ReNewVax Ltd.

Protecting Our Future Through Vaccine Research

Offer Type:
Equity Investment

Fundraise:
£3.9m

Location:
North-West UK

Sector:
Infectious Diseases/Vaccines

www.renewvax.com

Company Profile

ReNewVax Ltd is a next-generation vaccine company spun out from the University of Liverpool, which uses a novel platform technology for vaccine design, based on the concept of reverse vaccinology, with high throughput large-scale genomic analysis and ex vivo human predictive models. Our lead program, RVX-001, is entering IND-enabling studies, with first-in-human trials scheduled to take place in early-2025. ReNewVax's pipeline contains two further programmes, RVX-002 and RVX-003, targeted at major global pathogens Streptococcus agalactiae and Streptococcus pyogenes.

Opportunity

According to the WHO, Streptococcus pneumoniae (also known as the pneumococcus) kills more children under the age of five than measles, malaria and HIV-AIDS combined. It is the primary cause of life-threatening diseases such as pneumonia, meningitis and sepsis, accounting for over 1.9 million annual deaths worldwide.

The bacterium exists in at least 100 distinct variants (known as serotypes) which vary in their biological properties and distribution around the globe, and spreads through contact with people who carry the bacteria in their nose and throat, via respiratory droplets. People, especially children, can be carriers without showing any signs of disease, spreading the infection to others. As such, vaccines are the best way to control and prevent pneumococcal disease. Currently licensed pneumococcal vaccines, such as Prevnar13® have significantly contributed to reducing the incidence of invasive disease globally. However, they only offer protection against a limited range of serotypes, which in turn drives the spread of other, non-vaccine covered serotypes. This has led to the sustained prevalence of pneumococcal invasive diseases globally. Existing vaccines are also costly to manufacture due to the complexity of the processes involved.

These significant limitations, along with the concomitant rise of antimicrobial drug resistance, is driving the need for development of a pneumococcal vaccine with a broader – ideally universal – cross-serotype coverage, with WHO having this as one of their key priorities.

A novel de-risked approach to vaccine development

RVX-001

Streptococcus pneumoniae

RVX-001 is a novel and cost-effective protein-based vaccine against pneumococcal invasive disease, a tripartite pneumococcal vaccine that provides universal coverage through antibody and cell-mediated responses.

RVX-002

Streptococcus agalactiae

A vaccine to *Streptococcus agalactiae* has been identified as an international priority to reduce the burden of disease and decrease antibiotic use (WHO). RVX-002 is being developed to address this unmet clinical need.

RVX-003

Streptococcus pyogenes

Major obstacles in the development of vaccines to *Streptococcus pyogenes* have been its genomic heterogenicity and high sequence homology with human proteins. RVX-003 has been rationally designed to circumvent these roadblocks.

Lead Program - RVX-001: A novel and cost-effective protein-based vaccine against pneumococcal invasive disease.

ReNewVax's lead program, RVX-001, is focused on the development of a novel protein-based, universal pneumococcal vaccine.
The protective efficacy and immunogenicity of RVX-001 has been established in murine models of invasive pneumococcal disease (IPD) using both adult and infant mice, and in challenge experiments with vaccine and non-vaccine covered serotypes. Prevnar13® (Pfizer) was used as the benchmark vaccine throughout our investigations. Our results showed that RVX-001 offered cross-serotype protection that Prevnar13® failed to provide. This effect has been shown to be largely due to protein-specific cell-mediated immune responses.

Our discovery strategy (Figure 1) is based on the principle of reverse vaccinology, employing rational design in lieu of the classical hypothesis-led approach to vaccine development. The addition of an additional de-risking step, employing an ex vivo human predictive model gives increases the likelihood of clinical success.

