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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

**FORM 6-K**

REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934

*For the month of December 2014*

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**BioLineRx Ltd.**

(Translation of Registrant's name into English)

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**P.O. Box 45158  
19 Hartum Street  
Jerusalem 91450, Israel**

(Address of Principal Executive Offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

**Form 20-F**  **Form 40-F**

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934:

**Yes**  **No**

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On December 25, 2014, at 9:00 am (Jerusalem Standard Time), the Registrant will make a presentation to investors and analysts at the Tel Aviv Stock Exchange with an update regarding latest company developments, as well as future development plans and milestones for 2015-2017. The aforementioned presentation is filed as Exhibit 1 to this Report on Form 6-K.

This Form 6-K, including all exhibits hereto, is hereby incorporated by reference into all effective registration statements filed by the Company under the Securities Act of 1933.

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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.

**BioLineRx Ltd.**

By: /s/ Philip Serlin

Philip Serlin  
Chief Financial and Operating Officer

Dated: December 24, 2014

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**BIOLINERX**

## **Company Presentation**

Investor Breakfast at TASE  
December 25, 2014

## Forward Looking Statements

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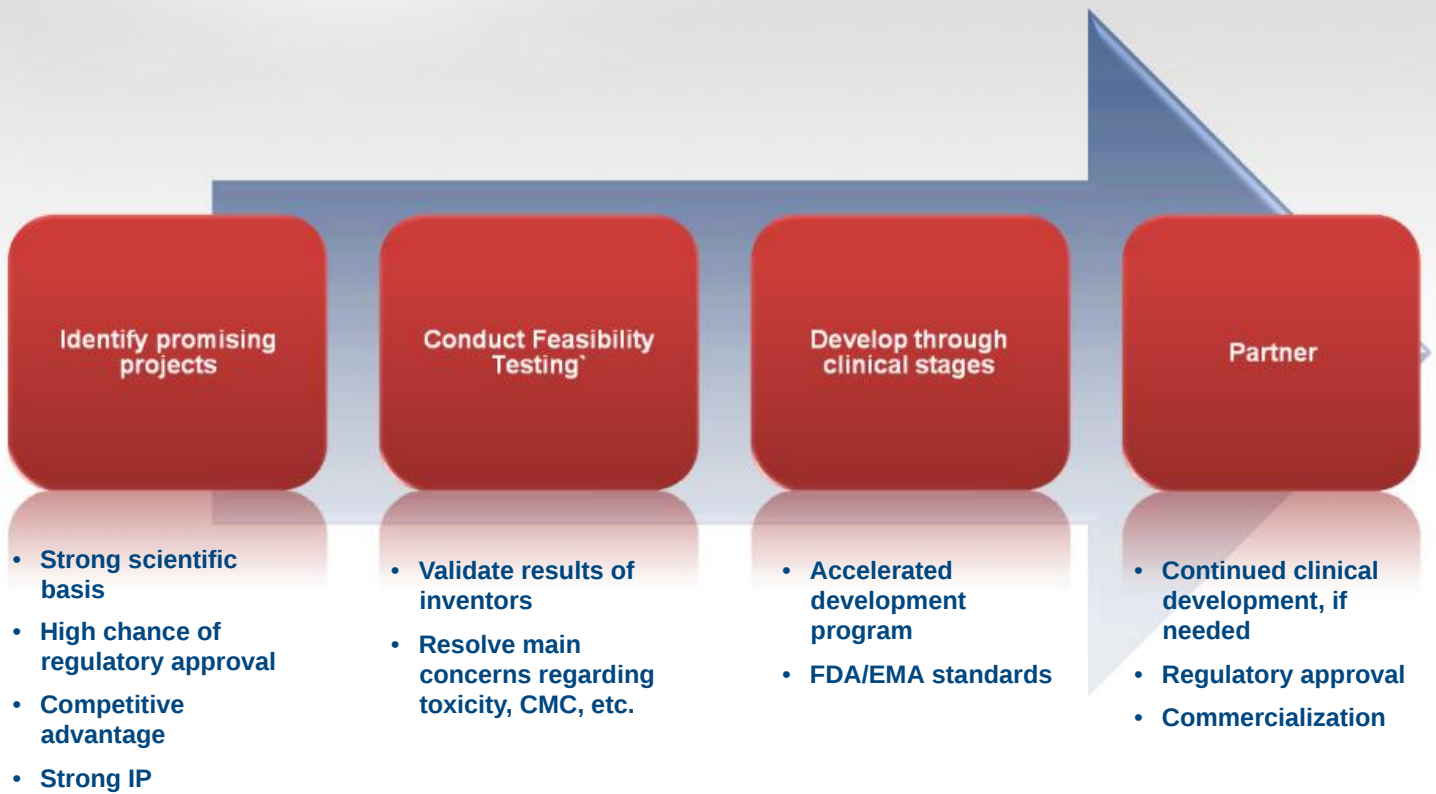
This presentation contains "forward-looking statements." These statements include words like "may," "expects," "believes," "plans," "scheduled," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements.

