Pacylex Pharmaceuticals, Inc.

MANAGEMENT TEAM
CEO Michael J. Weickert PhD
COO Michele Libonati, MSc
CSO Luc G. Berthiaume PhD
CMO John Mackey, MD, FRCPC

NON-MGR DIRECTORS
Chair - Cindy Jacobs PhD MD
Ajit Gill
Mark Huson PhD
Nola Masterson

INDUSTRY
Category: Life Sciences
Sub-category: Oncology therapeutics and diagnostics

FOUNDED 2012

ADDRESS
4000, 10230 Jasper Avenue
Edmonton, AB, T5J 4P6

INVESTORS
Founders, Angels, Greenfire Bio LLC

FUNDING TO DATE
Non-dilutive - >$10,400,000 USD
Founder capital - $507,000 USD
SEED Note - $5,900,000 USD
Series A - $7,000,000 USD

BANK
BMO

LAW FIRM
Norton Rose Fulbright Canada LLP
Borden Ladner Gervais LLP (IP)

ACCOUNTING FIRM
MNP LLP (auditors)
Wood De Bruijn LLP

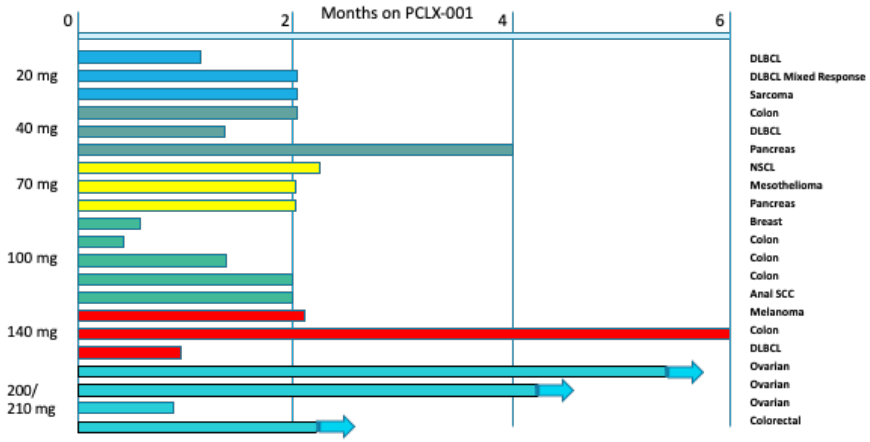
FUNDING SOUGHT
Convertible note:
- *Expansion studies in DLBCL and AML*

Series B in 2023
- *2 Phase 2 clinical programs in DLBCL, AML*
- *Expansion study in 1 solid tumor*
- *Add 1 or more new drug candidates and/or indications to pipeline*
- *Expand US operations*
- *Secure Pharma partnership*

Pacylex is Phase 2 stage pharmaceutical company developing a first in class myristoylation inhibitor (PCLX-001) as a new oral daily therapy for hematologic and solid tumor

Pacylex is developing PCLX-001, to selectively kill cancer cells while leaving normal cells unharmed. Animal tests show this drug eliminates tumors in leukemia and lymphoma xenograft models (AML, BL, DLBCL). PCLX-001 also kills many solid tumor cancer cell lines and retards tumor growth in xenograft models of human lung and breast cancer. An open-label Phase 1 clinical trial in Non-Hodgkin's Lymphoma and solid tumor patients completed 6 dose levels with no dose limiting toxicities (DLTs) (Figure 1). Patients at the highest dose are still on drug and a Phase 2a was launched at this dose. A clinical program in Acute myeloid leukemia is poised to start.

Figure 1. Patients on highest PCLX-001 dose continuing on Phase 1 study.



New target in cancer enables a breakthrough therapy:

- First in class therapy – PCLX-001 is an N-myristoyltransferase (NMT) inhibitor that inhibits human NMT1 and NMT2 enzymes
- Novel mechanism of action – PCLX-001 inhibits myristoylation of proteins in two important functions hijacked in cancer, cancer cell signaling and oxidative metabolism, critically important for rapidly growing cancer cells, triggering cancer cell death by apoptosis
- Proof of concept (POC) in blood cancers – PCLX-001 kills most leukemia and lymphoma cell lines at 100nM or less and completely regresses tumors in mouse xenografts of AML, BL, and DLBCL including drug resistant patient tumors
- POC in solid tumors – PCLX-001 inhibits growth of solid tumor cell lines and mouse xenografts through additional mechanisms under investigation

Value already created by clearing many risks:

