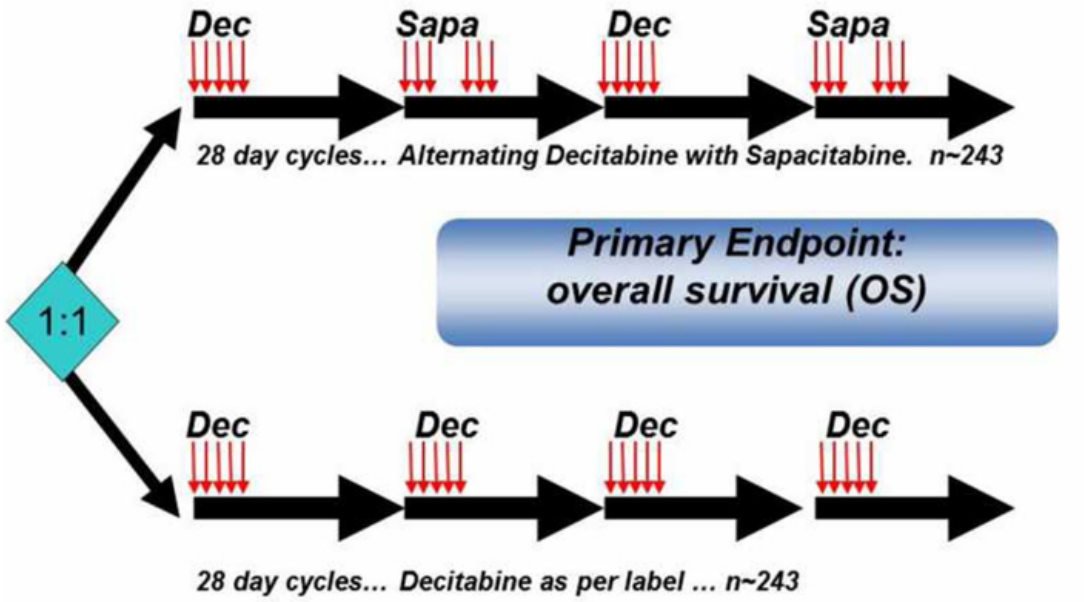
** Source: ASH 2012. Kantarjian et al, JCO, 2012.*

"SEAMLESS" Phase 3 Design

(Untreated AML: front line; ≥ 70 years; n=485; p=0.05; HR=0.725)



- ✓ In consultation with FDA under SPA enrolling at U.S. and European centers
- ✓ DSMB every 100 patients *(n=119; n=212*:"no safety or efficacy concerns")
- ✓ Interim analysis for futility after 212 events (50% of required events)

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SEAMLESS Milestones

- DSMB review at ~ 300 patients: 2H14
- Interim analysis for futility: Late 2014/Early 2015
- Enrollment > 75%; completion: Late ’14/Early ’15
- Top-line data: 2H15

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Will SEAMLESS Phase 3 Succeed?

Required reduction in risk of death: 27.5%

Median Overall Survival (OS):

Decitabine (DACO-016 , > 75 years, n=95): **~ 6 mos.** †

Sapacitabine/ Decitabine (ASH '12, > 75y, n=33): **~ 9 mos.** *

60-day mortality:

Decitabine (DACO-016, > 65y, n=242): **20%** †

Sapacitabine/ Decitabine (ASH '12, > 70y, n=46): **13%** *

** Interim data from pilot, lead-in study of Arm A in SEAMLESS; subject to change. ASH 2012, Abs. 2630; 76% > 75 years.*
† Caveat: cross-study comparison. Kantarjian, et al, JCO, 2012.

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NDA Enabling Activities

- External consultant review of available NDA content
- Planning a potential “rolling NDA” submission
  - Biopharm section
  - CMC section
  - Clinical section would be last to be submitted
- Core dossier also to be used for MAA submission in EU

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Sapacitabine for MDS

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MDS Unmet Medical Need

Treatment	Low Risk	High Risk
1st line	***lenalidomide #***	***azacitidine#*** ***decitabine***
2nd line	*Clinical trial*	Sapacitabine *Clinical trial*

…NCCN guidelines for 1st line hypomethylating agents: ***4-6 cycles*** *…‡*

Median OS int-2/high-risk MDS after ***treatment failure*** *of HM agents:* ***4.3-5.6 months†***

 # Revlimid®, Celgene. Vidaza®, Celgene. & Dacogen®, Otsuka. Dacogen & Vidaza are hypomethylating (HM) agents.
‡ NCCN Guidelines MDS v.2.2011 p. 19. † Prebet T, Gore S, et al, JCO 2011; Jabbour E, Garcia-Manero G, et al, Cancer 2010.