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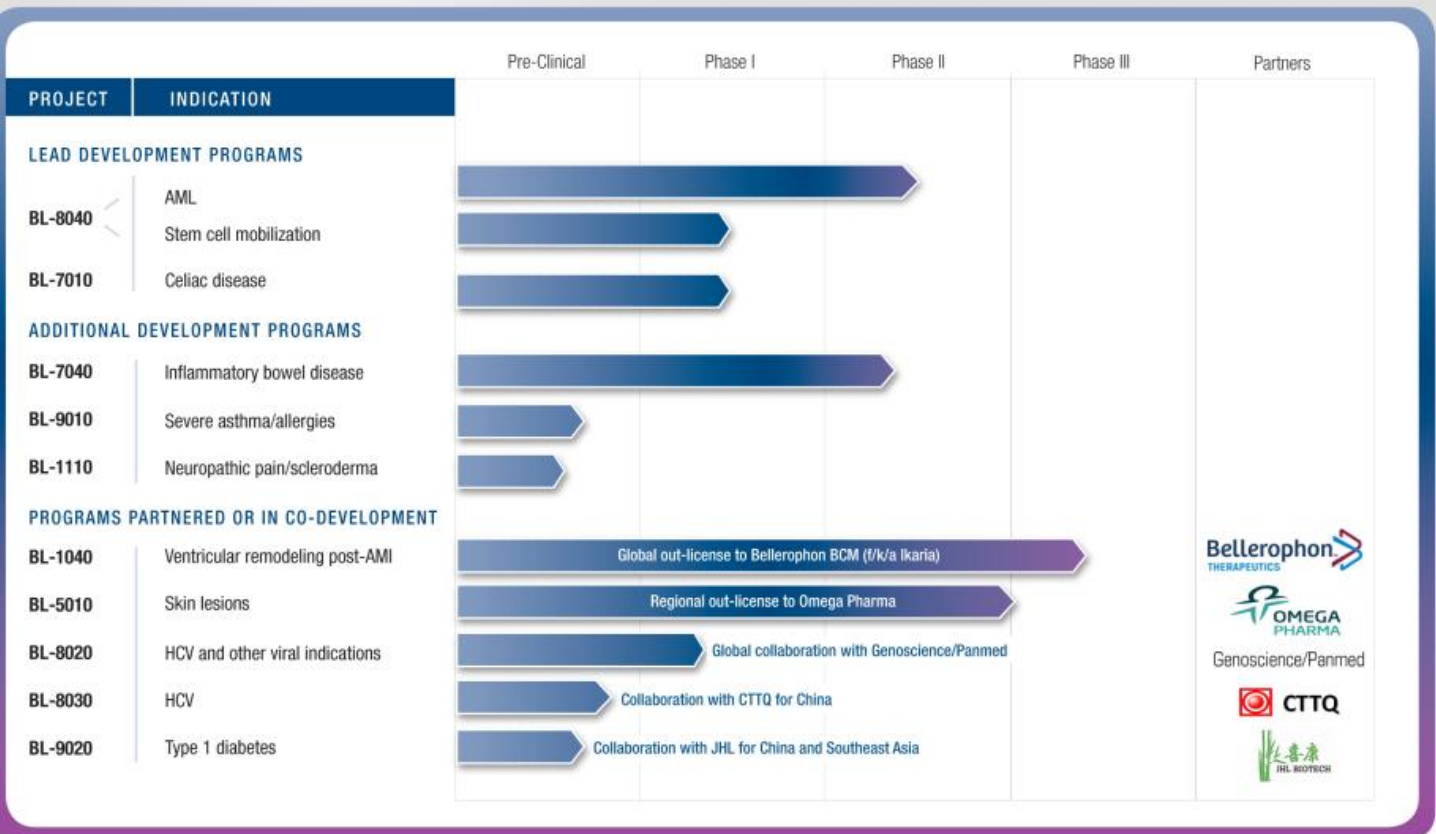
## BioLineRx Snapshot

- **Drug development company with core focus on oncology and immunology**
- **Bridge “development gap” for Israeli assets**
  - Leverage carefully selected early-stage technology, primarily at academia level, following proof of concept in animals (at a minimum)
  - Invest 3-6 years in asset through to major catalyst
  - Partner the asset (depending on the stage)
    - For commercialization
    - For late-stage clinical development
    - For early and mid-stage co-development
- **Current pipeline of 10 assets, 6 in clinical development**
- **Share listings:** TASE (BLRX.TA) since 2007; NASDAQ (BLRX) since 2011

