

Lakewood-Amedex Biotherapeutics, Inc.

(LABT-NASDAQ)

LABT: Initiating Coverage of Lakewood-Amedex; Building a Next-Generation Antimicrobial Platform

Based on our probability adjusted DCF model that takes into account potential future revenues for Nu-3, Lakewood-Amedex is valued at \$12.00 per share. This model is highly dependent upon continued clinical success of the company's assets and will be adjusted accordingly based on future clinical results.

Current Price (06/23/26) **\$3.65**
Valuation **\$12.00**

OUTLOOK

We are initiating coverage of Lakewood-Amedex Biotherapeutics, Inc. (LABT) with a \$12.00 valuation. Lakewood is a biopharmaceutical company developing a novel class of antimicrobial compounds known as Bisphosphocins®, a proprietary platform designed to address one of the largest and fastest-growing challenges in modern healthcare: antimicrobial resistance (AMR). The company's lead clinical candidate, Nu-3, is being developed for the treatment of infected diabetic foot ulcers (iDFU), an indication affecting millions of patients worldwide that continues to have limited treatment options. The company will be initiating a Phase 2a trial of Nu-3 in iDFU in 2026 ahead of a larger placebo controlled Phase 2b program. Positive data from that study would represent a significant inflection point for the company as it would not only support further development of Nu-3 but also provide initial clinical validation for the broader Bisphosphocin platform.

SUMMARY DATA

52-Week High **\$7.67**
52-Week Low **\$3.65**
One-Year Return (%) **N/A**
Beta **N/A**
Average Daily Volume (sh) **53,265**

Shares Outstanding (mil) **2**
Market Capitalization (\$mil) **\$6**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **N/A**
Insider Ownership (%) **N/A**

Annual Cash Dividend **\$0.00**
Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates
Sales (%) **N/A**
Earnings Per Share (%) **N/A**
Dividend (%) **N/A**

P/E using TTM EPS **N/A**
P/E using 2026 Estimate **N/A**
P/E using 2027 Estimate **N/A**

Risk Level **High**
Type of Stock **Small-Blend**
Industry **Med-Drugs**

ZACKS ESTIMATES

Revenue

(in millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2026	0.0 A	0.0 E	0.0 E	0.0 E	0.0 E
2027					0.0 E
2028					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025					\$5.53 A
2026	\$1.32 A	\$0.65 E	\$0.56 E	\$0.48 E	\$2.52 E
2027					\$1.32 E
2028					\$1.16 E

WHAT'S NEW

Initiating Coverage



We are initiating coverage of Lakewood-Amedex Biotherapeutics, Inc. (LABT) with a valuation of \$12.00. Lakewood-Amedex is a clinical-stage anti-infective company developing a proprietary class of antimicrobial compounds known as Bisphosphocins®. While many biotechnology companies are focused on developing incremental improvements to existing therapeutic approaches, Lakewood-Amedex is pursuing what may represent an entirely new antimicrobial class. The company's lead candidate, Nu-3, is currently being advanced for the treatment of infected diabetic foot ulcers (iDFU), an indication where infection control remains a critical determinant of patient outcomes and where antibiotic resistance continues to complicate treatment decisions.

We believe Lakewood-Amedex occupies a unique position within the anti-infective sector. The company combines a clinical-stage lead asset addressing a significant unmet medical need with a platform technology that may have applications across multiple high-value infectious disease indications. The upcoming Phase 2a study of Nu-3 represents the next major value-creating event and has the potential to provide the first meaningful clinical validation of the Bisphosphocin platform.

A Potentially New Class of Antimicrobials: Most antimicrobial innovation over the past several decades has involved modifications of existing antibiotic classes that remain vulnerable to established resistance mechanisms. Bisphosphocins were developed as a distinct antimicrobial class and have demonstrated broad-spectrum activity against Gram-positive organisms, Gram-negative organisms, multidrug-resistant pathogens, and biofilms in preclinical studies with no indications of resistance development.

Positioned to Address One of the Largest Global Healthcare Challenges: Antimicrobial resistance continues to represent a growing public health and economic burden worldwide. The World Health Organization (WHO) has identified AMR as a major healthcare priority, while economic analyses suggest that resistance-related costs could reach trillions of dollars globally over the coming decades. Any antimicrobial platform capable of maintaining activity against resistant organisms while reducing the emergence of new resistance mechanisms would address a substantial unmet need.

Nu-3 Targets a Large and Underserved Diabetic Foot Ulcer Market: DFU affect approximately one-third of diabetic patients during their lifetime, with roughly half of those ulcers becoming infected. Infection is one of the primary drivers of hospitalization, wound progression, and eventual amputation. Current treatment relies heavily on systemic antibiotics despite increasing concerns regarding resistant pathogens and limited tissue penetration into poorly vascularized wound environments. Nu-3's topical administration strategy may provide an opportunity to deliver high antimicrobial concentrations directly to the site of infection while minimizing systemic exposure.

Multiple Pipeline Expansion Opportunities: Beyond diabetic foot ulcers, Lakewood-Amedex is advancing additional Bisphosphocin compounds for catheter-associated urinary tract infections and pulmonary infections. These indications represent large commercial opportunities where biofilms, resistant pathogens, and limitations of current therapies continue to create significant unmet medical needs. If the platform is validated clinically, the potential addressable market could extend far beyond the initial diabetic foot ulcer indication.

Extensive Intellectual Property Portfolio: The company has assembled a substantial intellectual property estate surrounding the Bisphosphocin platform, including composition-of-matter, formulation, and therapeutic-use patents. According to company filings, the portfolio currently consists of 71 issued patents and 28 pending patent applications worldwide, providing a potentially important competitive advantage as development progresses.