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Predicament of 60+ year old High-Risk MDS Patient

High risk MDS after failure of front-line drugs

- Already failed 1st line hypomethylating agents (HMAs): azacitidine (Vidaza®) and/or decitabine (Dacogen®)
- Higher risk from infections; transformation into AML
- Multigenetic, heterogeneous disease

Options:

- Investigational agent(s) in a clinical trial
- Hospice or terminal care at home

- Expected median survival of 4.3 - 5.6 months †

† Source: Prebet T, Gore S, et al, JCO 2011; Jabbour E, Garcia-Manero G, et al, Cancer 2010.

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Sapacitabine Phase 2 MDS Design: 682-06, Part 4

High-risk MDS: 2nd, 3rd or 4th line; ≥ 60 years; n=63; all arms 28-day cycles

- ✓ Intermed-2 or hi-risk IPSS after HMA failure; blasts 6% -19%
- ✓ Primary Endpoint: 1-year survival

G. Sapacitabine 200mg bid x 7d (n=21)

H. Sapacitabine 300mg qd x 7d (n=21)

I. Sapacitabine 100mg qd x 5d x 2w (n=21)

Source: Garcia-Manero et al, J. Clin. Oncol. 2012:30:Abs. 6520. HMA = hypomethylating agents.

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MDS HMA Failures: Key Benchmarks

MDS int-2 & high-risk IPSS experimental Standard of Care after frontline failure

Treatment	*m OS*	*1 year survival*
Azacitidine 2nd line	~ 6 months †	- †
Decitabine 2nd line	~ 4 months †	- †
Best Supportive Care	~ 4 months †	17% †
Sapacitabine:		
Phase 2 study 2nd, 3rd, 4th line	~ 9 months@	38% @

† Prebet T, Gore S, et al, JCO 2011 (95% CI, 14% to 26% on best supportive care; 29% on investigational agents). @ Garcia-Manero G et al, American Society of Hematology Annual Meeting Dec. 2013, Abstract #2752 (Arm G 1-year survival).

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Sapacitabine Phase 2 MDS Data

(High Risk MDS: 2nd, 3rd or 4th line; aged ≥ 60 years; n=63) *

	Total (63)	*Arm G (21)*	*Arm H (21)*	*Arm I (21)*
Prior Azacitidine	30	9	10	11
Prior Decitabine	15	4	3	8
Prior Aza + Decitabine	18	8	8	2
Median OS (days)	**260**	**291**	**290**	**227**
≥ 10% blasts in b.m.	*291*	*266*	*307*	*153*
60-day deaths	8	3	2	3
Responders	32	11	11	10

** Garcia-Manero G et al, American Society of Hematology Annual Meeting Dec. 2013, Abstract #2752. Response = CR/CRp, major HI, stable disease over 16 weeks.*

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Sapacitabine MDS Phase 2b RCT

Study Objectives

- Prolong overall survival
- Convenient outpatient treatment

Active control options

1. Low dose cytarabine (LoDAC)
   - Differentiated mechanism
   - Outpatient convenience
   - Activity in 1st line setting *
2. *Other HMA*
   - *Patients failed/progressed 1st line HMA*
   - *IV administration*
   - *HMA cross-treatment data inconclusive*

** Zwierzina H et al, Leukemia, 2005.*

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Rationale for Randomized Phase 2b RCT

- Limited knowledge
- Genetic heterogeneity & treatment complexity
- Sapacitabine Phase 2 clinical data encouraging
- Cyclacel approach
  - Review recent MDS trials
  - Confer with MDS KOLs
  - Conduct feasibility assessment
- Goal: determine path that may
  - Add to understanding of sapacitabine's role in the indication
  - If RCT data exceptional, discuss with regulators

