

# *Innovation for the benefit of patients*

Financial Analysts Meeting - March, 2009



# Important notice



This communication expressly or implicitly contains certain forward-looking statements concerning BioAlliance Pharma SA and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of BioAlliance Pharma SA to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. BioAlliance Pharma SA is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

For a discussion of risks and uncertainties which could cause actual results, financial condition, performance or achievements of BioAlliance Pharma SA to differ from those contained in the forward-looking statements please refer to the Risk Factors (Facteurs de Risque) section of the reference document approved by the AMF on 11 April 2008 under the number R. 08-021, which is available on the AMF website (<http://www.amf-france.org>) or on BioAlliance Pharma S.A.'s website.

To develop and market innovative products  
in severe diseases:

Supportive care, opportunistic infections, cancer, HIV

# Competitors panorama



## ■ Big pharma companies

- High investments in fundamental research
- Mass market
- Presence in all segments
- Search for the Blockbuster

## ■ Specialty pharma companies

- Niche market segments
- No investment in fundamental research
- Unmet medical needs
- Specialized sales team

## ■ Biotechnology companies

- Specialty market
- BtoB Supplier

## ■ Generic companies

- No investment in R&D
- Commercialization of products with expired patent
- Mass market
- Volume

# Identity Card



- Founded by:
  - **Dominique Costantini**, PhD, immunologist
  - **Gilles Avenard**, PhD, hematologist
- Pierre Morgon, PharmD, joined BioAlliance in 2008
- 60 years of cumulated experience in the pharmaceutical specialty area
- Innovative drugs in cancer, AIDS, opportunistic infections and supportive care
- An initial product successfully launched: **Loramyc<sup>®</sup>**

- Partnerships with academic research institutes (Inserm, CNRS, universities, IGR, ENS, AP -HP...)



- A portfolio of products protected by 25 families of patents and 231 applications, of which over 50% granted
- Staff: 90

- Specialized in niche products for inpatients with severe diseases or unmet medical needs (strongly growing markets: oncology, HIV and opportunistic diseases)
- A strategy relying on a balance between its portfolio of products and the diversification of its sources of revenues
- A specialist of innovation with shortened development duration
- An international expansion after 11 years of value creation and growth:
  - A performing French sales network and **a new European organization in 2009**
  - International partnerings with significant royalties

# 2008 key figures and achievements



- 2008 consolidated turnover: 8.2 M€, +143% vs 2007
- 2008 Cash balance: 31.7 M€
- Partnerships in Asia:
  - Handok (Korea, Malaysia, Singapore, Taiwan, Philippines)
  - Novamed (China)
- A total of up to 73 M€ agreements signed as of end 2008  
25 M€ booked in 2007-2008 and 16 M€ expected in 2009-2010
- **Acquisition of European commercial rights for 3 M€**
  - Ondansetron RapidFilm™
  - Ondansetron Oral Spray

# 2008 Consolidated Profit & Loss Account



€	Year ended 31/12/2008	Year ended 31/12/2007
Net sales	8 173 943	3 529 333
Other income	0	- 8 016
Purchases	- 314 142	52 302
Personnal costs	- 9 641 939	- 7 057 795
External expenses	- 19 295 258	- 14 431 649
Tax expense other than income	- 888 782	- 388 132
Amortization expense net	- 402 268	- 188 140
Depreciation expense net	164 827	- 516 957
Other operating income	2 259 010	1 613 198
Other operating expense	- 3 247 876	- 2 168 739
<b>Operating profit/loss</b>	<b>- 23 192 485</b>	<b>- 19 564 594</b>
Financial income/loss	1 827 567	1 316 848
Income tax expense	- 1 154	- 1 125
<b>Profit/loss for the period</b>	<b>- 21 366 072</b>	<b>- 18 248 871</b>

# 2008 Balance Sheet

NET ASSETS €	31/12/2008	31/12/2007
<b>Non current assets</b>		
Intangible assets	89 177	119 525
Fixed assets	2 077 399	614 170
Financial assets	235 355	294 984
Other non current assets	-	1 904 835
<i>Total non current assets</i>	2 401 931	2 933 514
<b>Current assets</b>		
Inventories	25 546	211 529
Trade receivable	673 932	455 447
Other current assets	7 574 972	3 673 388
Marketable securities & cash equivalent	31 200 514	56 210 656
Cash	490 490	52 275
<i>Total current assets</i>	39 965 454	60 603 295
<b>ASSETS</b>	<b>42 367 385</b>	<b>63 536 808</b>