## Our Business Model



# Multiple High-Value Shots on Goal





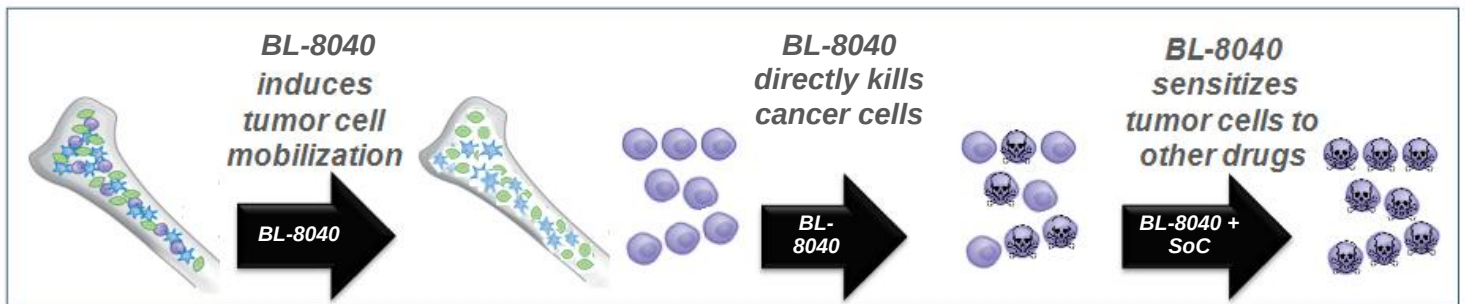


## LEAD PROGRAMS

**BL-8040:  
BEST-IN-CLASS CXCR4  
ANTAGONIST FOR  
TREATMENT OF  
HEMATOLOGICAL  
CANCERS**

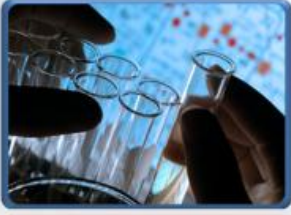
## BL-8040 Highlights

- **Indications:** Acute myeloid leukemia (AML) & other hematological cancers
- **Mode of Action:** CXCR4 antagonism
  - CXCR4 over-expressed in >70% of tumors, and correlates with disease severity.
- **Status:**
  - Phase II trial ongoing (AML)
  - Phase I trial ongoing (Stem cell mobilization )
- **Product MOA:**



# Projected Clinical Program Targets Several Hematological Indications With High Unmet Need

PROTOCOL	INDICATION	Pre-Clinical	Phase I	Phase II	Phase III
<b>ACUTE MYELOID LEUKEMIA (AML)</b>					
BL-8040.01	r/r AML	Ph2a - Ongoing - Topline results Q1/2015			
BL-8040.04	AML Consolidation (BLAST)	Ph2b - Planned - Q1/2015-Q3/2017			
BL-8040.05	AML FLT3-ITD	Ph1/2 - Planned - Q1/2015-Q3/2016			
<b>OTHER HEMATOLOGICAL INDICATIONS</b>					
BL-8040.06	hMDS and Aplastic Anemia	Ph1/2 - Planned - Q2/2015-Q2/2017			
BKTSC001	SCM with G-CSF (Myeloma)	Ph1/2 - Completed			
BL-8040.02	SCM as Single Agent	Ph1 - Ongoing - Q1/2015			

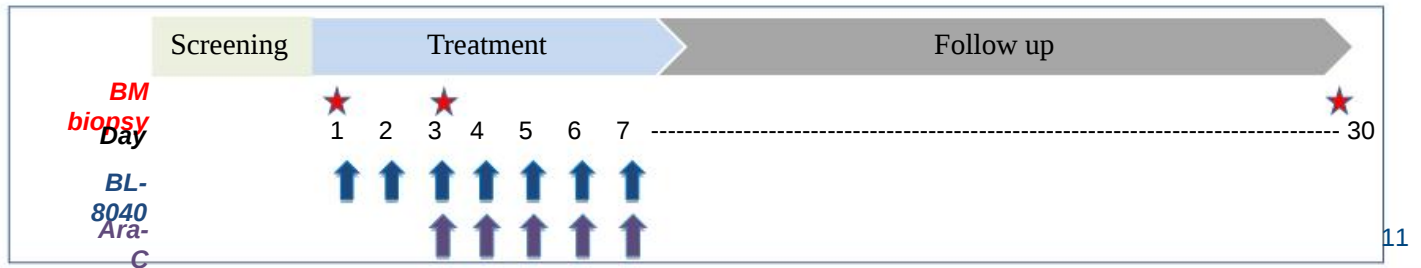


## **ON-GOING STUDIES**

**rr AML & Stem Cell  
Mobilization**

## Results from r/r AML Phase 2a (under IND)

- First four cohorts were completed
- There were no BL-8040 related SAEs and none of the AEs were considered DLTs
- Robust leukemic blast mobilization was observed (median of 6-fold increase)
- BL-8040 monotherapy decreased amount of leukemic cells in BM by median of ~70%
- 3.5-fold increase in AML cell apoptosis (BL-8040 monotherapy)
- Topline results are expected during H2/2015



# BL-8040.01 Currently Taking Place in Multiple Leading Medical Centers in the US and Israel



Dr. Gautam Borthakur



Dr. Jessica Altman



Dr. James Foran



Dr. Martin Tallman



Shaare Zedek Medical Center in Jerusalem  
Affiliated with the Hebrew University School of Medicine

Dr. Jacob Rowe



Dr. Yishai Ofran



Dr. Nadav Sarid



Dr. Arnon Nagler



Dr. Dina Ben-Yehuda

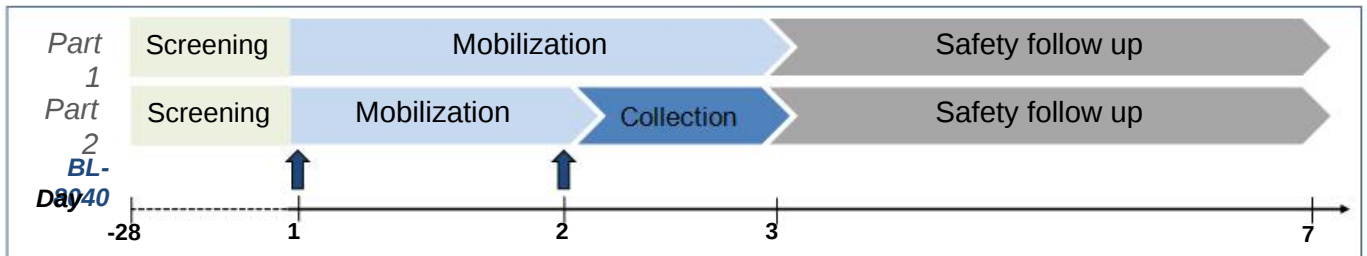
# Phase 1 - Single Agent Stem Cell Mobilization