INVESTMENT THESIS

Lakewood-Amedex Biotherapeutics (LABT) is developing a novel class of antimicrobial compounds known as Bisphosphocins®, a proprietary platform designed to address one of the largest and fastest-growing challenges in modern healthcare: antimicrobial resistance (AMR). The company's lead clinical candidate, Nu-3, is being developed for the treatment of infected diabetic foot ulcers (iDFU), an indication affecting millions of patients worldwide and one that continues to suffer from limited treatment innovation despite significant clinical and economic burden. If clinical efficacy is demonstrated, Nu-3 has the potential to offer a differentiated approach through direct local delivery of a broad-spectrum antimicrobial agent capable of targeting both susceptible and resistant pathogens while minimizing systemic exposure.

The broader investment thesis extends well beyond a single product candidate. AMR is widely recognized as one of the most significant healthcare challenges of the 21st century. Existing antibiotics continue to lose effectiveness as bacterial resistance evolves, yet innovation within anti-infective drug development has slowed considerably. Lakewood's Bisphosphocin platform was specifically designed to address many of the shortcomings associated with traditional antimicrobial therapies through a mechanism that appears capable of rapidly disrupting bacterial membranes, resulting in broad-spectrum antimicrobial activity while demonstrating a low propensity for resistance emergence in preclinical testing.

The most important near-term catalyst for investors will be the planned Phase 2a study of Nu-3 gel in patients with mildly infected diabetic foot ulcers. The trial is designed to evaluate multiple dose levels and generate an early proof-of-concept dataset in the target patient population prior to advancing into a larger placebo-controlled Phase 2b program. We believe positive data from this study would represent a significant inflection point for the company, as it would not only support further development of Nu-3 but could also provide initial clinical validation for the broader Bisphosphocin platform.

Beyond diabetic foot ulcers, management is advancing additional Bisphosphocin compounds for other local infection indications where high local antimicrobial concentrations, biofilm activity, and limited systemic exposure may provide meaningful advantages. These programs include catheter-associated urinary tract infections (CAUTI) and pulmonary infections, both of which represent large markets characterized by increasing rates of antimicrobial resistance and substantial unmet medical need. While these programs remain at the preclinical stage, they highlight the potential breadth of the platform and the possibility that successful development of Nu-3 could ultimately support expansion into multiple infectious disease indications.

	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Indications
Nu-3	[Progress bar from Discovery to Phase 2]				[Circle]	<ul style="list-style-type: none"> Diabetic Foot Ulcers Two clinical studies completed Phase 2 in initiation
Nu-8	[Progress bar from Discovery to Preclinical]	[Circle]	[Circle]	[Circle]	[Circle]	<ul style="list-style-type: none"> Profiling for further potential indication developments, e.g.:
Nu-10	[Circle]	[Circle]	[Circle]	[Circle]	[Circle]	<ul style="list-style-type: none"> Pulmonary Infections Urinary Tract Infections
Nu-11	[Circle]	[Circle]	[Circle]	[Circle]	[Circle]	<ul style="list-style-type: none"> Oral Mucositis Otitis Media Externa

Source: Lakewood-Amedex Biotherapeutics, Inc.

Antimicrobial Resistance

The emergence of antimicrobial resistance (AMR) is increasingly viewed as one of the most significant threats to global public health. While advances in antibiotics transformed medicine during the twentieth century, widespread use of antimicrobial agents over several decades has created powerful evolutionary pressure favoring the emergence of resistant bacterial strains. As resistance continues to spread, many previously routine infections are becoming progressively more difficult to treat, increasing morbidity, mortality, healthcare utilization, and economic burden worldwide.

The scale of the problem is substantial. According to the landmark Global Research on Antimicrobial Resistance Project published in *The Lancet*, bacterial antimicrobial resistance was directly responsible for approximately 1.27 million deaths globally in 2019 and was associated with nearly 4.95 million deaths overall ([GBD 2021 Antimicrobial Resistance Collaborators, 2024](#)). By comparison, AMR-related mortality now exceeds that attributed to HIV/AIDS and malaria individually, highlighting the extent to which antimicrobial resistance has evolved from a future concern into a present-day global healthcare crisis.

The World Health Organization (WHO) has repeatedly identified AMR as one of the top global public health threats facing humanity ([WHO](#)). Resistant pathogens threaten not only the treatment of routine infections but also many medical procedures that depend upon effective antimicrobial prophylaxis, including cancer chemotherapy, organ transplantation, major surgery, intensive care medicine, and the management of chronic diseases. As resistance increases, the risk associated with these interventions rises as well, potentially undermining decades of medical progress.

The economic implications are equally concerning. The World Bank has estimated that antimicrobial resistance could reduce global economic output by approximately \$3.8 trillion annually by 2050 if effective interventions are not developed ([World Bank Group, 2017](#)). In the United States alone, treatment of infections caused by just six common multidrug-resistant pathogens was estimated to cost more than \$4.6 billion in 2021. These figures reflect not only direct healthcare expenditures but also productivity losses, prolonged hospitalizations, increased disability, and premature mortality.

Importantly, AMR is not confined to rare or exotic pathogens. Some of the most clinically problematic resistant organisms today include methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), multidrug-resistant *Pseudomonas aeruginosa*, carbapenem-resistant Enterobacterales, and resistant strains of *Klebsiella pneumoniae* and *Escherichia coli*. These organisms are frequently encountered in hospitals, long-term care facilities, chronic wounds, urinary tract infections, and pulmonary infections, which are the same settings that Lakewood-Amedex is targeting with its Bisphosphocin platform.