Other current assets 7,6 M€ including R&D tax credit 4,6 M€

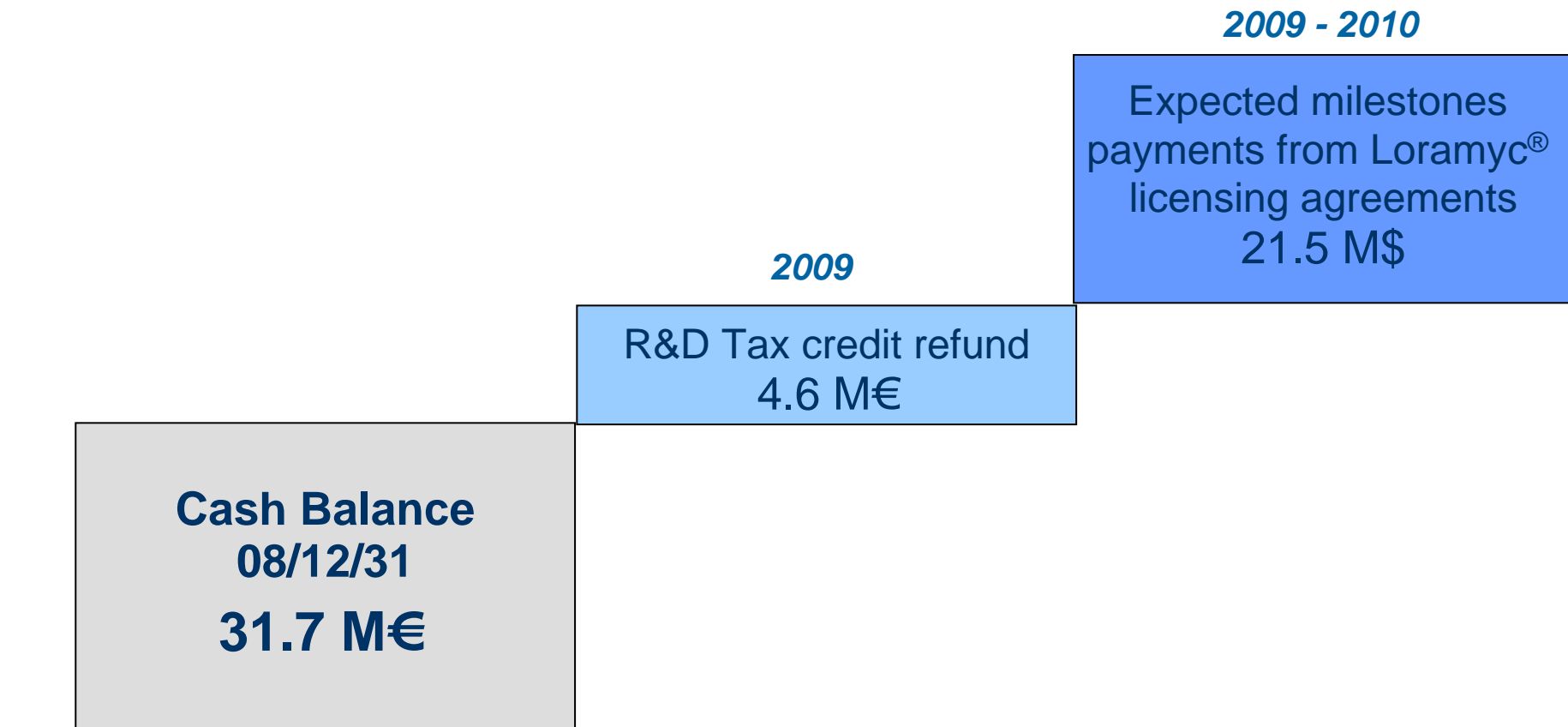
# 2008 Profit & Loss Account



EQUITY AND LIABILITIES €	31/12/2008	31/12/2007
<b>Shareholder's equity</b>		
Share capital	3 224 209	3 115 474
Less: treasury shares	- 155 723	- 108 223
Additional paid-in capital	97 944 440	96 985 385
Retained profits	- 52 427 121	- 35 253 366
Minority interest	-	-
Net profit/loss for the period	- 21 366 072	- 18 248 871
<i>Total equity</i>	27 219 733	46 490 398
<b>Non current liabilities</b>		
Provisions	556 134	646 585
Other long-term liabilities	350 000	350 000
<i>Total non current liabilities</i>	906 134	996 585
<b>Current liabilities</b>		
Short-term borrowings	11 689	21 497
Trade payables	5 045 813	4 918 842
Other payables	9 184 016	11 109 486
<i>Total current liabilities</i>	14 241 518	16 049 825
<b>TOTAL EQUITY &amp; LIABILITIES</b>	<b>42 367 385</b>	<b>63 536 808</b>