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Phase 2b MDS RCT Design

(int-2 or high risk MDS after HMA failure: aged ≥ 60 years; n~250)

A. Alternating sapacitabine & LoDAC (n~125)

Primary Endpoint: overall survival (OS)

B. LoDAC* (n~125)

- ✓ Feasibility in over 100 US & EU sites
- ✓ Est. enrollment ~15 months , excl. lead-in stage
- ✓ Interim safety reviews at 100 & 200 patients

** LoDAC=low-dose cytarabine.*

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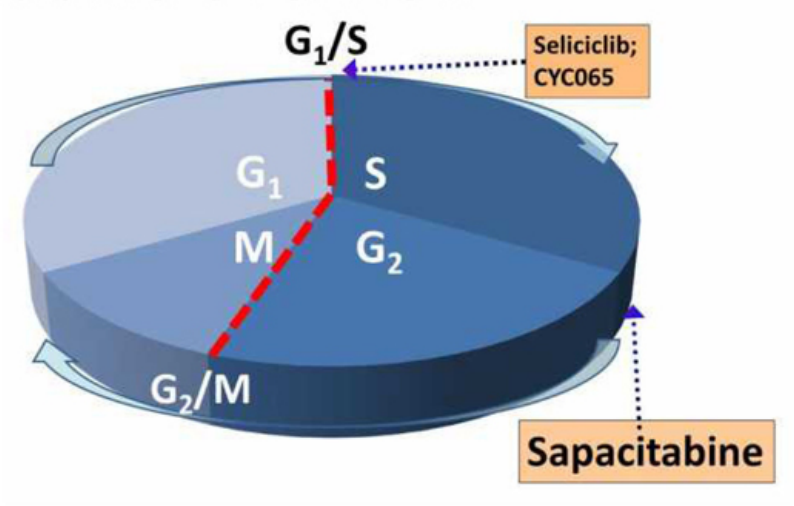
Sapacitabine Overview



Interferes with cancer cell repair via HR pathway

Therapeutic strategy: QOL maintenance vs. toxic cure attempt

- Oral administration; well-tolerated; administered over multiple cycles

Significant market opportunity beyond AML and MDS

- Solid tumor activity in HR-deficient patients incl. gBRCA +ve

Exclusivity: IP to 2027-30; Orphan Drug Status for AML & MDS

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Cyclacel Early-stage Pipeline

Candidate	MOA	Use	Pre-clinical	Phase 1	Phase 2	Phase 3
Sapacitabine + seliciclib	DNA synthesis inhibitor + CDK2,7,9 inhibitor	HR repair-deficient solid tumors	→	→		
CYC065	CDK2,5,9 inhibitor	Blood (incl. MLLr) & solid tumors*	→			
CYC140	PLK1 inhibitor	Blood & solid tumors*	→			

**Both mainly funded by government grants.*

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Financial Position & Capitalization

Cash runway beyond SEAMLESS Phase 3 data

- ~$34 m cash & cash equivalents [1]
- Complete SEAMLESS ~ end of 2014; data read-out ~ 2H 2015 (costs to data readout ~ $12 m)
- Other R&D costs and G&A: ~ $8-9 m annually [2]

Fully diluted shares: ~ 25.3 million [1, 3]

No debt

1. Company 10-Q June 30, 2014. Common stock outstanding: 22.7 million. 2. Excludes cost of MDS Ph 2b RCT. 3. Includes 1.1 million warrants and options with an exercise price > $10 per share.

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Key Milestones

Sapacitabine

- SEAMLESS: 300-patient DSMB review
- SEAMLESS: interim analysis for futility
- SEAMLESS: complete enrollment
- MDS: open enrollment of Phase 2b after HMA failure
- Sapacitabine & seliciclib in patients with solid tumors: update Phase 1 data

Other

- Advance early-stage pipeline

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Summary

- Sapacitabine opportunity in front line AML: SEAMLESS approaching completion
- Sapacitabine in MDS: Phase 2 data, high-reward
- Strong financial position: sufficient capital beyond SEAMLESS data read-out
- Early-stage pipeline addressing high-interest targets & mechanisms of action

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Cyclacel Pharmaceuticals

Cell cycle pioneers

Improving patient lives

With orally-available

Innovative medicines

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