



Callisto
Pharmaceuticals
Amex: KAL

Rodman & Renshaw Investor Conference
November 7, 2007
Gary S. Jacob, Ph.D., CEO

CALLISTO PHARMACEUTICALS, INC.

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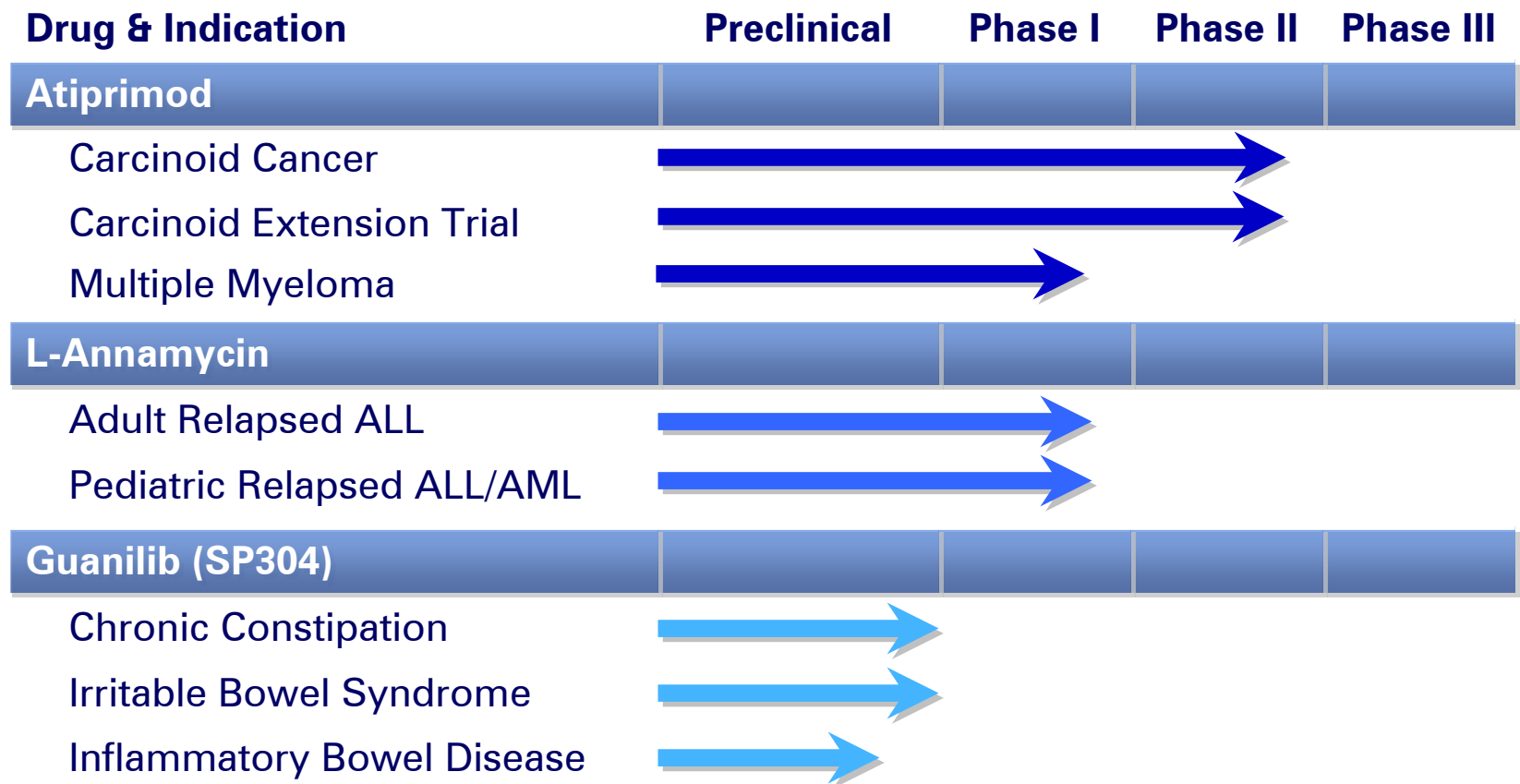
Callisto Pharmaceuticals, Inc.

