Share

Akttyva Therapeutics

We're going to make pandemics history by developing a cure for Acute Respiratory Distress Syndrome (ARDS). Pneumonia, flu, COVID-19 and other respiratory infections kill because of ARDS. Help turn COVID-19 into a simple cold by investing in Akttyva.

HealthCare

Mansfield, MA

Website

Akttyva Therapeutics, Inc. is considering raising capital through a Regulation Crowdfunding campaign to be conducted by Fundify Portal, LLC. We are running this “Test the Waters” campaign (branded by Fundify as a Fast Pitch Preview™) to gauge Investor interest and also determine the appropriate funding method. During this Test the Waters campaign, (1) no money or other consideration is being solicited, and if sent, will not be accepted; (2) no offer to buy the securities can be accepted and no part of the purchase price can be received until the offering statement is filed and only through Fundify's funding portal platform; and (3) a prospective purchaser's indication of interest is nonbinding.

Summary

Akttyva Therapeutics is a platform technology company developing therapies for unmet medical needs with the same underlying condition - **vascular leak**. Its first program is a drug for Acute Respiratory Distress Syndrome (ARDS), a deadly condition with no treatment, which is the cause of **tragic loss of human life** and **economic consequences** of **the COVID-19 pandemic.**

Akttyva has developed an **efficient computational AI-assisted drug-discovery approach** that allows it to rapidly discover and validate our candidate drugs in the laboratory experiments. In order to address this unmet need as rapidly as possible, **our first candidate has already been approved** for another indication and, thus, has a known safety profile. This will allow us to get to human clinical trials faster and with fewer resources. Akttyva is a recipient of a competitive National Science Foundation Award, a winner of IBM prize in MassChallenge Accelerator competition and has recently raised $200,000 angel funding. We are raising $1M seed round to get our drug candidate to Investigational New Drug Application (IND) with the US FDA.

Key Reasons to Invest:

- Selected as a **finalist** in the MassChallenge 2021 cohort.
- The biggest risk in these types of investments is safety profile of new drugs: majority fails in clinical trials when they are first tested on humans. Akttyva's ARDS program drug candidate has already been approved and in the market for another indication. Subsequently,this asset is significantly de-risked.
- The downside of an existing drug is that the exclusivity will be limited, but Akttyva has developed a patent strategy for a new indication and is reformulating the drug for an additional 7 years of exclusivity.
- Akttyva is already in early discussions with a large pharmaceutical company and is planning to partner development of its ARDS therapeutic, further reducing the risk to early investors.
- Akttyva is co-founded and led by seasoned drug-discovery and development entrepreneurs who have co-founded 16 companies, took 2 of them to IPO and have brought multiple life-saving medicines to patients.

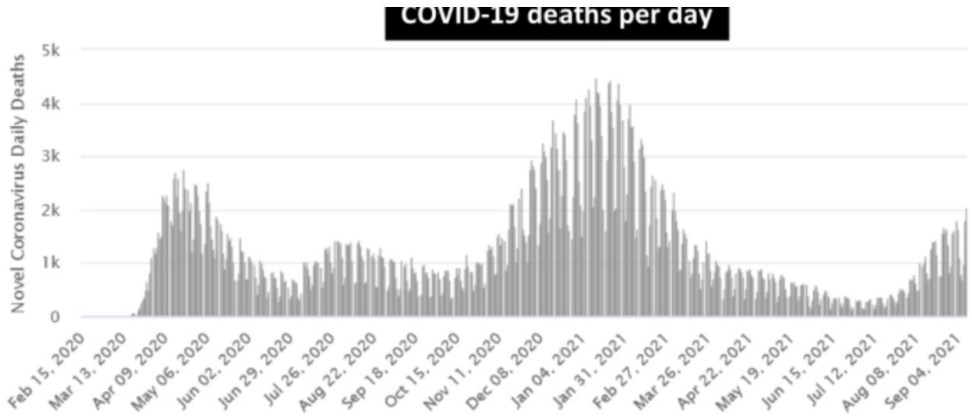
Problem

Endothelial vascular leak is a hallmark of multiple acute and chronic conditions

The vascular endothelium separates circulating fluid from the surrounding tissues. Endothelial dysfunction, or **vascular leak**, occurs in response to wide-spread inflammatory processes, including acute viral, bacterial or direct toxin exposure.