Why Current Antibiotic Development Has Struggled

Most antibacterial drugs approved during the past several decades have been derivatives, reformulations, or incremental improvements of previously established antibiotic classes. While these therapies often provide important clinical benefits, they generally remain vulnerable to the same underlying resistance mechanisms that affect older members of their respective classes.

Bacteria possess several highly effective methods for evading traditional antibiotics. These include modification of drug targets, enzymatic degradation of antimicrobial compounds, active efflux pumps that remove antibiotics from bacterial cells, and reduced permeability that prevents antibiotics from reaching intracellular targets. Once resistance mechanisms emerge, they can spread rapidly through bacterial populations via horizontal gene transfer, further accelerating the problem.

The economics of antibiotic development have also discouraged investment. Unlike oncology or chronic disease therapeutics, antibiotics are typically administered for relatively short treatment durations and are often reserved for severe infections to preserve effectiveness. Consequently, many large pharmaceutical

companies have reduced or eliminated anti-infective research programs over the past two decades, resulting in a thinner development pipeline despite increasing medical need.

As a result, healthcare systems find themselves confronting a widening gap between the growing prevalence of resistant pathogens and the availability of truly novel antimicrobial mechanisms. We believe this backdrop creates a potentially attractive environment for innovative anti-infective technologies that can demonstrate broad-spectrum antimicrobial activity while reducing the likelihood of resistance emergence.

The Opportunity for a New Antimicrobial Class

Historically, some of the most important advances in infectious disease treatment have occurred through the introduction of entirely new mechanistic classes rather than incremental modifications of existing therapies. Penicillins, aminoglycosides, fluoroquinolones, glycopeptides, and carbapenems each transformed clinical practice because they introduced fundamentally new approaches to bacterial killing.

Lakewood-Amedex's Bisphosphocin platform was developed with a similar objective: to create a novel class of antimicrobial compounds capable of rapidly eliminating susceptible and resistant pathogens through a mechanism distinct from conventional antibiotics. While clinical validation remains necessary, the available nonclinical data suggest that Bisphosphocins may possess several characteristics that are particularly relevant in the current AMR environment, including:

- Broad-spectrum antimicrobial activity against Gram-positive and Gram-negative bacteria
- Activity against multidrug-resistant organisms
- Demonstrated activity against bacterial biofilms
- Rapid bactericidal effects
- Local administration directly at sites of infection
- Minimal anticipated systemic exposure
- Low observed propensity for resistance emergence during laboratory testing

Taken together, we believe these attributes position Bisphosphocins as one of the more intriguing emerging antimicrobial platforms currently under development. Importantly, the company's lead program, Nu-3, is not being developed as a traditional systemic antibiotic. Instead, Lakewood-Amedex is pursuing local delivery strategies designed to maximize antimicrobial exposure at the site of infection while minimizing systemic toxicity, a strategy that may be particularly advantageous in chronic wound infections, catheter-associated infections, and pulmonary infections where local drug concentrations are often critical determinants of therapeutic success.

The Bisphosphocin Platform

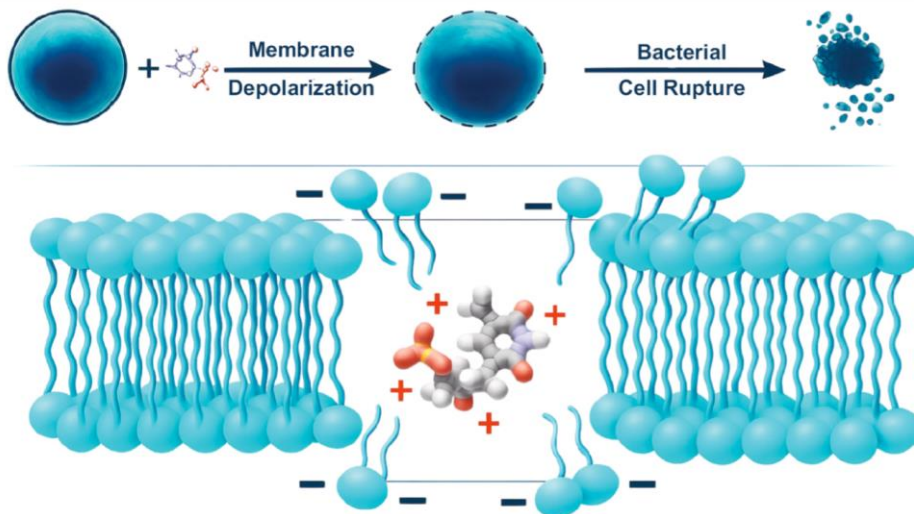
While Lakewood-Amedex's lead clinical asset, Nu-3, represents the company's most advanced program, we believe the core value proposition of the company rests with the broader Bisphosphocin platform. In our view, investors should think of Nu-3 not as a standalone wound-care product, but rather as the first clinical validation opportunity for a potentially novel antimicrobial class. If successful, the implications could extend far beyond iDFUs into numerous infectious disease settings where AMR, biofilm formation, and poor drug penetration remain significant therapeutic challenges.

The company's scientific approach is based on a fundamental observation that has become increasingly important in the modern era of AMR: many bacterial resistance mechanisms evolved specifically to evade conventional antibiotic targets. An overview of resistance mechanisms for different classes of antibiotics is shown in the table below. As resistance continues to accumulate across multiple drug classes, therapeutic strategies that rely upon entirely different mechanisms of bacterial killing may become increasingly valuable.