Income differed in 2009: 6 M€ incl. PAR 4 M€

# A solid cash position



# Targeted innovative products



- Products targeting:
  - The organs
  - The cell
  - The key receptors
  
- 4 key principles to drive their development:
  - Targeted efficacy
  - Avoid resistance issues
  - Increase compliance
  - Minimize side effects

# A diversified portfolio of products



Pre-clinical

Phase I

Phase II

Phase III

Registration

Launch

## Most advanced products

Acyclovir  
Lauriad<sup>®</sup>

Ondansetron  
RapidFilm<sup>™</sup>

Loramyc<sup>®</sup>

Ondansetron  
Oral spray<sup>®</sup>

## Products close to enter clinical phase

Fentanyl Lauriad<sup>®</sup>

Clonidine Lauriad<sup>®</sup>

Corticosteroid Lauriad<sup>®</sup>

AMEP<sup>™</sup>

## Promising new products

Integrase Inhibitor

Irinotecan Transdrug<sup>®</sup>

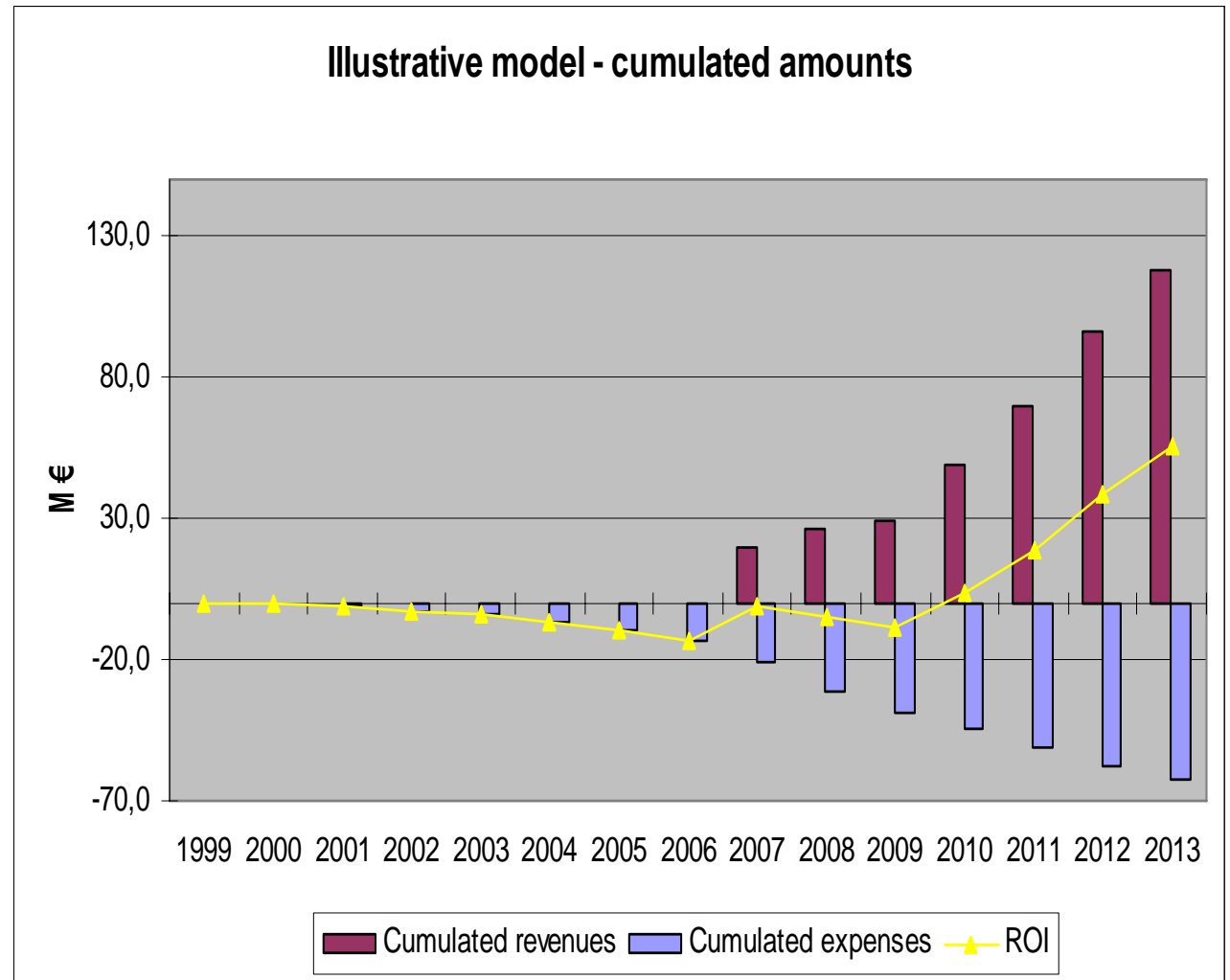
Zyxine

Doxorubicin  
Transdrug<sup>®</sup>

# Loramyc<sup>®</sup>, an initial product successfully launched



- Oropharyngeal candidiasis in immunocompromised patients
- Market: 330 M€ ww (IMS Health data)
- Objective: 30% market penetration
- Launch in the French market in September 2007
- Result one year after commercialization = 20 000 treated patients in Europe
- PAR Pharmaceutical in the US
- Commercial partnerings in south-east Asia and China
- Patent granted until 2021 in France & Europe and 2022 in the US



# Ondansetron RapidFilm™



European rights from APR (Applied Pharma Research S.A.) and its joint venture partner Labtec GmbH.

## Indication

- Nausea and vomiting induced by chemotherapy, radiotherapy and surgery

## Innovation

- Innovating rapid delivery dissolved in 6 seconds

## Market

- **Europe** (Anti-emetic European market – IMS data)
- Total of **400 M€** and 300 M€ for setrons class
- Ondansetron: **16%** of growth in volume
- **15,8 millions** defined daily doses (hospital 66% and retail 34%)
- **1 million** prescriptions (2007 retail and hospital evaluation)

## Development plan

- European filing: validated in Feb. 09