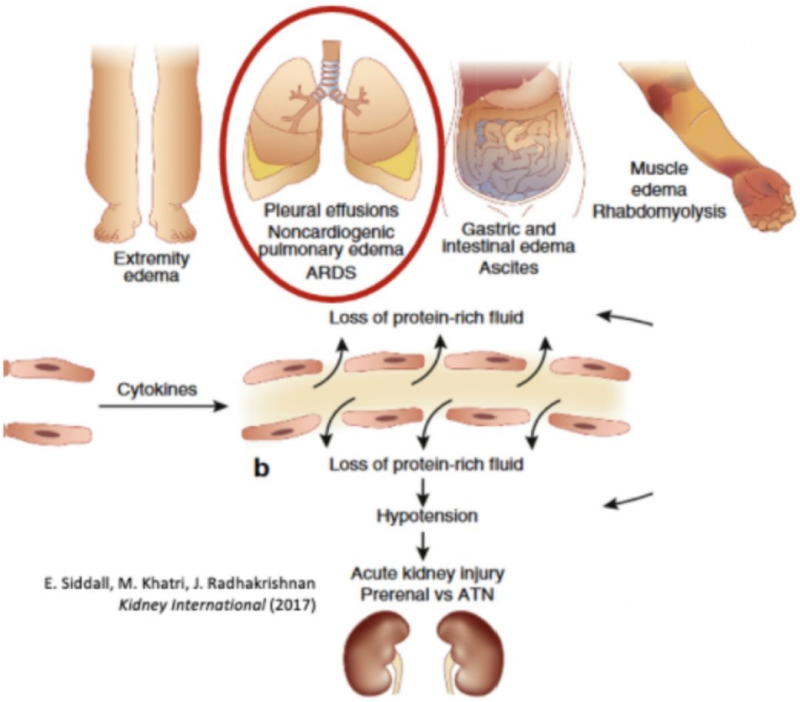
In the lung, vascular leak leads to **Acute Respiratory Distress Syndrome** (ARDS), a deadly condition with no treatment. **ARDS is the most common cause of death among intensive care units (ICU) patients**. Before COVID-19, ARDS affected about 200,000 patients in the U.S., causing 75,000 deaths (>35% mortality rate) and an economic burden of $1.6B. The COVID-19 pandemic has doubled these numbers and further highlighted the need for effective therapies to treat this deadly condition.

Acute Respiratory Distress Syndrome (ARDS)



[1]Uckun, F.M., Front.Pharmacol. 2020, 11:796 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7264370/#B8
[2]2018 Data, https://www.openaccessgovernment.org/acute-respiratory-distress-syndrome/43754/

ARDS has many causes, which include acute pancreatitis, cardiac surgery, direct toxins, radiation or sepsis. ARDS patients end up in ICU with the only therapeutic options being supportive mechanical ventilation and fluid management.



Vascular leak cuts across multiple organ systems and disease states.

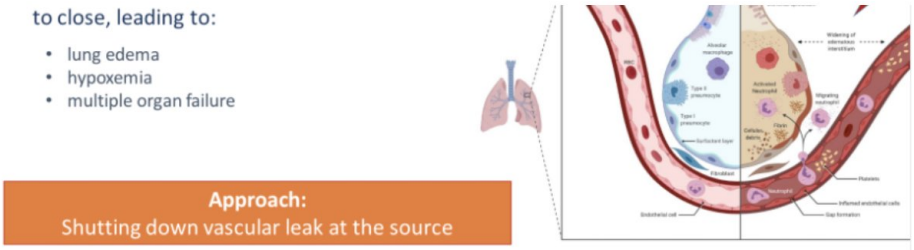
Siddall, M. Khatri, J. Radhakrishnan Kidney Int. (2017) doi: 10.1016/j.kint.2016.11.029

