**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): September 5, 2023**

# NETWORK-1 TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-15288** | **11-3027591** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |

**65 Locust Avenue, Third Floor, New Canaan, Connecticut 06840**

(Address of Principal Executive Offices) (Zip Code)

**(203) 920-1055**

(Registrant's telephone number, including area code)

**N/A**

(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.01 per share | NTIP | NYSE American |

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 8.01 Other Events.**

On September 5, 2023, ILiAD Biotechnologies, LLC ("ILiAD") reported the first-ever demonstration of protection against B. pertussis (whooping cough) colonization in a Phase 2b Human Challenge study of its BPZE1 vaccine. ILiAD announced that its BPZE1 intranasal vaccine has met the primary endpoint of protection against nasopharyngeal B. pertussis colonization (p=0.03) in the Phase 2b CHAMPION-1 study. To date, Network-1 Technologies, Inc. has invested an aggregate of $7,000,000 in ILiAD which represents approximately 6.8% of the outstanding units of ILiAD on a non-fully diluted basis.

A copy of the press release issued by ILiAD on September 5, 2023 is attached as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| **Exhibit No.** | **Description** |
|---|---|
| 99.1 | Press Release, dated September 5, 2023, issued by ILiAD Biotechnologies, LLC. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**NETWORK-1 TECHNOLOGIES, INC.**

Dated: September 6, 2023

By: /s/ Corey M. Horowitz
Name: Corey M. Horowitz
Title: Chairman and Chief Executive Officer

# ILiAD Biotechnologies Reports First-ever Demonstration of Protection Against *B. pertussis* Colonization in Phase 2b Human Challenge Study of BPZE1 Vaccine

**Weston, FL; September 5, 2023 – ILiAD Biotechnologies, LLC (ILiAD), a clinical stage biotech company developing the world's most advanced next generation pertussis vaccine announces positive primary data outcomes in the CHAMPION-1 clinical trial conducted at University Hospital Southampton (UK) and University of Oxford (UK).**

ILiAD Biotechnologies reported today that its BPZE1 intranasal pertussis vaccine has met the primary endpoint of protection against nasopharyngeal *B. pertussis* colonization (p=0.03) in the Phase 2b CHAMPION-1 Study. This pre-specified sensitivity analysis included participants challenged with sufficient colony forming units (CFUs) of 5 x$10^4$ – 2.4 x$10^5$ CFUs of wild-type *B . pertussis* in the per-protocol adequate challenge inoculum group. BPZE1 was well tolerated with most participants experiencing no or mild systemic and nasal/respiratory symptoms of short duration with no serious adverse events. Notably, a post hoc analysis of quantitative *B. pertussis* CFU counts estimated that BPZE1 vaccination reduced the burden of *B. pertussis* by 98.0% compared with placebo.

The CHAMPION-1 Phase 2b Human Challenge study is a randomized, double-blind, placebo-controlled study of BPZE1 vaccine in healthy adults. The study has a primary objective to demonstrate that prior immunization with BPZE1 protects against colonization as evidenced by negative *B. pertussis* culture following virulent *B. pertussis* challenge 2–4 months after vaccination. Additional objectives include demonstration of safety, nasal mucosal and serum immunological response, functional serum bactericidal activity, and reduction in overall bacterial load following virulent *B. pertussis* challenge. The study included vaccination of 53 participants at University Hospital Southampton and University of Oxford in the United Kingdom, with 46 participants inoculated with a targeted $10^5$ CFU of virulent *B. pertussis* 2–4 months after vaccination, followed by a 16-night stay in a quarantined challenge facility where nasal mucosal and blood samples were collected. All study participants were treated with antibiotics before leaving quarantine.

Chief investigator for the CHAMPION-1 study Prof. Robert Read, Professor and Chair of Infectious Diseases at the University of Southampton stated, "This study marks the first-ever demonstration of a pertussis vaccine preventing *B. pertussis* colonization in a human challenge model. BPZE1's ability to induce sterilizing mucosal immunity and prevent *B. pertussis* colonization at all post-challenge timepoints in most participants is a high bar to have achieved, especially given the substantial challenge dose."