## Study design

- Part 1 - Dose escalation, randomized, placebo controlled - up to 4 escalating doses
- Part 2 - Dose expansion of safe and efficacious dose group

## Timelines

- Topline results expected by end of Q1/2015







## **3 NEW INDICATIONS**

## 3 New Studies will be Initiated in 2015

- **AML Consolidation**

- Collaboration with the German Study Alliance Leukemia Group
- Double blind, placebo controlled, repeated administrations, multiple treatment cycles
- Sample size - ~200 patients
- 20-25 sites in Germany
- Topline results expected by Q4/2017

- **AML FLT3-ITD**

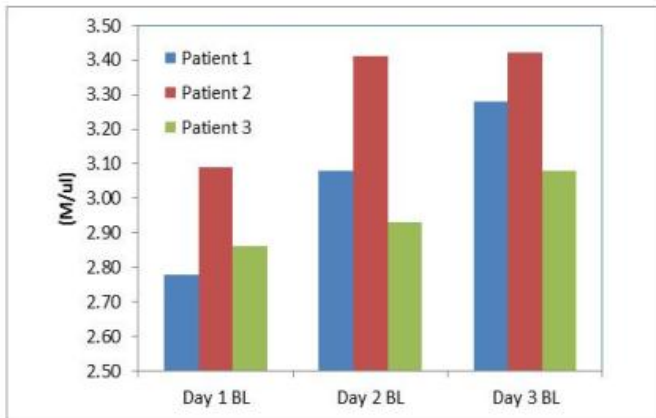
- Collaboration with MD Anderson Cancer Center
- Open label, two parts:
  - Part I: Dose selection, assessment of MTD of Sorafinib in combination with BL-8040
  - Part II: Combination in different FLT3-ITD patient populations
- Topline results expected by Q1/2017

- **Myelodysplastic Syndrome (MDS) & Aplastic Anemia (AA)**

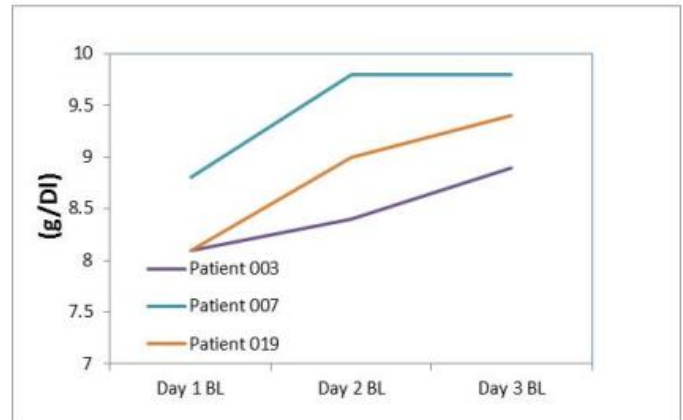
- Collaboration with MD Anderson Cancer Center
- Open label, repeated administrations, single treatment cycle
- Topline results expected by Q3/2017

## MDS & Aplastic Anemia (AA)

- MDS and AA are hematological disorders characterized by bone marrow dysplasia, ineffective hematopoiesis and cytopenias
- Effect of BL-8040 on BM regeneration:
  - Both pre-clinical and clinical signs of efficacy (from the on-going study)