Solution

Activation of a stress response pathway to restore vascular barrier

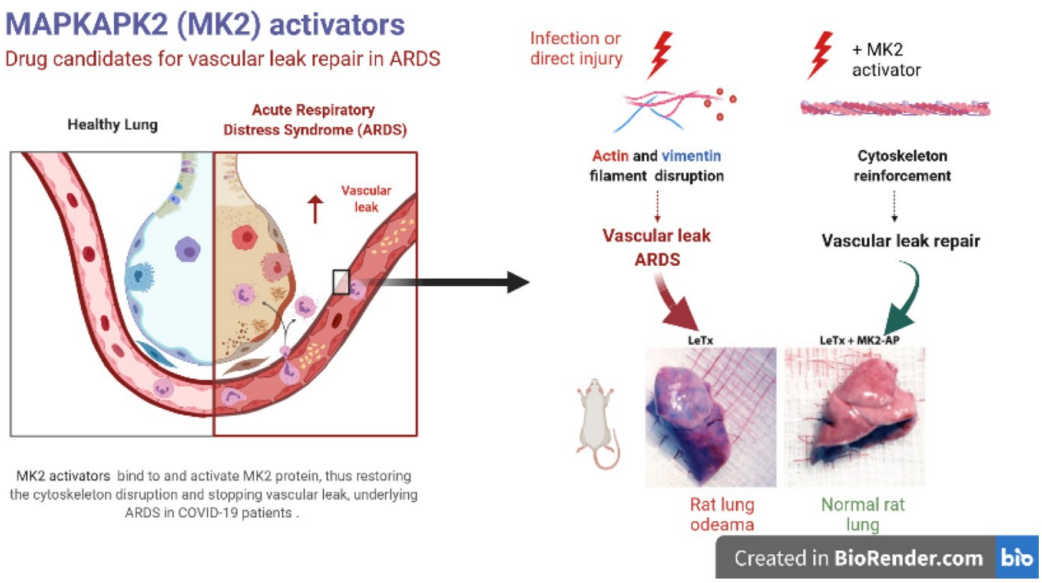
Akttyva addresses the root cause of ARDS and over 60 other medical conditions - with a drug that regulates the permeability of endothelial barrier and stops vascular leak. The connection between the MK2 stress response pathway and cytoskeleton of the endothelial cells has been first described over 15 years ago and has been confirmed in numerous models of disease by other investigators. The foundation of Akttyva's approach is addressing the root cause of ARDS.

- Vascular leak is a natural response to injury
- The problem arises because the barrier fails



The Science Behind It

Fundamental research at Tufts University Medical Center has demonstrated that direct activators of MAP Kinase-Activated Protein Kinase 2 (MK2) pathway stops vascular leak and prevent ARDS in vitro and in vivo in a rat model:



Key references:

1. *Liu, Kayyali, J. Appl. Physiol, 2015 https://pubmed.ncbi.nlm.nih.gov/26066827/*
2. Kayyali, U. S. et al.Cytoskeletal changes in hypoxic pulmonary endothelial cells are dependent on MAPK-activated protein kinase MK2. J Biol Chem 277, 42596–42602 (2002).
3. Liu, T. et al. Anthrax lethal toxin disrupts the endothelial permeability barrier through blocking p38 signaling. J Cell Physiol 227, 1438–1445 (2012).
4. Liu, T. et al. Lack of MK2 inhibits myofibroblast formation and exacerbates pulmonary fibrosis. Am J Respir Cell Mol Biol 37, 507–517 (2007).

Product

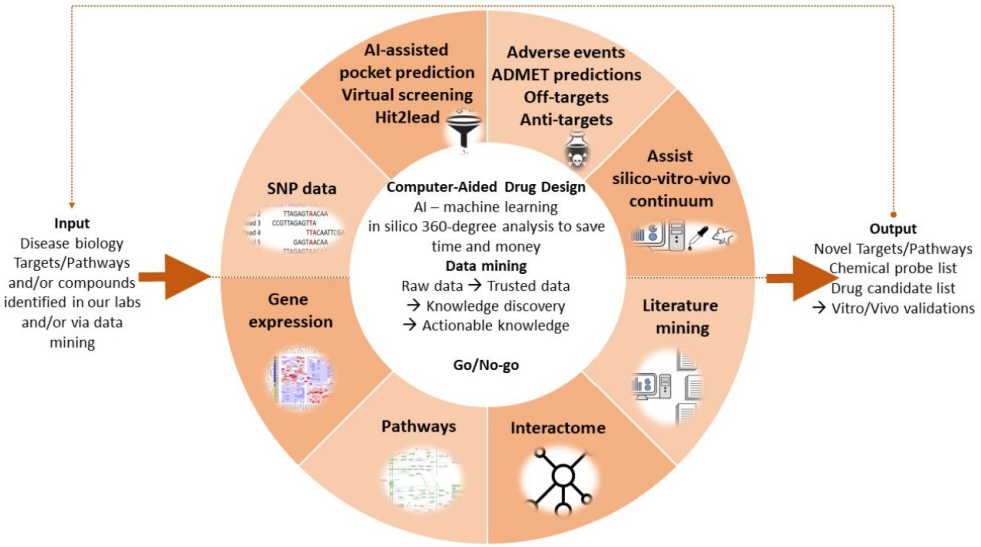
A solution for ARDS discovered with proprietary AI technology

Akttyva is developing first-in-class small molecule therapy for ARDS, which addresses the direct cause, endothelial vascular leak. Akttyva's first product AKT-001 is a small molecule drug, which has been in human safety Phase 1 trials. Akttyva has filed for patent protection for the methods of use, formulations and composition of matter for this compound and is planning to take it to human Phase 2a clinical trial in ARDS patients.