**Biotechnology Company Focused on
Drugs to Treat Cancer and GI Conditions**

Investment proposition

- Callisto Pharmaceuticals is highly undervalued
- A major investment opportunity
- Current valuation is about \$30 M
- In 2 years we plan to have a compound in phase 2b, Guanilib, likely worth well over \$500 M
- We plan to hold an investor conference call to outline the details of the Guanilib opportunity

Callisto Pipeline



Atiprimod – First-in-Class Azaspirane

- **Novel drug candidate in clinical development for late-stage cancers**
 - **Small-molecule, orally available**
 - **Displays multiplicity of anti-cancer activities**
 - Promotes apoptosis, inhibitor of key signaling enzymes, anti-angiogenic activity
 - Animal-model data show Atiprimod works in milieu of bone marrow
 - Extensive peer-reviewed publications in cancer and inflammation
- **Orphan drug designations to treat carcinoid cancer and multiple myeloma**

Atiprimod Clinical Development

- Advanced Carcinoid Tumors

- **Potential benefit observed in carcinoid patients in Phase I trial of advanced cancer patients**
- **Phase II multi-center open-label clinical trial in advanced carcinoid cancer began November, 2006**
 - Objective: evaluate efficacy in patients with metastatic or unresectable cancer who have either symptoms or tumor progression
 - 7 sites presently open
 - Completed enrollment of 40 patients in September 2007
 - Interim data to be released in 1Q2008
- **Opened Phase II carcinoid extension trial in October 2007**
- **Next step: Proposed Meeting with FDA to Discuss Registration Trial (1Q2008)**
 - Establish agreed-upon end-point for approval

Atiprimod in Advanced Carcinoid Cancer

- Market Overview

- US prevalence: 80,000 – 100,000
 - 8,000 new cases of per year in U.S.; 6% increase per annum
- Chemotherapy relieves symptoms in <30% of metastatic tumors
 - Duration of response < 1 year
- Strong need for new effective therapy to treat advanced metastatic disease
- 1 approved drug:
 - Novartis: Sandostatin® (octreotide acetate) to treat symptoms
- Anticipated treatable carcinoid patient population for Atiprimod ~ 3,000 - 5,000 patients

L-Annamycin

- **Second generation Anthracycline**

- Unique patented liposomal formulation
- Potential to reduce cardiotoxicity and to treat multi-drug resistant tumors

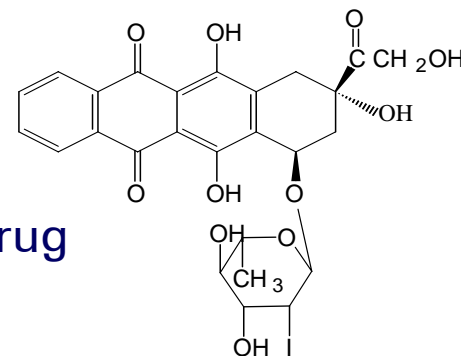
- **Proven class of anti-cancer drugs**

- Active against multi-drug resistant tumors

- **Strong myelosuppressive activity**

- **Potential to treat relapsed acute leukemia**

- **Orphan drug designations to treat ALL and AML**



ANNAMYCIN

L-Annamycin Clinical Development

ADULTS

- **Single-agent Phase I/IIa multi-center trial in adult relapsed or refractory ALL:**
 - Improvements in reconstitution and infusion protocol have led to de-escalation of drug dose
 - Once MTD is established, plan to move to fixed-portion of trial – expected 4Q 2007

PEDIATRIC

- **Multi-center, open-label, dose-escalation Phase I pediatric acute leukemia trial opened February, 2007:**
 - Relapsed or refractory ALL and AML patients
 - Utilizes POETIC consortium of pediatric cancer centers
 - Dose escalating until MTD reached

Next steps:

- Adult ALL: Finalize MTD and enroll at fixed-dose portion of Phase IIa trial
- Pediatric ALL/AML: Complete MTD study (1H2008) and evaluate potential

L-Annamycin

- Market overview

Target market – Adult Lymphocytic Leukemia

- **Significant market opportunity with significant unmet medical need:**
 - U.S. incidence – 4,000 per year
 - U.S. prevalence – 42,330
 - U.S. deaths – 1,400 per year
- **Annual peak market in refractory ALL estimated to be \$100 – \$150 million**
- **Notable drug candidates in development to treat relapsed ALL:**
 - Clolar™ Clofarabine (Genzyme) DNA chain terminator, nucleoside analog
 - Marqibo (Hana Biosciences) vincristine sulfate liposomes injection
 - Talotrexin (Hana Biosciences) nonpolyglutamate antifolate drug

Guanilib - New major strategic focus for Callisto

- **Peptide hormone analog to treat GI conditions**

- Chronic constipation and constipation-predominant irritable bowel syndrome (IBS-C)
- Inflammatory bowel disease