Study Highlights

- Results indicate that BPZE1 vaccine protects against *B. pertussis* colonization, as demonstrated by both the primary endpoint of the proportion of participants with no colonization post-challenge in the per-protocol adequate inoculum group and the substantial reduction in overall *B. pertussis* bacterial load.

- BPZE1 vaccination induced potent serum bactericidal activity, especially against a pertactin-deficient (PRN-) *B. pertussis* strain, in contrast to placebo controls. PRN- *B. pertussis* is currently the predominant circulating strain of *B. pertussis* in the U.S., which has been identified by CDC researchers to have emerged due to antigen drift in response to the use of current acellular pertussis vaccines.

- BPZE1 vaccination induced broad nasal mucosal and serum antibody responses which were absent from placebo controls, consistent with both nasal mucosal and systemic protection.

- The overall frequency of vaccine-related treatment-emergent adverse events was comparable between the BPZE1 and placebo groups, and there were no unexpected safety findings in the BPZE1 group.

Stephanie Noviello, MD, ILiAD Chief Medical Officer remarked, "The dramatic reduction in quantitative CFU counts in BPZE1 vaccinated participants compared to placebo, over the duration of post-challenge days, reinforces the potential clinical benefit of BPZE1, confirming previously published BPZE1 results in preclinical and attenuated human challenge studies. This study was intended to inform the primary endpoint, study parameters, and sample size to power a successful Phase 3 *B. pertussis* human challenge study, which we are confident has now been achieved. The primary data from the CHAMPION-1 clinical study will be presented at the World Vaccine Congress on October 19th in Barcelona."

Keith Rubin, M.D., Chief Executive Officer and Founder, commented, "These results represent a major milestone in global public health efforts to control *Bordetella pertussis*, a pathogen that harms tens of millions of people each year, especially children who account for the great majority of resulting deaths (over 150,000 annually). For more than a decade, ILiAD has been committed to stopping *B. pertussis* where it lives – the human upper respiratory tract. We've always believed that preventing nasopharyngeal colonization will prevent the subsequent disease, transmission and epidemics that have plagued humanity for hundreds of years. We still have a lot of work to do, but this is far and away the best evidence to date that we can fulfill our mission to eradicate all disease due to *B. pertussis*. My deep appreciation to everyone who contributed to this study, especially the study participants without whom achievement of this important milestone would not be possible."

Of note, early in study enrollment a small group of participants were identified to have received a lower dose of wild-type *B. pertussis* challenge than was originally specified in the protocol. As a result, the preparation method of the *B. pertussis* challenge dose was modified to achieve the per-protocol adequate inoculum of *B. pertussis* challenge as specified in the original study protocol. In an analysis of all study participants, including those who received the lower challenge dose, the primary endpoint showed a comparable trend of BPZE1 prevention of colonization.

**About Pertussis**

Pertussis (whooping cough) is a life-threatening disease caused by the highly contagious respiratory bacterium *Bordetella pertussis*. According to U.S. Centers for Disease Control and Prevention, each year pertussis affects approximately 16 million people globally, accounting for nearly 200,000 deaths. Although estimated global vaccination coverage is 84%, current vaccines have failed to control epidemics. In addition, current vaccines do not fully protect infants under

age 6 months, since immunization requires multiple injections, usually at 2, 4 and 6 months.

**About BPZE1**
BPZE1 is a next-generation live-attenuated pertussis vaccine designed to induce comprehensive and durable protection against *B. pertussis* infection (colonization) and disease (whooping cough). BPZE1 is being developed to block *B. pertussis* from colonizing adult and adolescent nasal passages, to protect adults and adolescents from whooping cough, and to potentially prevent transmission, including transmission to infants. While ILiAD is currently focused on developing a vaccine to directly protect adults and adolescents and to indirectly protect vulnerable infants, future development aims to immunize neonates directly. BPZE1 was developed at the Institut Pasteur de Lille (France) in the lab of Camille Locht and Nathalie Mielcarek.