Antibiotic Class	Primary Target	Common Resistance Mechanisms
Beta-lactams	Cell wall synthesis	Beta-lactamases, altered PBPs
Fluoroquinolones	DNA gyrase/topoisomerase	Target mutations, efflux pumps
Aminoglycosides	Ribosomes	Enzymatic modification
Macrolides	Ribosomes	Methylation of target sites
Glycopeptides	Cell wall precursors	Altered peptidoglycan targets
Bisphosphocins	Bacterial membranes	Currently under investigation

Source: Zacks SCR

Rather than targeting bacterial DNA replication, protein synthesis, cell wall biosynthesis, or other classical intracellular pathways, Bisphosphocins appear to exert antimicrobial activity primarily through rapid disruption of bacterial membrane integrity, producing bactericidal effects through a mechanism fundamentally distinct from many traditional antibiotic classes. This distinction forms the scientific foundation of the entire Lakewood-Amedex platform and may ultimately prove critical to its clinical differentiation. The following image provides a schematic representation of the proposed mechanism of action of the Bisphosphocin class of compounds.



Source: Lakewood-Amedex Biotherapeutics, Inc.

Additional evidence to support the proposed mechanism of action is shown in the following images in which bacteria were exposed to increasing concentrations of Nu-3 and SYTOX green nucleic acid stain. SYTOX green can only penetrate cells that have a compromised plasma membrane. The graph on the left shows that increasing concentrations of Nu-3 leads to greater uptake of SYTOX, with representative staining photos shown on the right.

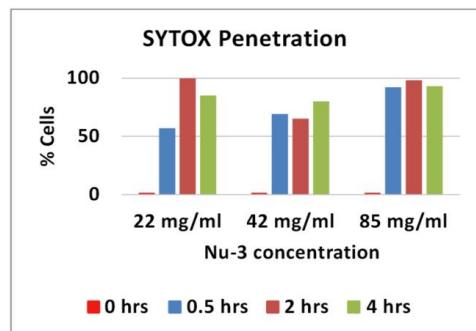


Figure 2a

Source: Lakewood-Amedex Biotherapeutics, Inc.

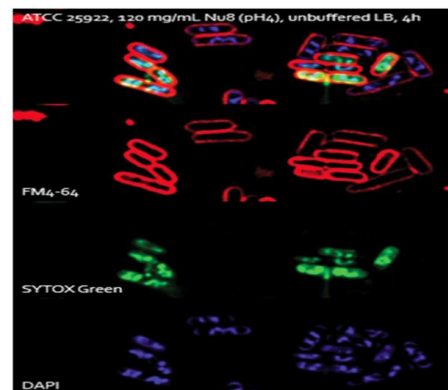
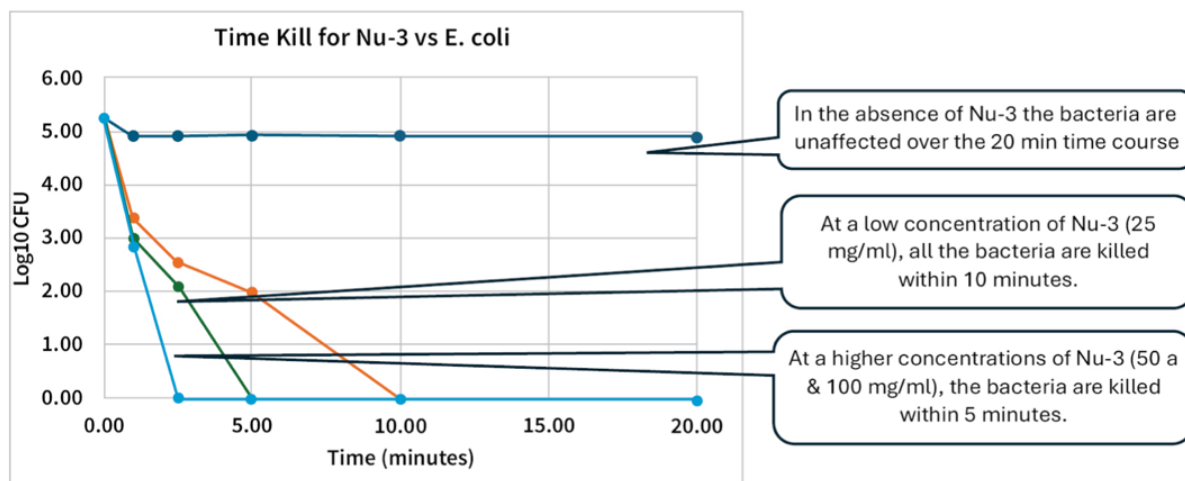


Figure 2b

Importantly, membrane-active antimicrobials often demonstrate rapid bactericidal activity compared with antibiotics requiring intracellular accumulation and metabolic disruption. The following image shows data from a time-kill assay in which three different concentrations of Nu-3 were tested against *E. Coli*. The results show that at a low concentration (25 mg/mL) Nu-3 kills all bacteria within 10 minutes while at higher concentrations of Nu-3 the bacteria are killed within five minutes.



Source: Lakewood-Amedex Biotherapeutics, Inc.

One of the most distinctive aspects of Lakewood's development strategy is its focus on localized antimicrobial delivery. Traditional antibiotic therapy relies primarily on systemic administration, either orally or intravenously. After administration, the drug must distribute throughout the body before reaching the infected tissue at concentrations sufficient to inhibit or kill pathogens. This approach may increase a patient's risk of systemic side effects, such as disruption of the intestinal microbiome or allergic reactions. Lakewood-Amedex has shown that local application of its compounds results in limited systemic exposure in multiple animal models. For example, Nu-3 was applied to wounds for 14 days in a porcine toxicology study where systemic exposure was very low and short-lived, with no adverse effects on any organ system.