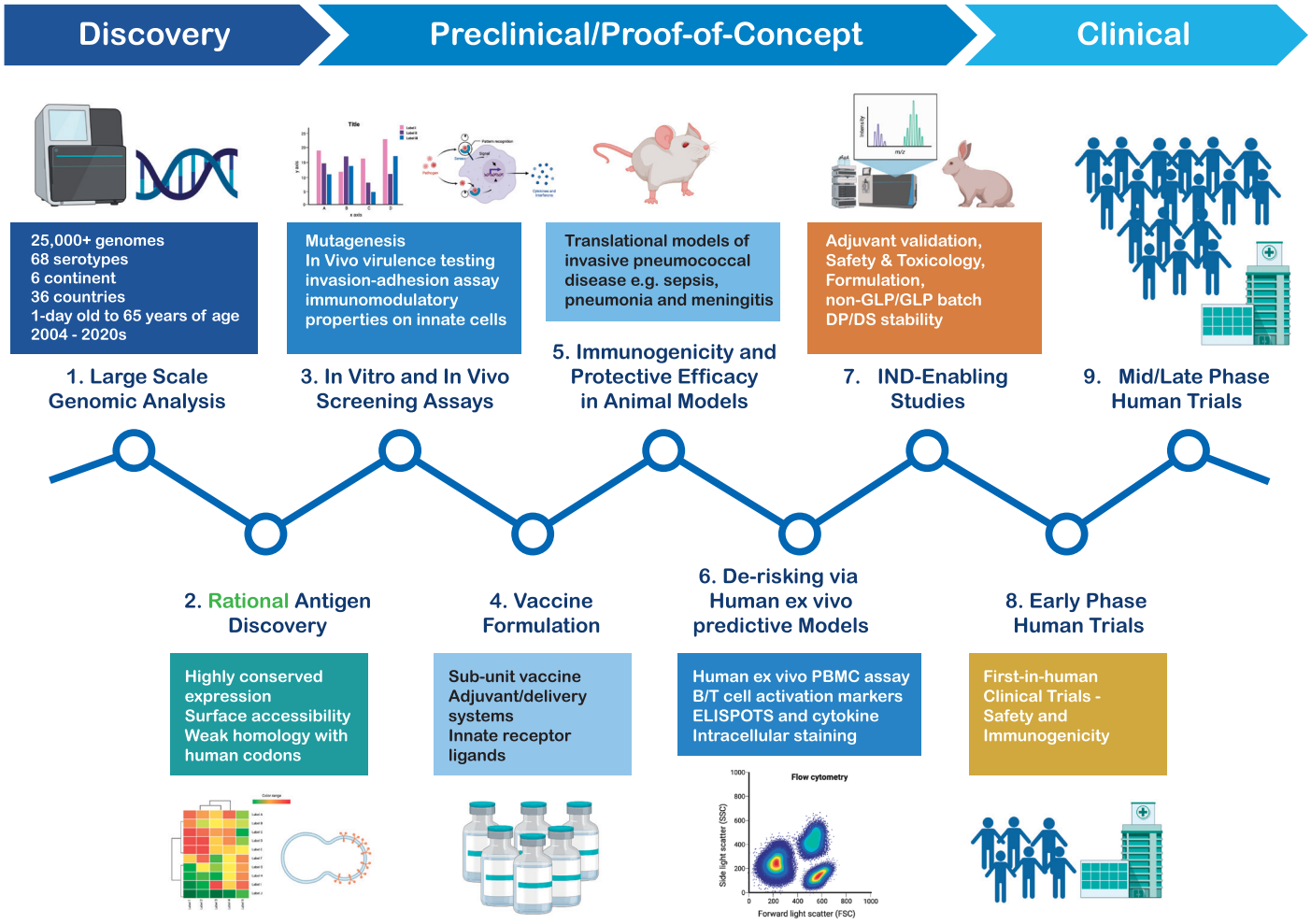

Figure 1. ReNewVax Novel Vaccine Technology Platform: Our platform is differentiated from the classical vaccine developmental pipeline in its discovery approach (depicted in Step 1) and its de-risking approach (depicted in Step 6). Our lead program, RVX-001, is a vaccine formulation that can address the limitations of currently licensed vaccines through its offering of a broad and potentially universal coverage. We have gathered robust evidence to show that RVX-001 is capable of inducing a potent immune response and protective efficacy.

Experienced Team

Dr Neil Murray
CEO
Experienced CEO with background in scaling companies from startup to IPO and working for large multinational enterprises.

Prof Aras Kadioglu
Co-founder and NED
Professor of Bacterial Pathogenesis and Immunity, University of Liverpool.

Dr Marie O'Brien
Co-founder and CSO
Trained as an immunologist with over 12 years of experience in preclinical development of vaccines.

Prof Neil French
Senior Scientific Advisor
Consultant in Infectious Diseases and member of the UK-JCVI and WHO pneumococcal vaccine sub-committee.

Targeted Vaccine Market

Pre-pandemic, the pneumococcal vaccine market was the most expensive (price/dose) and largest global vaccine market (£9.6bn, 2022); projected to grow to £14.7bn by 2028 (Mordor Intelligence, 2022). The market is split into the paediatric segment, dominated by Pfizer's PCV13 (£8.7bn, Pharma Insight 2021) and the adult segment, dominated by Merck's PPSV23 (£0.9bn, Global Data 2021). Pfizer and Merck recently introduced PCV-20 (AppeXXnar®) and PCV-15 (Vaxneuvance™), respectively, both higher valency vaccines, to maintain and grow their market position. Several potential early-stage entrants are focused on this market including Affinivax, recently acquired by GSK, a deal worth US$3.3bn (Figure 2).