- Pharmaceutical validation – PCLX-001 activity has been confirmed *in vitro* and *in vivo* at multiple independent pharma labs including by a large pharma
- Drug exposure and pharmacokinetics in patients is consistent with once-a-day dosing
- Excellent safety results in Phase 1 in patients; no drug limiting toxicity in first 6 patient dose cohorts; drug exposure exceeds 4x level toxic to cancer cells
- IND cleared, Orphan and Fast Track designations obtained for initiating a second clinical program in AML supported in part by the US Dept. of Defense
- GMP manufacturing underway at kg scale

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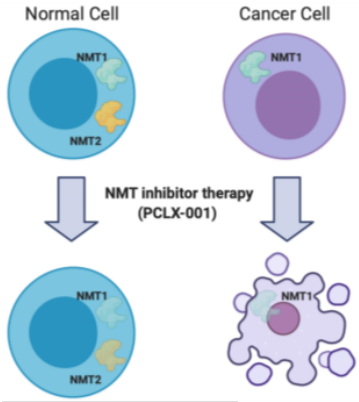
Figure 1. Initial clinical development plan for PCLX-001

Rapid development path; 3 years to market

- Initial indications have significant unmet needs and regulatory advantages
- Recent FDA approvals in AML and DLBCL indications required only open label, single arm studies with <200 patients (Monjuvi, Xpovio, Polivy, Idhifa, Tibsovo)
- Phase 2a for DLBCL launched at 4 clinical sites in Canada
- IND cleared for imminent AML trial at MD Anderson Cancer Center, Houston, US for DoD-supported clinical study of PCLX-001
- Orphan and Fast Track obtained for AML (~21,500 pts/yr)
- Rapid path to market: 3-4yrs IND to US NDA and European approval (Figure 2)

Mechanism:



Need:

DLBCL 5-year relative survival
64.6%

AML 5-year relative survival
30.5%

Competition and Advantages:

- Only 1 other NMT / cancer company: Myricx Pharma; preclinical, patents well after Pacylex
- PCLX-001 is 2x more potent than Myricx lead compound (IMP-1088) at killing select lymphoma and leukemia cell lines *in vitro*
- PCLX-001 is 10x more potent than BTK inhibitor ibrutinib (sales $9.8B in 2021)
- PCLX-001 is a logical successor to BTK inhibitors (very successful class of cancer compounds) – it works upstream of BTK inhibitors in B-cell receptor cascade before redundant pathways carry signals
- PCLX-001 is 14-times more potent against AML stem cells than circulating AML cells – clears bone marrow of stem cells in animal models of AML

Team with experience to deliver clinical results:

CEO: Michael J. Weickert, PhD. CEO Fe Pharmaceuticals, Former CEO at illumiSonics, Sonescence, SEA Medical Systems (co-founder), ran oncology and onc-related clinical programs at Nektar and Ligand, NCI/NIH.

COO: Michele Libonati, MSc, Former SVP Program Strategy Leadership, Gilead Sciences, CEO Proneurotech, Lifecycle Leader OCREVUS, LUCENTIS, Rituxan, Raptiva (Genentech/Roche), Development Leader Intermezzo (Trancept), Tysabri (Elan)

CSO: Luc Berthiaume, PhD. World leader in protein fatty acylation; Professor, U. Alberta, Founder of Eusera and Pacylex; 3 patents licensed to Pacylex; commercialized antibodies via Eusera.

CMO: John Mackey, MD, FRCP, FCAHS. Former head of clinical trials at the Cross Cancer Institute and Executive Director of TRIO (clinical trial organization, 200 people); ran ~100 clinical trials in oncology, founder of 3 cos.

Patents:

- Exclusive license on family of NMT inhibitors including PCLX-001: EP 2323987 A1, US 9,156,811, US 9,828,346
- Own 3 global patents on diagnostic, mechanism, and treatment. Patents issued so far in EU, KR, JP, RU, IS, NZ, SA, MX, AU, SG, CN, BR, others pending
- Provisional patent filed on crystal form of lead molecule with exclusivity to at least 2043

Additional Company Milestones:

- MOA published in *Nature Communications* Oct 2020
- Breast cancer potential published in *Breast Cancer Research and Treatment* Jan 2021
- Closed Series A with US fund May 2021
- Initiated clinical dosing in cancer patients Sept. 2021
- First patient published in *Current Oncology* Mar 2022

Key Take-Aways:

- PCLX-001 is a potential blockbuster drug
  - ✓ Potent, oral, once-a-day drug with broad tumoricidal anti-cancer activity
- Rapid development
  - ✓ Phase I established dose for Ph 2a with no DLTs
  - ✓ AML Fast Track and Orphan designations
- Potential for early partnering or exit
  - ✓ Superior to BTK inhibitors

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