Chronic wounds, diabetic foot ulcers, catheter-associated infections, and pulmonary infections frequently involve tissue compartments where antibiotic penetration may be limited. In addition, these infections often contain biofilms that create further barriers to antimicrobial activity. As a result, bacteria may be exposed to suboptimal drug concentrations that contribute both to treatment failure and resistance development.

Lakewood-Amedex's strategy is fundamentally different. Rather than relying upon systemic exposure, Bisphosphocin compounds are being developed as locally delivered therapies designed to achieve very high antimicrobial concentrations directly at the site of infection. The lead program, Nu-3, is administered topically as a gel to iDFU. The CAUTI program utilizes intravesical delivery directly into the bladder, while pulmonary candidates are being developed as inhaled aerosols delivered directly into the lung.

In support of each of these programs, Lakewood-Amedex has generated extensive pre-clinical evidence demonstrating *in vitro* antimicrobial activity against a broad range of pathogens. The following table is a partial list of the bacterial species that are susceptible to Nu-3 and other Bisphosphocin compounds, with the bacteria in red indicating those that are AMR. In addition, Bisphosphocins appear to be effective against several biodefense pathogens, which could have implications in national defense and public health.

Nosocomial Bacteria

Acinetobacter iwoffii – clinical isolate
Acinetobacter baumannii – clinical isolate
Clostridium difficile – multi-resistant
Enterococcus faecalis – W.T. & vancomycin resistant
Enterococcus faecium – vancomycin resistant
Klebsiella pneumoniae – clinical isolate, NDM-1
Pseudomonas aeruginosa – W.T.
Pseudomonas aeruginosa – ciprofloxacin, MDR
Serratia marcescens – oxacillin resistant
Staphylococcus aureus (MRSA) – vancomycin resistant
Staphylococcus epidermis – oxacillin resistant

Biodefense Organisms

Bacillus anthracis
Brucella abortus
Burkholderia mallei
Burkholderia pseudomallei
Francisella tularensis
Yersinia pestis

Community Acquired Bacteria

Aeromonas hydrophilia – clinical isolate
Alcaligenes faecalis – clinical isolate
Borellia burgdorferi
Haemophilus influenzae
Mycobacterium tuberculosis – W.T. & MDR
Moraxella catarrhalis
Neisseria meningitidis – rifampicin resistant
Propionibacterium acnes
Proteus mirabilis
Streptococcus pneumoniae – penicillin resistant

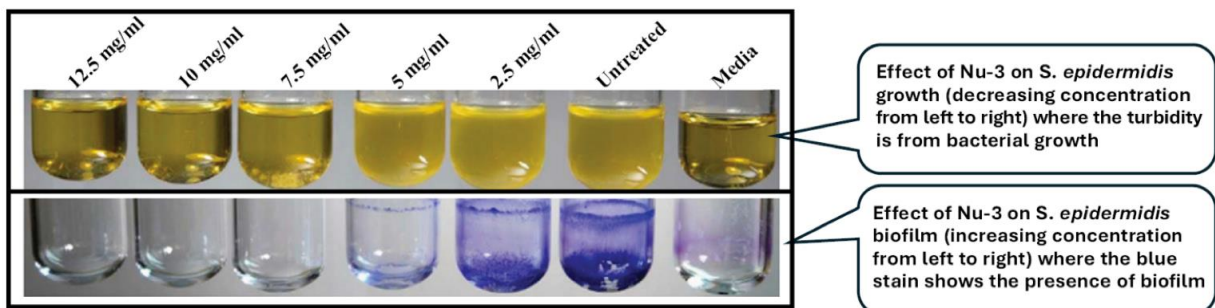
Yeast/Fungal Organisms

Trichophyton rubrum and mentagrophytes
Microsporum gypseum
Aspergillus fumigatus
Candida albicans
Saccharomyces pastorianis

Source: Lakewood-Amedex Biotherapeutics, Inc.

Another area where the Bisphosphocin platform appears to excel is in the treatment of infections where resistance and biofilm formation contribute significantly to clinical failure. Biofilms are highly organized microbial communities embedded within extracellular polymeric matrices that protect resident organisms from both host immune responses and antimicrobial therapies ([Khan et al., 2021](#)). Biofilm formation is now recognized as a major driver of persistent infection in chronic wounds, catheter-associated infections, implanted medical devices, and chronic pulmonary disease.