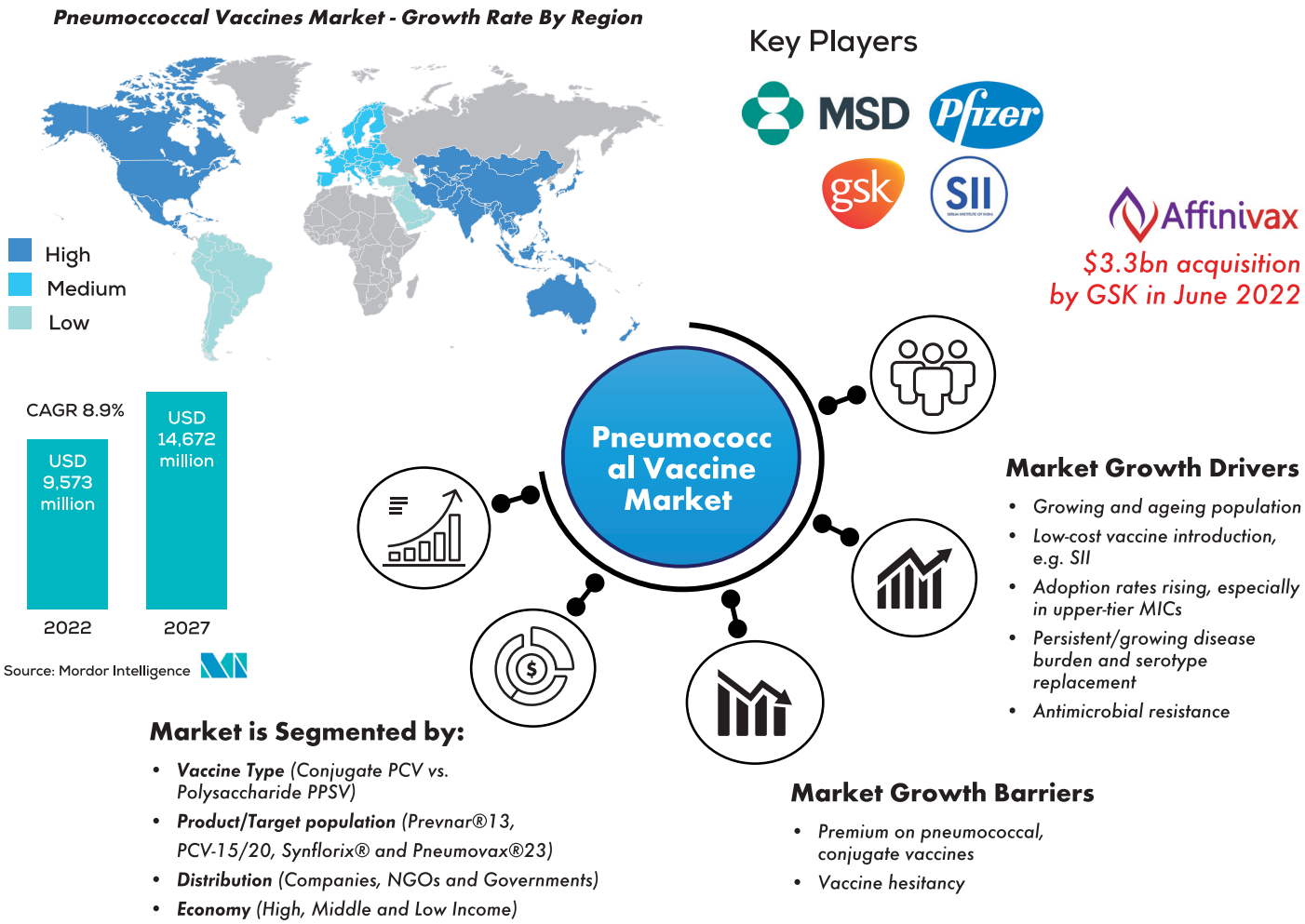

Figure 2. Pneumococcal Vaccine Market. The growth of the global pneumococcal vaccine market is driven by a sustained prevalence of pneumococcal invasive diseases across the globe due to the emergence of non-vaccine variants (aka serotype replacement) and particularly in poor-resource settings, a heightened governmental focus on routine immunisation programs in children, and the introduction of novel pneumococcal vaccines such as Pneumosil® (Serum Institute of India , Pvt., Ltd. (SIIPL) - WHO-prequalified in January 2020, and the alarming rise in antimicrobial resistance. However, the costs associated with development of such vaccines restrain the market growth. Hence the development of protein-based pneumococcal vaccines is expected to offer lucrative opportunities.

Current Status & Fundraising

ReNewVax Ltd. was awarded a £600K cash runway through seed funding from the University of Liverpool and a grant from Innovate UK.

ReNewVax is seeking to raise a further £3.9m to complete CTA/IND-enabling studies for RVX-001 and support early-stage studies for our other pipeline programs.

We anticipate that a further £5m will be required to complete RVX-001 Phase I first-in-human studies - subject to confirmation of clinical protocol.

Patents

A patent titled "A novel pneumococcal vaccine" was filed on 05 Jan 2021 i.e. PCT/GB2022/050003.