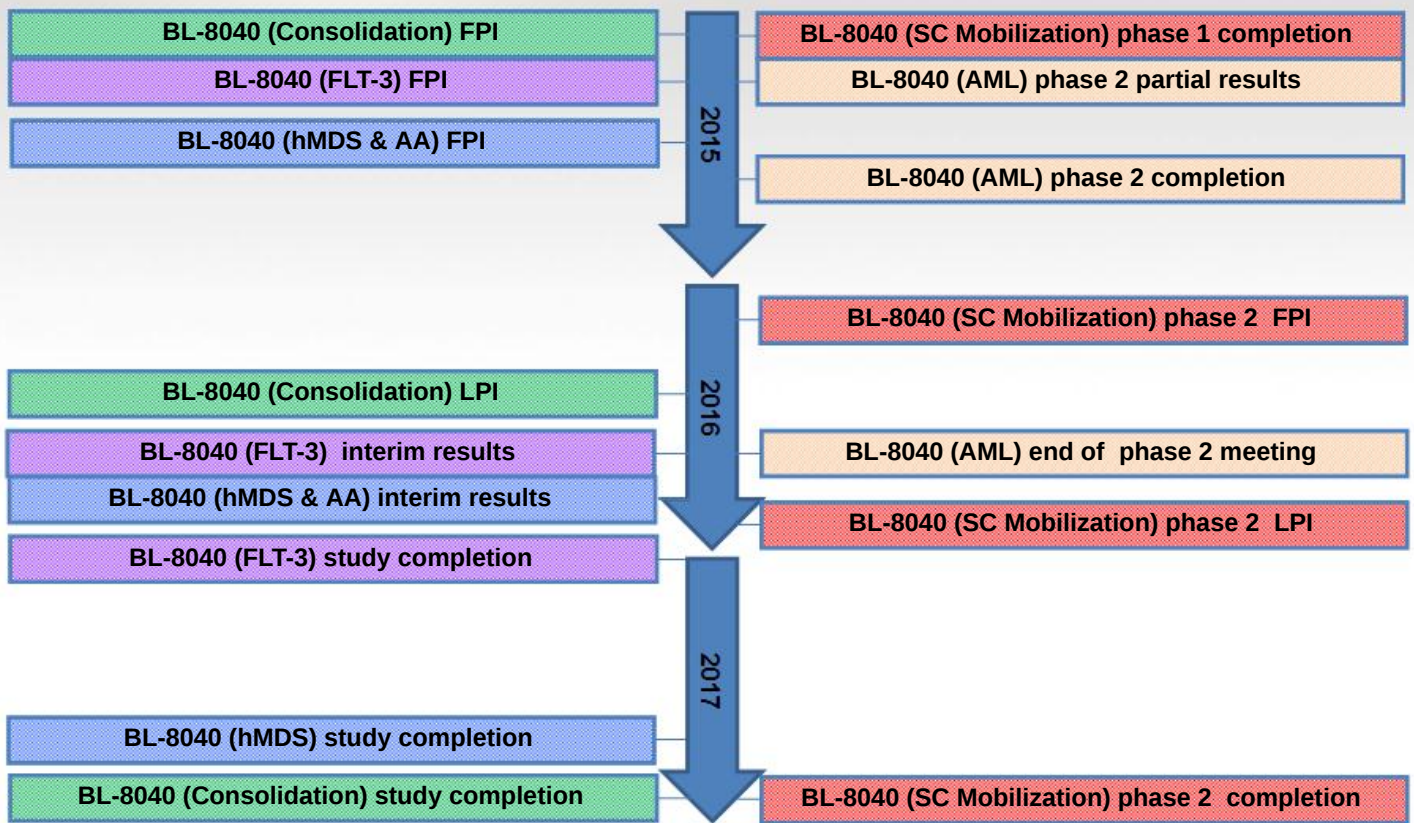


RBC



Hemoglobin

# Major BL-8040 Development Milestones (Next 3 Years)





**BL-1040:  
FIRST-IN-CLASS MYOCARDIAL IMPLANT  
FOR PREVENTION OF VENTRICULAR REMODELING  
FOLLOWING AMI**

*Out-licensed to Bellerophon (f/k/a Ikaria) and being developed  
as Bioabsorbable Cardiac Matrix (BCM)*

## BL-1040 Highlights

- **Indication:** Cardiac damage following heart attack
- **Mode of Action:** Provides structural support during healing
- **Status:** EU registration trial - completion expected in mid-2015
- **Device designation (including FDA)**
- **Partnered with Bellerophon BCM (f/k/a Ikaria)**
  - \$282.5 million total deal; \$17 million received; 11-15% royalties
  - All development costs funded by Bellerophon BCM
- **Market Opportunity:** >\$1 billion\*



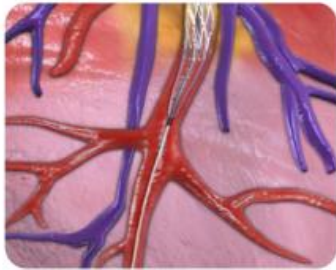
\*Based on a customized survey and report prepared for BioLineRx by Defined Health

# Unmet Medical Need

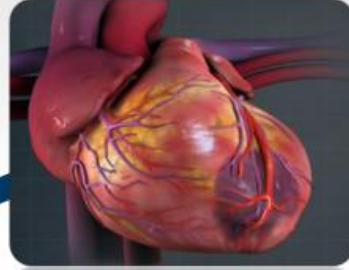
## Vessel occlusion



Successfully treated  
with PCI and stents



## Tissue damage



No sufficiently effective  
treatment for myocardial  
damage

# How Does BL-1040 Work?

Arterial injection deposits material into infarcted tissue



Turns from liquid to gel on contact



Gel-like scaffold provides mechanical support to damaged tissue



Transitions back to liquid and exits the body within 6 weeks

## Porcine AMI model, day 60

Untreated



- Dilated
- Thin wall

BL-1040



- Normal size
- Normal wall



## Promising Results from Pilot Study

- Designated as device by regulatory authorities (including FDA)
- Pilot study in Europe - completed January 2010
  - 27 patients, safety and preliminary efficacy in patients with primary MI at high risk for LV remodeling
    - 9 sites: 6 in Germany, 3 in Belgium
- Trial results show
  - No treatment related complications, arrhythmias, elevations in cardiac enzymes or occlusions
  - Comparison to historical data suggests superior efficacy



## **BL-1040 Pivotal Clinical Development Program**

- **Pivotal CE Mark Registration trial progressing at full steam**
  - Placebo controlled, total enrollment ~300 patients, six-month follow-up
  - ~80 sites currently active in nine countries (including 14 sites in US)
  - Over 280 patients enrolled to date
  - Endpoints: End diastolic volume index, QLQ, six-minute walk test
  - Trial to be completed by mid-2015
- **US pivotal trial in planning stages**
  - Final discussions with FDA
  - Placebo controlled, >1,000 patients, 12-month follow-up

