

AQUALUNG THERAPEUTICS

TARGETING RUNAWAY INFLAMMATION

Overview: Founded in 2016, Aqualung Therapeutics (**ALT**) is an early stage biotech company developing an immune-focused biologic platform, **eNamptor™**, comprised of a humanized monoclonal antibody (mAb), **ALT-100**, designed to limit activation of evolutionary inflammatory networks to reduce mortality in serious inflammatory disorders, and both a diagnostic **companion biomarker and genotyping assays** to deliver precision therapeutic targeting.

Problem and Solution: Unchecked inflammatory cascades are either a root cause or major contributor to the excessive mortality from both life threatening critical illnesses and chronic inflammatory disorders. Using genomic strategies, ALT identified a novel upstream innate immunity therapeutic target, extracellular NAMPT (**eNAMPT**, nicotinamide phosphoribosyltransferase), that drives inflammatory cascades via TLR4 receptor binding. ALT speculates that the eNAMPT-neutralizing mAb, ALT-100, will potentially reduce inflammation and address the staggering unmet need to improve survival in acute & chronic inflammatory disorders.

Business Model and Investor Inflection points: Major milestones will be achieved prior to initiation of Phase II or III trials (see chart below), with value inflection points in 2020 after management team expansion and NIH-funded pharmacology and toxicology milestones for initial indications. Antibody-based therapies have outpaced small molecule drugs as top-selling U.S. medications in the therapeutics market due to their improved target specificity and safety. Our objective is to either secure licensing for ALT-100 and its mAb platform (eNamptor™) or for ALT acquisition by a biopharma company seeking to expand its drug pipelines with a novel biologic agent targeting inflammation. ALT has been awarded more than \$5.5M in non-dilutive NIH funding to support target validation and mAb platform development.

eNamptor™ Platform Expansion Opportunities: ALT's lead indication is acute respiratory distress syndrome (ARDS) (~488K US cases/yr; ~30-40% mortality), a highly inflammatory lung disorder currently without any FDA-approved drugs (~\$2.8B market). ARDS is caused by infection and trauma with ventilator-induced lung injury (VILI) further contributing to ICU deaths. ALT was awarded a NIH Fast Track STTR Phase I/II grant (June 2019) to complete pharmacology & toxicology milestones for the initial indication of ARDS and VILI. A \$3M Dept of Defense award is pending for trauma-induced ARDS. In addition, ALT has outstanding pre-clinical data and has received NIH support to develop the utility of its eNamptor™ platform in pulmonary hypertension, and radiation-induced lung injury with multiple NIH awards pending for additional indications including pulmonary fibrosis, intrauterine infection/chorioamnionitis and premature births, prostate cancer in men, cardiac ischemia, and NASH/hepatic fibrosis.

Strong Marketing Strategy: If focused solely on ALT's lead indication of ARDS, with a minimum market penetration of 25%, ALT-100 could result in sales of ~\$700M. Pending an exit strategy with a large or mid-sized pharma company, ALT is prepared to execute a full commercialization and launch plan within the targeted hospital, ICU and ER segment.

Competitive Advantage in ARDS: A major market advantage of ALT-100 in ARDS is its dosage within an hour or close to the time of intubation, before cytokine storm and VILI fully develops, thereby reducing ARDS severity and ICU mortality. This distinguishes ALT-100 from clinical drug trials that have targeted a single cytokine (i.e. TNF-a, IL-1b, IL-6) in patients with an already established state of "cytokine storm." Given ALT's eNamptor™ biologic platform approach and with support from compelling preclinical studies, the mAb, ALT-100, has utility in attenuating systemic inflammation for multiple acute and chronic indications with the potential for both the diagnostic/prognostic NAMPT biomarker and *NAMPT* genotyping assays to further allow for risk stratification in clinical trials and identification of ALT-100 responders.

