Pacylex Pharmaceuticals, Inc.

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

FOUNDED
2012

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

CURRENT INVESTORS
Founders, Angels

FUNDING TO DATE
Non-dilutive capital to date - >$7,200,000 CAD
Founder capital - $690,000 CAD
Note - $1,200,000 USD

BANK
RBC

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

ACCOUNTING FIRM
Wood De Bruijn LLP

DIRECTORS
CEO Michael J. Weickert PhD
CSO Luc G. Berthiaume PhD
CMO John Mackey, MD, FRCPC
COO Ryan Heit, MSc, MBA

FUNDING SOUGHT

$3M in additional Note financing
- *Complete drug process scale-up*
- *Conduct 28-day GLP tox*
- *File IND*
- *Initiate first in man dosing*

$25M Series A in late 2019/early 2020
- *Conduct Phase 1 and 2 clinical programs including in other hematologic cancer indications*
- *Add 1 or more new drug candidates and indications to pipeline*
- *Expand US operations*
- *Secure Pharma partnership*

Large cancer cell line screen reveals a new target, N-myristoyltransferases (NMTs) using first-in-kind inhibitor

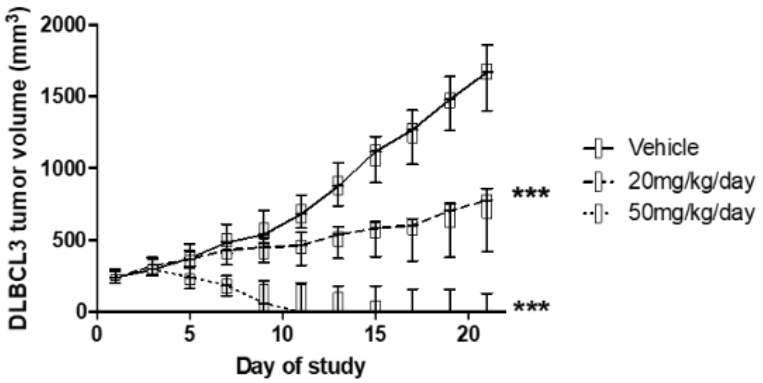
Pacylex is developing a first-in-class, oral drug, PCLX-001, to selectively kill various types of cancer cells, while leaving normal cells unharmed. Animal tests show PCLX-001 completely eliminates tumors in xenograft models of leukemias and lymphomas (Acute Myelogenous Leukemia; AML, Burkitt Lymphoma; BL, and Diffuse Large B Cell Lymphoma; DLBCL). PCLX-001 also kills many solid tumor cancer cell lines and slows tumor growth in models of human lung and breast cancer. **Pacylex keys are:**

- New target in cancer enables a breakthrough therapy;
- Team with experience to deliver clinical results;
- Rapid development path; 4 years to market;
- Value already created by clearing risks for clinical start.

New target in cancer enables a breakthrough therapy:

- First in class therapy – PCLX-001 is an NMT inhibitor that tightly binds both human NMT enzymes (IC50 <9nM).
- New mechanism of action – PCLX-001 inhibits B-cell receptor (BCR) signaling by disrupting several SFKs (Src family kinases) and inducing cancer cell death by apoptosis.
- Proof of concept in blood cancers – PCLX-001 kills most leukemia and lymphoma cell lines at 10nM concentrations or less and eliminates tumors in mouse xenografts of AML, BL and DLBCL including drug resistant tumors from a patient (Figure 1).
- Proof of concept in solid tumors – PCLX-001 inhibits growth of solid tumor cell lines and mouse xenografts, working through a different NMT mechanism.

Figure 1. PCLX-001 causes complete tumor regression of drug resistant patient Xenograft.



Management team with experience to deliver clinical results:

CEO: Michael J. Weickert, PhD. Former CEO at illumiSonics, Sonescence, SEA Medical Systems (also co-founder), CBO at Ohm Oncology, Corium, Stratagent Life Sciences, VP Development Auspex, ran oncology and oncology-related clinical development programs at Nektar and Ligand, NCI/NIH.

CSO: Luc Berthiaume, PhD. World leader in protein fatty acylation; Professor, U. Alberta, Founder of Eusera and Pacylex; global distribution experience; 3 patents; commercialized antibody design and production.