**BL-7010:  
NOVEL GLIADIN-BINDING  
POLYMER FOR  
CELIAC DISEASE**



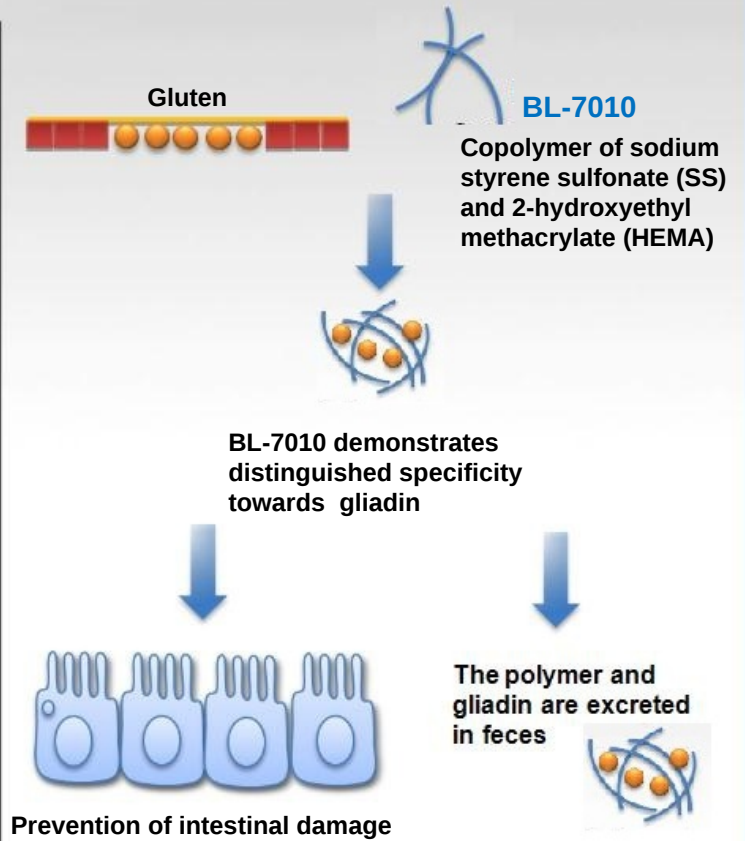
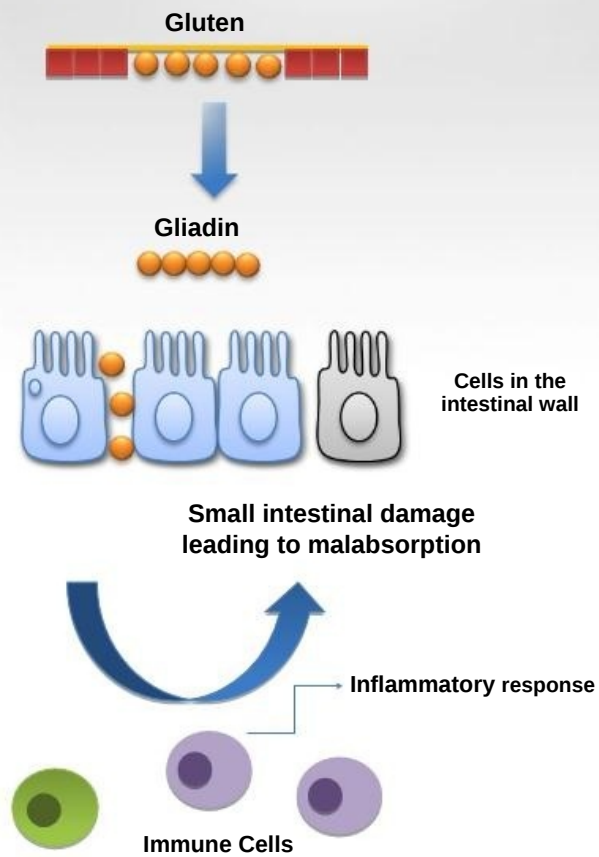
## ▶ **BL-7010: Polymeric Binder for Celiac Disease**

- **Indication:** Celiac disease (harmful immune response to gluten)
- **Mode of Action:** Novel polymer that binds to gluten peptides; prevents interaction with the immune system in the GI
- **Status:** Phase 1/2 study completed in celiac patients
- **Product Highlights**
  - Prevents damage to small intestine
  - Does not enter bloodstream (stays in the GI and is excreted)
  - Non-toxic

## **Celiac Disease - Large Unmet Medical Need**

- **1% of world's population suffers from celiac disease**
  - Underestimated due to lack of awareness/diagnostic tools
- **Market projected to reach \$8 billion by 2019**
- **No current therapies approved for celiac**
  - Only treatment option is life-long, strict gluten-free diet (GFD)
  - ~20% of celiac patients have symptoms even on GFD
- **Major interest shown by Big Pharma**
  - AbbVie acquired rights to phase 2 asset from Alvine (paid \$70 million upfront)

# BL-7010 Prevents Formation of Gliadin's Immunogenic Peptides

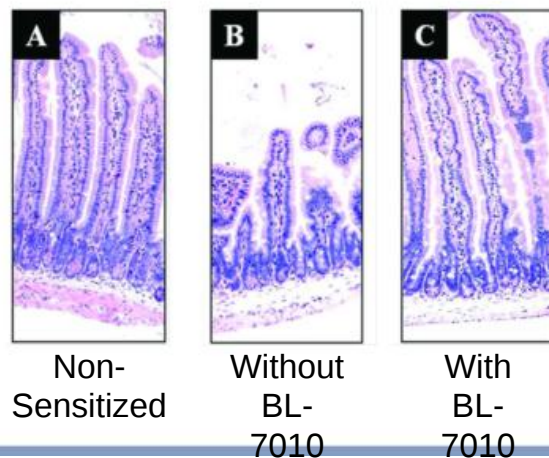


# BL-7010 Pre-clinical & Clinical Success to Date

- Phase 1/2 safety study completed in celiac patients
- Positive results presented in early November
  - Safe and well tolerated; no serious or dose-limiting side effects
  - Optimal dose identified: 1 gram x 3 per day
  - Confirmed no systemic absorption; supports medical device classification in Europe (significantly accelerates potential approval)
- Randomized, placebo-controlled efficacy study expected to commence in H2 2015