Akttyva's AI-Assisted Drug-discovery Engine (AIDE-360)

AKT-001 has been discovered using an internally developed computational platform: Akttyva's AI-Assisted Drug-discovery Engine with a 360-degree "human-in-the-loop" analysis (AIDE-360). AIDE-360 combines several types of algorithms (molecular simulation, machine learning, data mining, network analysis) that allows our team to prioritize putative therapeutic targets based on comprehensive real-time scientific evidence. AIDE-360 includes identification of new drug-binding pockets and fast docking and selection of high-quality small molecule drug candidates with acceptable safety profile, which are expected to modulate the function(s) of the selected protein targets. The AIDE-360 platform is not a frozen system, but is constantly evolving as new scientific evidence is generated in-house or reported in the scientific literature.

This drug discovery engine allows us to conduct large parts of the process on the computer, with only confirmatory experimental biological testing and results feedback loop into AIDE-360 to improve accuracy. This results in high efficiency and speed leading to a shortened drug development time from years to months, lowering the cost of development and time to market.



AIDE-360 Program is based on founders' published research

1. Singh N, Chaput L, Villoutreix BO. Virtual screening web servers: designing chemical probes and drug candidates in the cyberspace. Brief Bioinform. 2021 Mar 22;22(2):1790-1818. doi: 10.1093/bib/bbaa034.
2. Tsaioun K, Bandhakavi S, Dirven H. Evidence-based methodology for identifying drugs with potential human liver toxicities using US EPA ToxCast data set. 2018 Dec 20 [cited 2018 Dec 29]; Available from: https://zenodo.org/record/2463115#.XCgNy89Kh-V
3. Tsaioun K, Bottlaender M, Mabondzo A, Alzheimer's Drug Discovery Foundation. ADDME--Avoiding Drug Development

Mistakes Early: central nervous system drug discovery perspective. BMC Neurol [Internet]. 2009;9 Suppl 1:S1. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19534730
4. Tsaioun K, Jacewicz M. De-risking drug discovery with ADDME -- avoiding drug development mistakes early. Altern to Lab Anim ATLA [Internet]. 2009 Sep;37 Suppl 1:47–55. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19807206

Business Model

B2B

Akttyva will build a **sustainable B2B business model** through the development of a pipeline of new projects. Akttyva will license new lead candidates to pharmaceutical companies, reinvesting the revenues in R&D efforts for new indications. The licensing agreement is envisaged after the completion of Phase 2 clinical trials and will likely comprise the exclusivity of worldwide commercialization upon market authorization.

Pharmaceutical companies will make milestone-based payments to Akttyva during the development and commercialization, consisting of industry-standard upfront, milestone payments and royalties on marketed product*. Such discussions are already underway.

Akttyva also is engaged in discussions with smaller pharma companies with goals:

I. to provide synergistic treatment for conditions of mutual interest;
II. to establish partnerships for the identification of drug candidates using Akttyva's AIDE-360.

*Estimates made based on recent comparable deals.

Traction

Awards and Notable Achievements:

- Akttyva was a semi-finalist of X-Y Factor business pitch competition at Biotech Gate.
- Akttyva is a finalist of MassChallenge 2021 cohort, selected out of 3,000 companies.

Traction with Government Agencies:

- Akttyva has been invited to submit an application for NSF award and BARDA DRIVe.
- Akttyva was selected for NIH Application Assistance Program.

Competition

Akttyva is developing first-in-class therapy for ARDS

In the absence of an effective cure for ARDS, the market is mainly **dominated by manufacturers of ventilators and supplemental oxygen** including GE Healthcare (US, yearly revenue $3.7B), Hamilton Medical AG (Switzerland, $138M), Smiths Medical (US, $500M), ResMed (US, $3B). These companies provide solutions for supportive care, without addressing the underlying medical condition.

Different companies are developing small molecules with antiviral properties or targeting the inflammation state associated with ARDS, but the direct cause. Among them, Veru (US, $31M) is developing a treatment based on sabizabulin, an antiviral and anti-inflammatory agent; Vanda Pharmaceutical (US, $248M) is performing clinical trials using tradipitant to target inflammatory lung injury associated with COVID-19 infection; Foresee pharmaceuticals (Taiwan, $3M) is developing an MMP-12 inhibitor targeting inflammation and fibrosis; Biomarck pharmaceuticals (US, $8M) is developing treatments based on the inhibition of MARCKS peptides to prevent the influx of inflammatory cells into the lung. Windtree Therapeutics (US, $ 1M) are developing a pulmonary surfactant indicated to improve lung function and reduce duration and risk of mechanical ventilation in children. Other companies such as Stemedica (US, $24M) and Arthersys (US, $24M) are developing approaches based on stem cells with immunomodulatory effects to suppress pro-inflammatory responses.