**About ILiAD Biotechnologies, LLC**
ILiAD Biotechnologies (http://www.iliadbio.com) is a privately held, clinical stage biotechnology company dedicated to the prevention and treatment of human disease caused by *Bordetella pertussis*. The company is developing and acquiring key technologies, working with leading scientists to overcome the limitations of current vaccines, investigating the impact of *B. pertussis* in a range of human disease, and is focused on validating its proprietary vaccines in human clinical trials.

**About University Hospital Southampton**
University Hospital Southampton NHS Foundation Trust (UHS) is one of the largest acute teaching trusts in England with a turnover of more than £1.15 billion in 2021/22. UHS provides hospital services for 1.9 million people living in southern Hampshire and specialist services to more than 3.7 million people in central southern England and the Channel Islands. UHS is consistently one of the UK's highest recruiting trusts of patients to clinical trials and in the top ten nationally for research study volume as ranked by the NIHR Clinical Research Network. In partnership with the University of Southampton, UHS has £35 million of NIHR infrastructure dedicated to bringing the latest treatments to patients.

**About University of Oxford**
Oxford University has been placed number 1 in the Times Higher Education World University Rankings for the seventh year running, and number 2 in the QS World Rankings 2022. At the heart of this success are the twin-pillars of our ground-breaking research and innovation and our distinctive educational offer. Oxford is world-famous for research and teaching excellence and home to some of the most talented people from across the globe. Our work helps the lives of millions, solving real-world problems through a huge network of partnerships and collaborations. The breadth and interdisciplinary nature of our research alongside our personalised approach to teaching sparks imaginative and inventive insights and solutions. Through its research commercialisation arm, Oxford University Innovation, Oxford is the highest university patent filer in the UK and is ranked first in the UK for university spinouts, having created more than 200 new companies since 1988. Over a third of these companies have been created in the past three years. The university is a catalyst for prosperity in Oxfordshire and the United Kingdom, contributing £15.7 billion to the UK economy in 2018/19, and supports more than 28,000 full time jobs.

**About the Oxford Vaccines Group – Medical Science Division**
The Oxford Vaccine Group (OVG) conducts studies of new and improved vaccines for children and adults and is based in the Department of Paediatrics at the University of Oxford. The group is led by Professor Andrew J Pollard. OVG was founded in 1994 by Professor E. Richard Moxon. The multidisciplinary group, led by Professor Pollard since 2001, includes consultants in vaccinology, a Director of Clinical Trials, a Senior Clinical Trials Manager, adult and paediatric clinical research fellows, adult and paediatric research nurses, project managers, statisticians, QA manager, Clinical Trials IT and Development Lead, and an administration team. Our team also includes post-doctoral scientists, research assistants and DPhil students and we work together with professionals from a range of specialities such as immunologists, microbiologists, epidemiologists, health communicators, and a sociologist, a community paediatrician, the local Health Protection team and a bioethicist.

## Contact

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*"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995.*

*In addition to historical facts or statements of current, this press release may contain forward-looking statements. Forward-looking statements provide ILiAD's current expectations or forecasts of future events. These may include statements regarding anticipated development of potential products, interpretation of clinical results, prospects for regulatory approval, outsourcing trends in the pharmaceutical industry, levels of industry research and development spending, rapid technological change, risks associated with acquisitions and investments, risks associated directly with BPZE technologies including but not limited to uncertainties of product development, and uncertainties of clinical development, dependence on third parties, competition, protection of patents and proprietary technology, potential for infringement and other statements regarding matters that are not historical fact. Some of these forward looking statements may be identified by use of words in the statements such as "estimate," "intend," or other words and terms of similar meaning. Statements in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore actual outcomes and results may differ materially from what is expressed in such forward-looking statements. ILiAD cautions investors not to place reliance on the forward-looking statements contained in this press release. These statements speak only as of the date of this release and ILiAD undertakes no obligations to update or review these statements, except as may be required by law.*