In-Vivo results

Transgenic male





## **BUSINESS DEVELOPMENT ACHIEVEMENTS**



## Major Business Development Activities in Last 2 Years

- **BL-8030 (HCV) out-licensed to CTTQ (Chinese leader for liver diseases)**
- **BL-9020 (type I diabetes) collaboration with JHL**
- **BL-5010 (skin lesions) out-licensed to Omega Pharma**
  - Leading European OTC healthcare company with operations in 35 countries and over 2,500 employees.
  - Omega generated sales of more than €1.2B in 2013
  - A definitive agreement for the acquisition of Omega by Perrigo
  - BL-5010 is expected to begin marketing in 2016
- **Strategic collaboration with Novartis**
  - For screening and development of novel drugs
  - Strategic collaboration was a major objective for BioLineRx
    - Our pipeline and proven expertise were the basis for this collaboration
    - This collaboration will enable expansion of our pipeline and maximize number of programs we can in-license from Israel

## Facts about Novartis

- **Second largest pharma company worldwide, Market cap ~\$225B**
  - Expected to become the #1 in ethical drug sales by 2020 (by Decision Resources)
- **135,000 employees**
- **2013 annual sales of ~\$58B**
  - Approximately \$46.5B is estimated from ethical drugs
- **Sales growth rate: 2-4%**
  - Ethical drug growth at CAGR of 5.5% since 2009 (twice as much as big pharma average of 2.8%).
- **2013 R&D budget: \$9.9B (\$7.25B in pharmaceuticals)**
- **Key areas: oncology, ophthalmology, cardiovascular, CNS**
- **Top-selling drugs:**
  - Gleevec: \$4.7B in 2013 sales , CML (leukemia)
  - Diovan: \$3.5B in 2013
  - Lucentis: \$2.4B in 2013, AMD
  - Gilenya: \$1.9B in 2013 (>60% growth), MS
  - Sandostatin: \$1.6B, oncology



# NOVARTIS PARTNERSHIP

Overview

## ▶ What is Background and Rationale for the Deal?

- **The key objectives of such a partnership are:**
  - Increase likelihood of future licensing transaction
  - Reduce cost and risk of drug development, especially in clinical stages
  - Increase likelihood of success by incorporating inputs from industry leader
  - Validate BioLineRx's capabilities in identifying and developing promising projects
- **All of these objectives have been met via Novartis transaction**

## Specifics of Deal

EQUITY INVESTMENT	<ul style="list-style-type: none"><li>• \$10m at &gt;20% premium</li><li>• Represents 12.8% of BLRX equity</li><li>• No Board seat/presence</li></ul>
JOINT EVALUATION	<ul style="list-style-type: none"><li>• Joint committee established to routinely evaluate projects</li><li>• Only Israel-originated projects are reviewed</li><li>• BLRX existing portfolio is NOT included in this partnership</li><li>• If Novartis passes on a project, BLRX has full freedom to act</li></ul>
JOINT DEVELOP.	<ul style="list-style-type: none"><li>• Selected project will be in-licensed solely by BLRX</li><li>• Cost sharing of clinical development on up to three projects</li><li>• Joint development until clinical proof-of-concept (POC)</li></ul>
POTENTIAL LICENSING	<ul style="list-style-type: none"><li>• For joint projects reaching POC, Novartis will have right-of-first-negotiations for several months</li><li>• No obligation by BLRX to out-license to Novartis</li><li>• Likelihood of out-licensing deal is increased significantly</li></ul>

## Co-Development Principles

- **Companies will agree on:**
  - Endpoints for development (typically around Phase 1b or Phase 2a)
  - Development plan
  - Budget
- **Novartis will provide the following financing:**
  - \$5M “option fee” at time of signing (non-dilutive)
  - 50% of the remaining development budget via equity (at premium to share price at that time)
- **For example:**
  - Agreed endpoint is Phase 2a
  - Agreed development budget = \$15M
  - Novartis pays option fee = \$5M
  - Remaining budget = \$10M
  - Novartis pays 50% of that, meaning an additional \$5M (in equity)
  - Total investment by Novartis in this project: \$10M out of total of \$15M

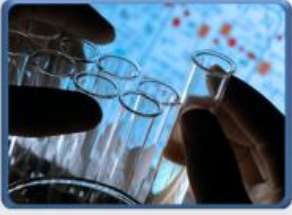
## How do we Protect BLRX Shareholder Interests?

- **Equity investment by a leading and sophisticated partner**
  - Clear limitations in place on Novartis' ability to sell shares in the future
- **Corporate governance is very strong**
  - No board seat for Novartis
  - No rights to know about additional partnering discussions
  - Standstill limitation: Novartis cannot go over a certain % of the equity (but can increase its existing stake somewhat)
- **Leave significant room to maintain BioLineRx independence**
  - Existing pipeline is excluded from the deal
  - All projects are in-licensed solely to BLRX and managed by BLRX

## ▶ How does Deal Meet our Strategic Objectives?

- √ Increases likelihood of future licensing transaction
- √ Reduces cost & risk of development, especially in clinical stages
- √ Increases likelihood of success by incorporating inputs from industry leader
- √ Validates BLRX's capabilities in identifying and developing promising projects





## **OUT-LICENSING OF BL-5010 TO OMEGA**

## Deal Overview

- **Omega Pharma Facts**

- Leader in OTC market in Europe, with over €1.3B in annual sales
- Recently bought by Perrigo for €3.6B
- Omega has existing products in leading relevant categories