ALT Management Team & Scientific Advisory Board: **ALT:** Skip Garcia MD (CEO) is a former Division Chief (Johns Hopkins Univ.), Department Chair (Univ. of Chicago) and CEO of two academic health systems, each with budgets of >\$1.3B. Stan Miele (President & Chief Business Officer) is former President of Sucampo Pharma Americas and Mariam Morris (CFO) is former CFO for Cerecor. Leadership team has experience bringing products through development to commercialization. SAB members include: Robert P. Schleimer, PhD (Chief, Allergy & Immunology, Northwestern Univ.); Augustine M. Choi, MD (Dean, Cornell Medical College); Jesse R. Hall, MD (Chief, Pulmonary & Critical Care, Univ. of Chicago); William L. Macias MD, PhD, (former Director, BioMedicine Business Unit, Eli Lilly Co). ALT has a strong advisory group of CMC, clinical development and regulatory experts.

Funding Status Seed Stage: \$700,000 raised as a convertible note, converted May 2019 at 20% discount.

Funding Status Series A Stage: \$15 Million preferred share raise; Tranche I (\$5M) in process

Funding Status Undiluted Grant Funding:

- ◆ \$631,300 - NIH STTR Phase I award, R41 HL110707 "NAMPT/PBEF neutralizing humanized monoclonal antibodies as novel therapeutics approaches" 09/2011-06/2014.

- ◆ \$1,920,000 - NIH P01 HL134610 “Critical role of NAMPT and Toll-Like Receptor 4 in mechanical ventilation-induced lung inflammation and injury (VILI)”. 2/2018-1/2023.
- ◆ \$1,680,000 – NIH R01 HL141387 “Novel Involvement of NAMPT and TLR4 in PAH Vascular Remodeling.” 12/01/2018 – 11/31/2023.
- ◆ \$1,750,000 - NIH Fast Track STTR Phase I/II award, R42 HL145930 “Novel Therapeutic Antibody Targeting of Extracellular NAMPT in Ventilator-Induced Lung Injury” 6/2019-11/2021.
- ◆ \$210,200 - NIH STTR Phase I award, R41 HL147769 “The CRIT-ICU Biomarker Panel for Stratification of Mortality Risk in ARDS Patients” 08/2019-07/2020.

Intellectual Property: ALT has exclusive license on an issued utility patent -USPTO Aug 9, 2016: U.S. Patent (12/842,773) “Methods and Compositions involving NAMPT inhibitors for lung inflammation” held by the University of Arizona. ALT has filed a solely owned eNamptor™ composition U.S. patent (Q3 2019) on multiple humanized mAb targets. PCT patent filings have been submitted for IPF, pulmonary hypertension (PCT April 2018), and radiation injury (Oct 2019), and provisional for prostate cancer (Aug 2019).

Summary: The ALT management team is aggressively developing and patenting the eNamptor™ platform comprised of the humanized mAb, ALT-100, eNAMPT biomarker assay and *NAMPT* SNP genotyping assay. This platform is designed to improve survival globally across multiple acute and chronic indications.

- ◆ ALT’s initial indication: the US ICU market for ARDS/VILI (>\$2.8B); will also develop ALT-100’s platform for other serious inflammatory indications that represent real expansion opportunities.
- ◆ \$15M Series A Round (\$5M Tranche I in progress) to obtain FDA IND approval and finance Phase 1A/B ARDS trials.
- ◆ Series B round to fund Phase IIA/B ARDS trials and support early development of eNamptor™ for other chronic and acute indications.

Timing	eNamptor™ Milestones for Lead Indication of ARDS/Trauma
Q2 2019	Lead ALT-100 IgG candidate identified by <i>in vitro</i> studies and <i>in vivo</i> lung injury models
Q2 2019	NIH STTR Fast Track Award funding begins to support FDA approval for ALT-100
Q2-3 2019	NIH STTR Phase I CRIT-ICU Biomarker Award funding begins Provisional U.S. patent filed on ‘composition’ & ‘method of use’ for ALT-100
Q3 2019	Stable human cell line development for ALT-100 initiated
Q1 2020	Acute and chronic pharmacodynamic/pharmacokinetic studies completed
Q3 2020 Q1 2021	Pre-clinical toxicology studies completed. Stable cGMP ALT-100 human cell lines established IND filed with US FDA and approved
Q2 2022 Q3 2023 Q4 2024	Phase IA safety trials completed (healthy volunteers), Phase IB POC -dose studies (ARDS subjects) Phase IIA trial completed evaluating 2 ALT-100 doses, (n=60 ARDS) stratified by mortality risk Phase IIB RCT trial completed evaluating ALT-100 (120 ARDS) stratified by mortality risk

Management Team



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