## Extended franchise

- Ondansetron Oral spray :  
European filing forecasted in H1 2010 as extended franchise

# Aciclovir Lauriad<sup>®</sup>: recurrent herpes labialis



International patent granted: exp. 2022

New patent in national phase: exp. 2027

## Indication

- Recurrent oral herpes, herpes labialis, oral herpes

## Innovation

- Innovative delivery of the active ingredient in the area of the infection achieving 17 000 times the rate of concentration of systemic acyclovir
- Early and sustained drug delivery to oral cavity – Single pill therapy

## Market

- Topical and systemic herpes labialis market estimated at €430 m<sup>(1)</sup>
- Europe represents 20 000 000 treatment days (IMS 07), 170 M€ EU

## Development Plan

- End of the international pivotal phase III Q2 09
- Dossier filing - According to the ongoing results for Europe and 2010 for the US (a second trial recommended by FDA)

<sup>(1)</sup> Source : IMS 2006

# Fentanyl Lauriad<sup>®</sup>



International patent granted: exp. 2022

New patent application exp. 2030

## Indication

- Chronic pain

## Molecular target

- Morphine-like agent

## Innovation

- Early and sustained systemic release of Fentanyl with once daily application
- Low variability of plasma concentrations
- No overdosing and no drug abuse potential

## Market

- Duragesic(R) and generic equivalents: U.S. sales over \$1billion, IMS Health 07 data.
- 30% of cancer patients are suffering from pain (Management of Cancer Pain, Levy M., & all 2005)

## Development plan

- Expected clinical entry in 2009

# Corticosteroid Lauriad<sup>®</sup>



International patent granted: exp. 2022

New patent application exp. 2030

## Indication

- Erosive Lichen Planus (Orphan indication) and Lichen Planus
- Aphthous Ulcers

## Molecular target

- Cell mediated immune suppression

## Innovation

- Innovating delivery of Corticosteroids in the buccal cavity
- Early and sustained release of Corticosteroids at the site of lesion
- Once daily administration without systemic adverse effects