- **New class of drug**

- Guanylate cyclase C (GC-C) receptor agonists
- Only competitor is Linaclotide from Microbia

- **Non-absorbed safe compound**

- Acts on receptor in gut lining
- Oral administration
- Not systemically absorbed – not needed for activity
- Very low toxicity

Guanilib - New major strategic focus for Callisto

- **Clinical proof-of-principle for the class**

- Linacotide has provided strong proof-of-principle for the class in phase 2 clinical trials

- **Strong IP position**

- Callisto has dominant IP position
- Key patent granted 2006

- **Huge markets with only one approved drug**

- Only drug currently on market is Amitiza from Sucampo/Takeda

Guanilib – GC-C Receptor Agonist

Uroguanylin Natural Hormone

NDDCELCVNVACTGCL



Guanilib Uroguanylin Analog

NDECELCVNVACTGCL

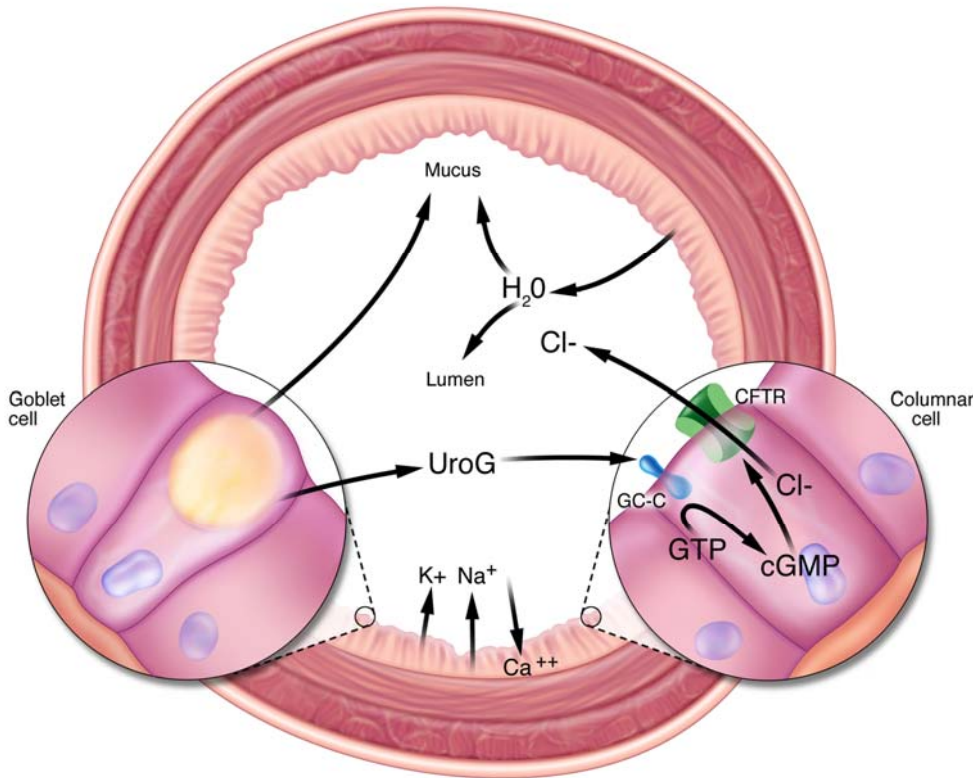


GC-C Receptor

- **Agonist of Guanylate Cyclase C receptors**
- **16-mer analog of uroguanylin**
 - Uroguanylin is a natural peptide produced in the lining of the gut
 - Role in maintaining proper gut function
- **Compact stable molecule**
 - Thermo and acid stable, resistant to proteases
 - Behaves like a small molecule drug
 - More potent than the natural hormone

Guanilib

- Physiological mechanism



- **Agonist of guanylate cyclase C (GC-C) receptor on luminal membrane of gut**
- **Agonists include guanylin (15-mer), uroguanylin (16-mer), bacterial enterotoxin – ST peptide (19-mer), linacotide (14-mer)**
- **Activation elevates cGMP second messenger**
- **cGMP increases secretion of fluid, Cl⁻ and HCO₃⁻ into intestinal lumen**
- **Additional role in apoptosis & proliferation rates of colonocytes**