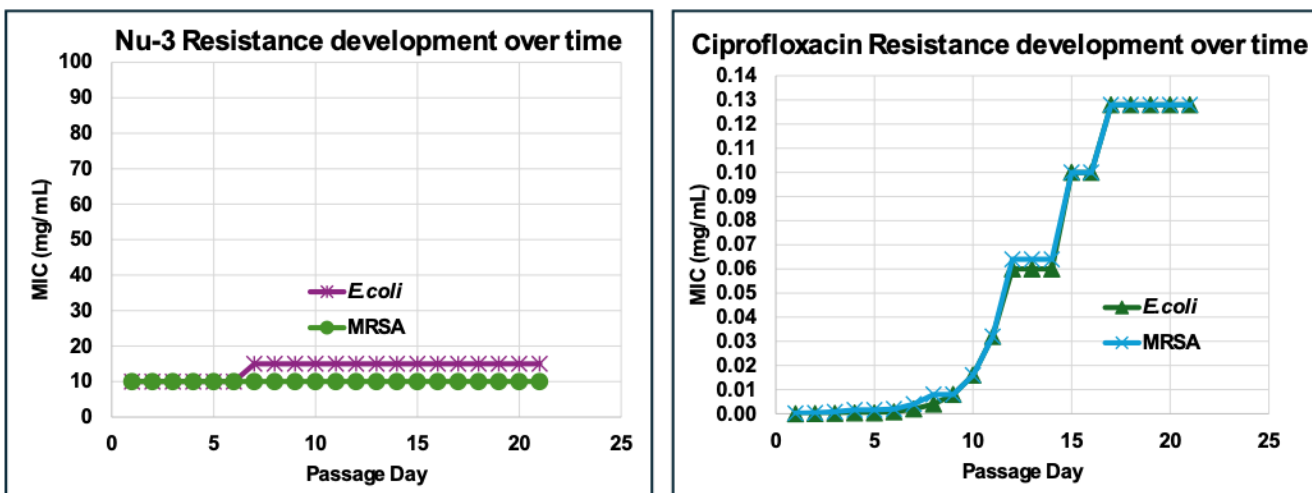
Lakewood-Amedex now has data indicating that Bisphosphocin compounds are effective against biofilms. The following image shows the effect of Nu-3 on *S. epidermidis* biofilm growth. The top panel shows the growth of *S. epidermidis*, with the cloudy solutions showing qualitative bacterial growth and the clear solutions showing little to no growth. In the bottom panel, the blue stain shows the presence of biofilm. As the concentration of Nu-3 is increased (from right to left in the image), the growth of bacteria cells and biofilm formation decreases. Given the high prevalence of biofilm formation in iDFUs and catheter-associated urinary tract infections, Bisphosphocin compounds may offer a new approach to treating those infections given their ability to combat biofilm formation.



Source: Lakewood-Amedex Biotherapeutics, Inc.

As discussed previously, resistance development is a great concern for most classes of antimicrobials. However, the rapid action of Bisphosphocin compounds presents a challenge to resistance development. The following graphs shows the results of an *in vitro* serial passage experiment for *E. Coli* and *S. aureus*

(MRSA) over 21 days. The results show that the minimum inhibitory concentration (MIC) for Nu-3 was slightly increased by Day 21 for *E. Coli* while being unchanged for MRSA (left-hand panel). This is in comparison to the MIC for ciprofloxacin, which increased over 2000-fold for *E. Coli* and 600-fold for MRSA over the same time period (right-hand panel). The MIC values were also unchanged for Nu-3 when assessed against the bacteria that had developed resistance to ciprofloxacin, indicating that cross-resistance did not occur.



Source: Lakewood-Amedex Biotherapeutics, Inc.

While the scientific characteristics of the Bisphosphocin platform are compelling, the ultimate value of any antimicrobial technology depends upon its ability to address clinically meaningful unmet needs. Lakewood-Amedex's lead candidate, Nu-3 gel, is being developed for iDFU, an indication that we believe is particularly well-suited to the platform's strengths, including local delivery, broad-spectrum antimicrobial activity, potential biofilm disruption, and minimal systemic exposure. To understand the opportunity facing Nu-3, it is first necessary to understand the substantial clinical burden associated with DFUs and the limitations of current treatment approaches.

Diabetic Foot Ulcers

DFUs affect approximately 19 million individuals worldwide, with approximately 1.6 million in the U.S. ([Armstrong et al., 2023](#)). It's estimated that approximately 19-34% of patients with diabetes will develop a foot ulcer during their lifetime and the incidence rate for recurrence is 40% within one year and 65% within five years ([Armstrong et al., 2017](#)). Two of the leading risk factors for developing foot ulcers are peripheral vascular disease and peripheral neuropathy (sensory, motor, and autonomic). These conditions can combine to cause alterations to a patient's foot and decrease their awareness to injuries, thus resulting in ulcer formation.

Standard treatment for DFUs includes debridement, off-loading, managing any infection, moisture control, and adequate glycemic control. Chronic foot ulcers that are resistant to treatment are the precursors to amputation in 80% of cases. Approximately 50-60% of ulcers become infected (iDFU) and require broad spectrum antibiotics, with 20% of moderate to severe infections leading to lower extremity amputations. A recent meta-analysis showed the overall prevalence of MRSA in DFU was 17% ([Zhou et al., 2024](#)). Another study showed that approximately 60-80% of iDFUs involve the formation of biofilms, thus contributing to the ineffectiveness of oral antibiotic therapy ([Pouget et al., 2020](#)). Tragically, diabetics who develop a foot ulcer have a 5-year mortality rate of approximately 30%, which then exceeds 70% for those with an amputation ([Armstrong et al., 2023](#)). Hence, the necessity to quickly treat iDFUs is of the utmost importance for a patient's health.

Nu-3 in iDFU

Lakewood-Amedex's lead compound, Nu-3, is being developed as a gel formulation for the treatment of iDFU. The company has aligned with the FDA on a protocol for a Phase 2b study, however a smaller Phase 2a study will be conducted first to establish initial proof-of-concept in patients before moving on to the larger Phase 2b study. The company has amassed a wealth of preclinical data supporting the use of Nu-3 in DFUs, which is discussed below.