- **Deal scope:**

- Geography: Europe, Australia and other selected countries
- OTC uses only
- BLRX maintains full rights in the US, as well as the Rx rights globally

- **Deal structure:**

- BL-5010 is regulated as a medical device in Europe and other countries, with expected commercial launch as early as 2016
- BLRX will be entitled to receive undisclosed amount for each unit sold, plus commercial milestone payments
- Omega will develop BL-5010 for more than one indication, allowing for additional future growth in sales

## Deal Implications

- **Additional validation of BioLineRx's business model**
  - Develop early-stage Israeli projects until advanced clinical stages
  - Identifying leading relevant partners for commercialization of these projects
- **Value creation from non-core projects as well**
  - Potential for relatively near-term stream of income
- **Further focusing on strategy**
  - Resources and attention can be further directed at lead clinical projects in oncology and immunology
  - Allow further support and attention for partnership with Novartis



# CORPORATE

# Financial and Corporate Summary



## Strong cash position

- \$29.6 million as of September 30, 2014 (latest financials)
  - Does not include \$10 million received from Novartis
- Current resources fund operational capital through end of 2016
- Expect to reach several value inflection points during this time



## Capital structure

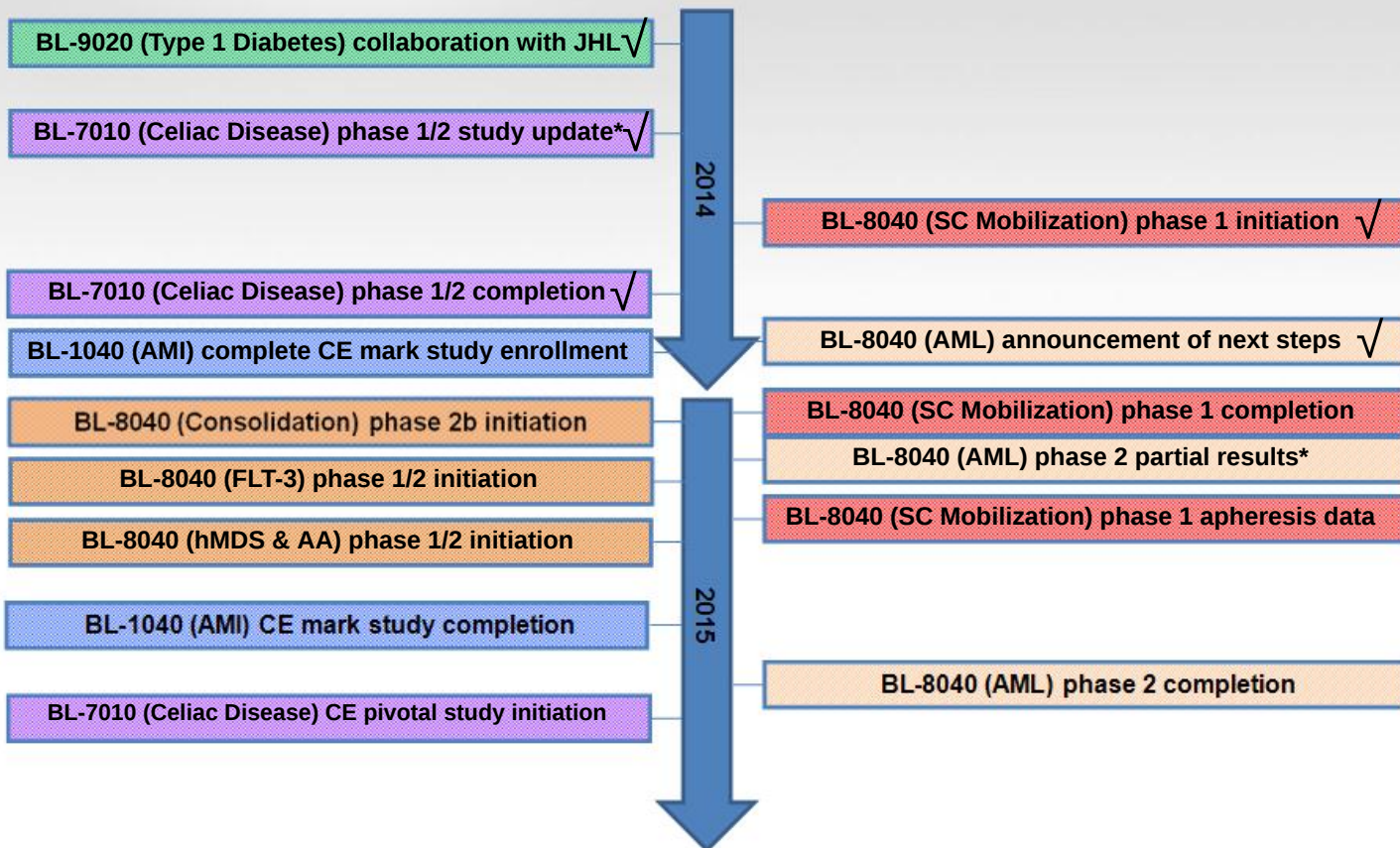
- Traded on NASDAQ and TASE (Symbol: BLRX)
- 39 million shares outstanding; 45 million fully diluted (based on ADSs)
- US and European shareholders represent >60% of investor base



## Other

- 46 employees, approximately 2/3 with advanced degrees
- Covered by several analysts: Aegis Capital, Roth Capital, Maxim Group, Edison Investment Research

# Major Development Milestones - 2014 and 2015



\* End of dose escalation phase

# *Bench to Bedside to Partner*



THANK YOU!

**BIOLINEARX**