CMO: John Mackey, MD, FRCP. Director of clinical trials at the Cross Cancer Institute; former Director of TRIO (clinical trial organization, 200 people); ran >50 clinical trials in oncology, founder of 3 companies including Pacylex.

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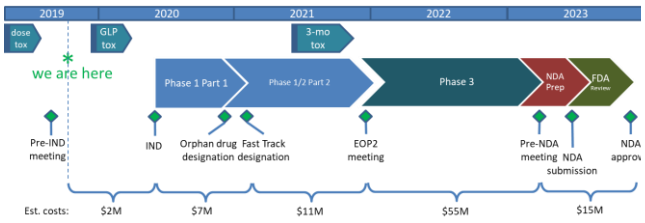
Rapid development path; 4 years to market

- Pre-Investigational New Drug (IND) meeting completed – clear path to IND.
- IND filing in 6-9 months, after 28-day GLP tox studies in late 2019.
- Orphan and Fast Track eligible for initial indications in DLBCL (~18,000 patients/yr), AML (~21,500 pts/yr), and BL (~1,200 pts/yr).
- Phase 1 program, protocol, principal investigator and 3 clinical sites are ready in Canada to dose DLBCL and solid tumor patients.
- Rapid development (3-4yrs IND to New Drug Application [NDA] and European approval); precedence in Orphan oncology indications includes Tagrisso for NSCLC (basis for Figure 2)

Figure 2. Clinical development plan for PCLX-001



Additional Company Milestones:

- Oral administration equivalent to drug injection in mouse xenograft leukemia tumor model (Pharma experiment).
- No off-target effects seen in kinase binding screen of 468 normal and mutant kinases.
- PCLX-001 has broad activity when profiled against ~300 cancer cell lines.
- Pacylex selected for first class of 4 companies in Merck-sponsored incubator.
- Closed >$1.8M US initial seed note.
- 2 posters presented at AACR 2019.
- Acute & 14-day toxicology completed in rats & dogs.
- ADME studies completed.
- Secured rights to additional indications for PCLX-001 & analogs.
- MD Anderson Cancer Center to host parallel US AML Phase 1 program.
- Pre-IND meeting completed with US FDA.
- >$500k CAN raised for PCLX-001 program in "World's Longest Baseball Game" – August 2019.

Value already created by clearing risks for clinical start:

✓ Pharmaceutical validation – one of the biggest risks of new discoveries is the ability to independently replicate results. PCLX-001 activity has been confirmed in multiple independent labs including by big Pharma in their own cell and animal models.

✓ Risks cleared for path to the clinic – the completion of acute and 14-day toxicology studies in 2 species and the FDA feedback received from the pre-IND meeting, provides a clear path to filing an IND and starting clinical trials in early 2020.

✓ In vitro cell-based testing showed PCLX-001 was 10x more potent than top cancer drugs including ibrutinib and dasatinib at inhibiting cell growth and proliferation in lymphoma, selectively sparing normal cells.

✓ PCLX-001 has genuine blockbuster drug characteristics:

- ➢ Oral availability ~100%
- ➢ Activity against many blood and solid tumor cancers
- ➢ New mechanism – not redundant with other products – potential for therapeutic synergy
- ➢ Tumor killing not tumor inhibiting

Patents:

- Exclusive license on issued patents for a family of over 50 NMT inhibitors including PCLX-001: EP 2323987 A1, US 9,156,811, US 9,828,346
- Pacylex owns global patents on diagnostic, mechanism, and treatment. Patents issued so far in JP, RU, IS, NZ, SA, allowed in MX, others pending.

Key Take-Aways:

- PCLX-001 is a potential blockbuster drug
  - ✓ Potent, oral, once-a-day drug with broad tumoricidal anti-cancer activity.
  - ✓ New mechanism of action suggests PCLX-001 can be added to other cancer therapies and potential synergy rather than competition.
- Rapid development
  - ✓ On path to IND filing in 6-9 months
- Potential for early partnering or exit
  - ✓ >10x as potent as Ibrutinib (Imbruvica; $4.4B 2017) and Dasatinib (Sprycel; $2.3B 2017) in lymphoma cell studies

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