- **Broad Activity Against DFU Pathogens**

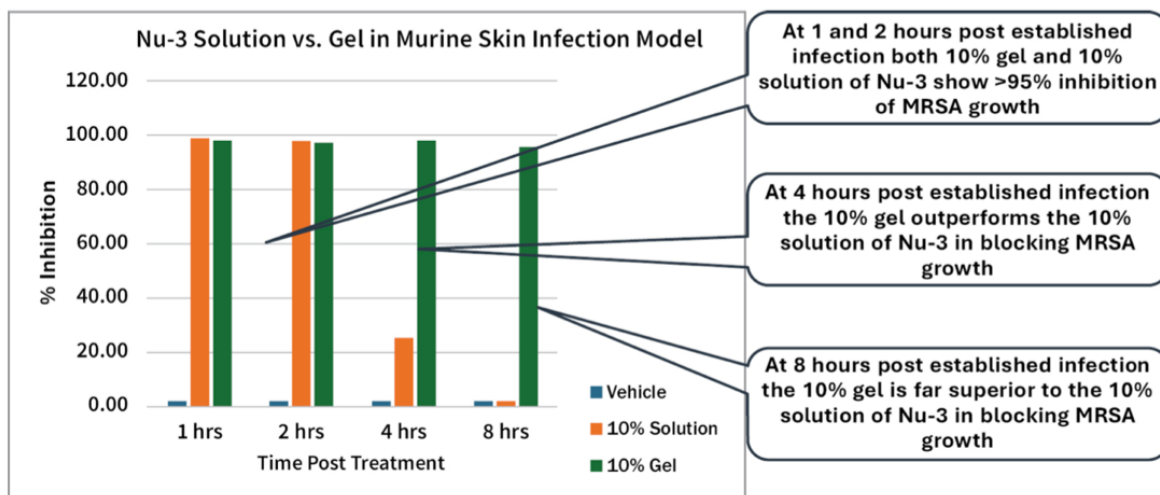
Preclinical studies show that Nu-3 exhibits broad activity against a wide range of bacterial pathogens that can cause infection in DFUs. The following table shows the MIC for the top 10 bacterial isolates from DFU infections. Of note is the fact that one of the clinical doses (10% gel – 100 mg/mL) is 8 to 50 times the MIC values shown in the table.

Bacterial Species	MIC (mg/ml)
<i>Staphylococcus aureus</i>	12.5 – 25
<i>Staphylococcus epidermidis</i>	3.125
<i>Escherichia coli</i>	6.25
<i>Streptococcus dysgalactiae</i>	1.56
<i>Enterococcus faecalis</i>	6.25
<i>Staphylococcus haemolyticus</i>	6.25
<i>Proteus mirabilis</i>	6.25
<i>Pseudomonas aeruginosa</i>	1.56
<i>Acinetobacter radioresistens</i>	3.125
<i>Corynebacterium striatum</i>	1.56
<i>Serratia marcescens</i>	3.125

Source: Lakewood-Amedex Biotherapeutics, Inc.

- **Single-Dose Murine Skin Infection Model**

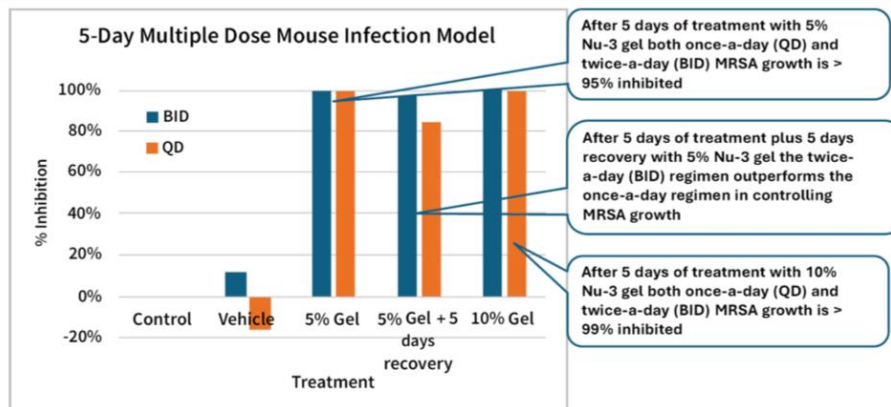
A MRSA infection was introduced to skin abrasions on mice and allowed to establish for four hours before applying placebo, 10% Nu-3 solution, or 10% Nu-3 gel. The results showed that the Nu-3 10% gel inhibited bacterial growth up to 8 hours, while the Nu-3 10% solution only inhibited growth for the first two hours.



Source: Lakewood-Amedex Biotherapeutics, Inc.

- Multiple-Dose Murine Skin Infection Model

A MRSA infection was introduced to skin abrasions on mice and allowed to establish for four hours before applying placebo, 10% Nu-3 gel, or 5% Nu-3 gel either QD (once daily) or BID (twice daily) for five days, followed by a five-day observation as a recovery period before analyzing the treated sites for bacterial growth. The results showed that both 5% and 10% Nu-3 gels inhibited MRSA growth, with the BID regimen outperforming the QD regimen.



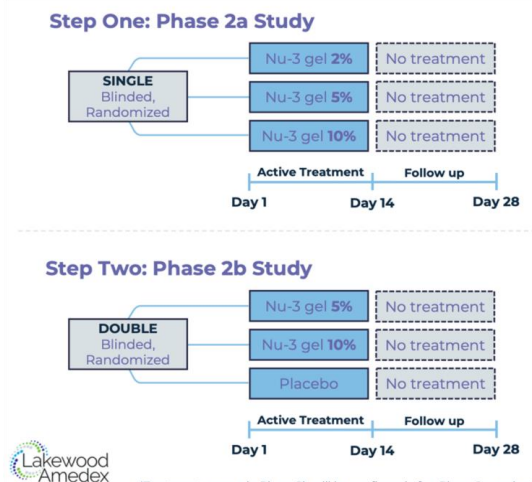
Source: Lakewood-Amedex Biotherapeutics, Inc.