Guanilib

- Market overview

- **The market potential for chronic constipation and IBS therapeutics is huge**
- **In the US alone, about 25 M suffer from constipation, about 5 M of them severe**
- **3 subtypes of IBS, diarrhea-predominant (-D), mixed (-M) and constipation- predominant (-C)**
- **About 10 M people with IBS-C in US, about 2.5 M of these with severe symptoms**
 - About 70% women
 - Accounts for 12% of primary care visits
 - About 80% of these are seen by primary care physicians
- **Similar incidence in other developed countries**

Guanilib

- Competitive landscape – Approved products

U.S. products for chronic constipation and IBS-C:

- Withdrawn products:

- Zelnorm (tegaserod, 5-HT₄ agonist), Novartis

- Withdrawn in US (2007) due to cardiovascular toxicity

- Sales in 2006 \$560 M WW, growth 32%

- Recently approved products:

- Amitiza (lubiprostone) from Sucampo/Takeda

- Chloride C-2 channel activator – increases fluid secretion into small intestine

- Absorbed compound – main side effect is nausea

Guanilib

- Competitive landscape – Pipeline (1)

GC-C receptor agonist pipeline

- **Only two compounds in this class**

- Identical mechanisms of action

- **Linaclotide from Microbia**

- First in class
- Analog of *E. coli* enterotoxin ST-peptide (cause of travelers diarrhea)
- In Phase 2b for chronic constipation and IBS-C
- Recently partnered with Forest Labs, for \$70 M upfront and \$260 M milestones and profit split for US only – Valued compound at well over \$500 M

- **Guanilib advantages**

- Analog of uroguanylin
- Mechanism-of-action enhances a natural process
- Potential to become best in class compound

Guanilib

- Competitive landscape – Pipeline (2)

Other compounds in chronic constipation / IBS pipeline

- **TD-5108 from Theravance Inc.**
 - 5-HT₄ receptor agonist. Phase 2
 - GSK abandoned partnership Sept 2007
- **Renzapride from Alizyme (UK)**
 - 5-HT₄ agonist & 5-HT₃ antagonist. Phase 2
- **LX1031 from Lexicon Genetics, Inc.**
 - Reduces serotonin levels. Phase 1
- **DDP733 from Dynogen**
 - 5HT₃ agonists. Phase 1.

Guanilib clinical development

- Guanilib will be developed for chronic idiopathic constipation, constipation-predominant irritable bowel syndrome, and for ulcerative colitis.
- IND filing planned for 1Q 2008
- Phase I start 2Q 2008
- Phase Ib start 4Q 2008

Callisto expected key developments

- Next 12 months

Event	Timing
Release interim data on Atiprimod Phase II carcinoid trial	1Q 2008
FDA meeting to discuss pivotal trial for Atiprimod in carcinoid cancer	1Q 2008
File IND for Guanilib in GI disorders	1Q 2008
Initiate Guanilib Phase I trial	2Q 2008
Commence Phase Ib repeat-dose trial for Guanilib in chronic constipation	4Q 2008

Experienced Management Team

- **Gary S. Jacob, Ph.D.; CEO, CSO**
 - 20 years experience in drug discovery & development
 - G.D. Searle, Oxford University, and Monsanto Co.
- **Robert C. Shepard, M.D., F.A.C.P.; Chief Medical Officer**
 - Former Medical Officer, oncology branch of CBER at FDA
- **Kunwar Shailubhai, Ph.D., MBA; Senior VP, Synergy Pharma**
 - > 15 years experience at NIH and G.D.Searle
 - Discoverer of Guanilib for GI inflammation
- **Craig Talluto, Ph.D.; Senior Director, Clinical Operations**
 - 10 years experience in clinical research
 - Kos Pharmaceuticals, Amgen, Hoffmann La-Roche
- **Bernard Denoyer; VP, Finance**
 - Former CFO of META Group Inc.

Summary (1)

- **Atiprimod for carcinoid cancer**

- Progressing well, enrollment complete and trial extended
- Interim data to be released in early 2008

- **L-Annamycin for leukemia**

- Finalize MTD in adult and pediatric acute leukemia
- Development plan to be reviewed once data from adult trial is available

Summary (2)

- **Guanilib for chronic constipation and IBS-C**

- Major new strategic focus for company
- One of only two compounds in new class for very large and underserved markets
- Not absorbed – likely to be very safe
- Clinical proof-of-principle for the class – likely to be efficacious
- Huge market potential and deal opportunity - validated by Microbia deal

- **Callisto Pharmaceuticals is highly undervalued today – a major investment opportunity**

- Investor conference call planned to outline the Guanilib opportunity
- Announcement and call-in number will be made available shortly. Also see www.callistopharma.com for further details