## Market

- Erosive lichen planus: 0.5-2% population
- Aphthous Ulcers: > 10% population

## Development plan

- Expected clinical entry in 2009

# Clonidine Lauriad<sup>®</sup>



International patent granted: exp. 2022

New patent application exp. 2029

## Indication

- Chemotherapy and radiation therapy-induced oral mucositis

## Molecular target

- Inhibition of proinflammatory cytokine release (TNF)

## Innovation

- Innovating delivery of BA 028 in the buccal cavity
- Early and sustained release of BA 028 at the site of cancer treatment-induced mucositis
- Limited systemic effect

## Market

- Oral mucositis market estimates: 40% of treated cancers, Sonis 2004

## Development plan

- Pharmacological ex-vivo and in-vivo Proof of Concept completed
- Expected clinical entry in 2009

# New targeted entity: AMEP™



Disintegrin biotherapy: plasmid coding for AMEP™ protein  
3 patent families exp. 2029

## Indication

- Invasive cancers (melanoma)

## Molecular target

- $\text{Iv } \beta 3$  and  $\alpha 5 \beta 1$  integrins

## Innovation

- Original anti-angiogenic, anti-proliferative and anti-invasive properties
- Worldwide exclusive licensing rights from IGR/CNRS and INSERM

## Market

- 160,000 invasive melanoma
- Target market estimate: 500 M€<sup>(1)</sup>

## Development plan

- Expected clinical entry in 2009

<sup>(1)</sup> Business Insight

# Oral Irinotecan Nanoparticles



Irinotecan by oral route (nanoparticles of bioerodible polymers)  
2 patent families exp. 2029 plus industrial know how

## Indication

- Colon cancer

## Molecular target

- Topoisomerase I inhibition
- Prodrug (SN 38 active metabolite)

## Innovation

- Oral route (IV route only available)
- Sustained release of irinotecan by nanoparticles formulation

## Market

- 2007 Irinotecan IV sales: 900 M\$ (Camptosar®)

## Development plan

- Expected entry into phase I in 2010 with partnership

# New targeted entity: Integrase Inhibitor



Quinolines family

3 patent families exp. 2029

## Indication

- HIV patients: high pill-burden patients (need for new classes)

## Molecular target

- Integrase: early integration process: 3'-processing step; 3rd key enzyme for HIV

## Innovation

- Targeting Integrase and acting on multi-resistant strains
- Original target: early step of integration (3'-processing)
- Quinolines family is active against Integrase Inhibitors mutants

## Market

- HIV patients: 33 Million living with HIV in the world (Onusida 08)
- Target market estimate: 1 B€<sup>(1)</sup>

## Development plan

- Expected entry into phase I in 2010 with partnership

<sup>(1)</sup> Business Insight

# New targeted entity: Zyxine, phenotypic reversion of tumor cells



Chemical targeted therapy  
3 patent families exp. 2027

## Indication

- Invasive cancers

## Molecular target

- Reversion of tumour phenotype, modulation of actin cytoskeleton

## Innovation

- Original mechanism of action in reversion of tumour phenotype

## Market

- Incidence of invasive cancers: pancreas = 232 000, Small Cells Lung Cancer = 90 000<sup>(1)</sup>

## Development plan

- Expected entry into phase I in 2010

<sup>(1)</sup> Datamonitor 2007 & Globocan 2002

# Next steps of products portfolio



- Acceptance of US filing for Loramyc™: Q2 09
- New European organisation for Loramyc® in 2009
- First Acyclovir Lauriad® phase III trial in Europe: H2 09
- New partnerings in 09
- Loramyc™ approval by the FDA: Q1 10
- European launch of Ondansetron RapidFilm™: H1 10
- Ondansetron Oral Spray EU filing: H1 10

# Our objectives



- Partnership opportunities and complementary revenues
  - Hosting of a late stage product to generate cash flow (nursing)
  - 4 Lauriad<sup>®</sup> products available for partnering agreements
  - Irinotecan Transdrug<sup>®</sup> or Integrase Inhibitor: an agreement prior entry into phase I
  - Search for partner(s) / grants for riskier projects (AMEP and Zyxine)
- A presence on the European market in 2010 with two products: Loramyc<sup>®</sup> and Ondansetron RapidFilm<sup>™</sup>
- Net sales over 8 M€ in 2009, plus 16 M€ of Loramyc<sup>®</sup> milestones in 2009-2010

# *Appendix*

# Shareholders