None of these solutions target the pathological process leading to ARDS, i.e. vascular leak of lung endothelium. Moreover, immunosuppression can potentially lead to complications such as infections or malignancy and would not be recommended for frail patients and therapies based on stem cells carry safety concerns and high costs. Importantly, since ARDS is a complex multi-factorial disease, **Akttyva's first-in-class therapy for an important hallmark of the disease, endothelial vascular leak, may be synergistic with many drug candidates that are currently being developed**. Akttyva has started discussions with a few companies in that space.

Company	Drug	Mechanism	Type	Safety	Cost
Faron Pharma	Traumakine (synergies, positive phase 2)	Indirect mechanisms	Complex molecules, equipment and skilled nursing for delivery	Unknown human safety	$$
BioMarck Pharma	BIO-11006				$$
Athersys	MultiStem				$$$
Bayer	BAY1097761 BAY 1211163				$$$ $
Akttyva	AKT-001	Underlying mechanism	Easy manufacturing	FDA APPROVED	$

Targeted cost-effective therapy focused on patient and human biology

Market

$30 billion market

By developing innovative therapies for vascular leak, Akttyva will enter the Global Endothelial Dysfunction Market at the intersection of different medical conditions. This market is expected to grow from $ 14B in 2020 to $ 34B by 2027, registering a compound annual growth (CAGR) of 12.7%. North America is expected to account for the highest market share over the forecast period.

Akttyva decided to focus its efforts first on the **identification of lead candidates to repair vascular leak in ARDS**, a deadly condition with no treatment. The Global Market for ARDS prior to the pandemic was expected to reach **$16.9B by 2027**, expanding at a CAGR of 7.2% from 2020 driven by increasing prevalence and incidence of acute lung injury and associated clinical conditions, rising aging population and lack of pharmacological treatments. The ongoing Covid-19 pandemic has increased the incidence of ARDS in the US more than two-fold, leading to market estimates of **$500M-1.5B for Covid-19-caused ARDS only, which doubles the market projection to over $30B.**

Akttyva's therapeutic compounds are going to be able to treat ARDS caused not only by COVID-19, but by other medical conditions such as viral/bacterial pneumonia ($1.5B market), sepsis, inhalation of direct lung toxicants, acute pancreatitis, kidney injury, and acute ulcerative colitis. In the long term, Akttyva's drug discovery programs will be directed towards other unmet needs in medical conditions associated with Endothelial Barrier Disorders such as capillary leak syndrome, diabetic macular edema, kidney injury and fibrosis.

Trends in drug discovery: The Covid-19 pandemic has underlined the need to have fast and efficient drug development processes. As a result, the global computational drug discovery market is gaining traction and is projected to reach $5B in 2025 with a CAGR of 13% from 2020. Artificial Intelligence and machine learning are the main innovation trends in the pharma industry. Akttyva is at the forefront of these trends with its fast AIDE-360 program capable of quickly predicting the best small molecules to treat a variety of diseases associated with protein targets.

Company Vision

Akttyva is harnessing the understanding of biological pathways, artificial intelligence, and machine learning on the structure of cell barriers to bring new therapies to patients. **Our mission is to develop life-saving therapies addressing cell barrier dysfunction across multiple indications.** Our vision is to be the leaders in the field to develop a portfolio of products addressing indications underlined by vascular leak, in partnership with government, foundations and industry stakeholders.

Founders

The company is co-founded by two scientists who discovered the pathway modulating vascular barrier (Usamah Kayyali, Ph.D.) and developed a computational approach to discover drugs repairing this pathway (Bruno Villoutreix, Ph.D.). The company is led by serial life sciences entrepreneurs Katya Tsaioun, Ph.D., Lana Gladstein, J.D. and Mark Tepper, Ph.D.. Together, they have built 16 companies, brought 10 drugs to market, and had 7 successful exits, including 2 IPOs. The company has an advisory Board which includes clinicians, regulatory, insurance reimbursement and pricing strategy experts.

Investor Interest

Investors Interested

14

Funding Interest So Far

$27,750

1-Click Reserve™

Offering Terms

Funding Goal

$25,000 - $1,000,000

Security Type

SAFE

SAFE

Min Investment
$100

Max Investment
$1,000,000

Valuation Cap
$10,000,000

Closing Date
Jul 31, 2022 10:59 PM CDT

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