- Porcine Toxicology Model

A porcine toxicology study was conducted to evaluate the effects of Nu-3 gel (up to 20%) on normal wound healing. Treatment was conducted for up to two weeks at concentrations well in excess of what will be evaluated in the clinic. There were no adverse effects on normal wound healing and no skin sensitization was seen.

Planned Phase 2b Trial

Lakewood-Amedex has designed a Phase 2 clinical trial to study Nu-3 in patients with iDFUs ([NCT06020235](#)). It will be a double blind, placebo controlled study that will test both 5% and 10% Nu-3 gel formulations. Participants will be non-hospitalized, diabetic patients with signs of a localized, mild foot infection who will be treated once or twice daily for 14 days. The primary outcomes of the study will be safety and efficacy, as measured by a reduction in CFUs ≥ 2 logs per pathogen identified at Day 7 and Day 14 compared to Day 0. Exploratory outcome measures will include wound size reduction and change in DFI score. Prior to the Phase 2b trial, Lakewood-Amedex will conduct a small dose-ranging Phase 2a study ([NCT07565506](#)) to establish a dose response curve using 2%, 5%, and 10% Nu-3 gel, with all other protocol components the same as the proposed Phase 2b trial.



Source: Lakewood-Amedex Biotherapeutics, Inc.

Platform Expansion Opportunities

While iDFUs represent Lakewood-Amedex's lead development program, management believes the broader Bisphosphocin platform may be applicable across multiple localized infectious disease settings. Beyond dermatologic infections, the company is advancing preclinical research in catheter-associated urinary tract infections (CAUTI) and pulmonary infections, two areas characterized by high rates of antimicrobial resistance, recurrent infection, and substantial healthcare costs.

A key advantage of the Bisphosphocin platform is its suitability for local administration directly at the site of infection. Similar to the rationale underlying Nu-3 gel in iDFUs, localized delivery may permit high antimicrobial concentrations at the site of disease while limiting systemic exposure and potentially reducing systemic adverse effects. Management believes this approach may be particularly attractive in bladder and pulmonary infections where direct administration through a catheter or nebulizer is feasible.

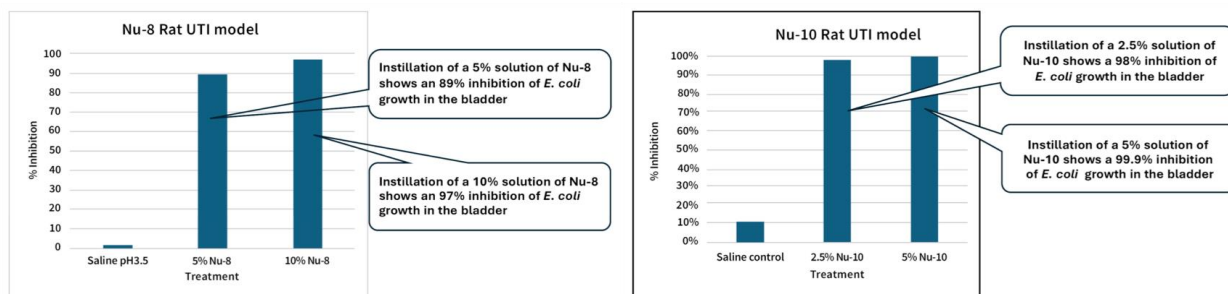
Catheter-Associated Urinary Tract Infections (CAUTI)

CAUTI are one of the most common healthcare-associated infections and remains a significant source of morbidity, healthcare utilization, and antibiotic consumption. There are an estimated one million cases annually in the U.S. ([Foxman, 2010](#)). The longer an individual is catheterized, the more likely they are to develop CAUTI with the risk increasing approximately 3-7% daily ([Nicolle, 2014](#)). Estimated annual U.S. healthcare expenditures attributable to CAUTI range from \$115 million to \$1.8 billion ([Umscheid et al., 2011](#)).

We believe that targeting CAUTI aligns well with the Bisphosphocin platform.

- 1) CAUTI are frequently associated with drug-resistant organisms and biofilm formation, two areas where Bisphosphocins have demonstrated encouraging preclinical activity. The company has reported broad *in vitro* activity against common urinary pathogens including *E. coli*, *K. pneumoniae*, and *P. aeruginosa*, along with activity against biofilm-forming organism.
- 2) The Bisphosphocin platform can target compounds to different indications based on their pH profile. For example, a compound utilized in the bladder, such as for CAUTI, would need to be formulated at a higher pH (> 3.5), while a compound targeted for the skin could be formulated at a lower pH. Lakewood-Amedex is currently screening its compound library to select the most indication-appropriate candidate to advance in CAUTI.

Lakewood-Amedex has conducted multiple proof-of-concept preclinical studies utilizing infected rat bladders and intravesical administration of Nu-8 and Nu-10. Female Wistar rats were infected with *E. Coli* through a guided sterile catheter on Day 0 and again on Day 1. The rats were then administered placebo, 5% Nu-8, or 10% Nu-8 solution for a duration of 30 minutes. The following graph on the left shows that both 5% and 10% Nu-8 solutions inhibited bacterial growth in the bladder compared to the vehicle control group. Similar results were seen with 2.5% and 5% Nu-10 solutions, as shown in the graph on the right. Importantly, all animals appeared to be in good health throughout the study. The company is planning to conduct additional experiments with these and other Bisphosphocin compounds in order to select the most appropriate to move into IND-enabling studies.

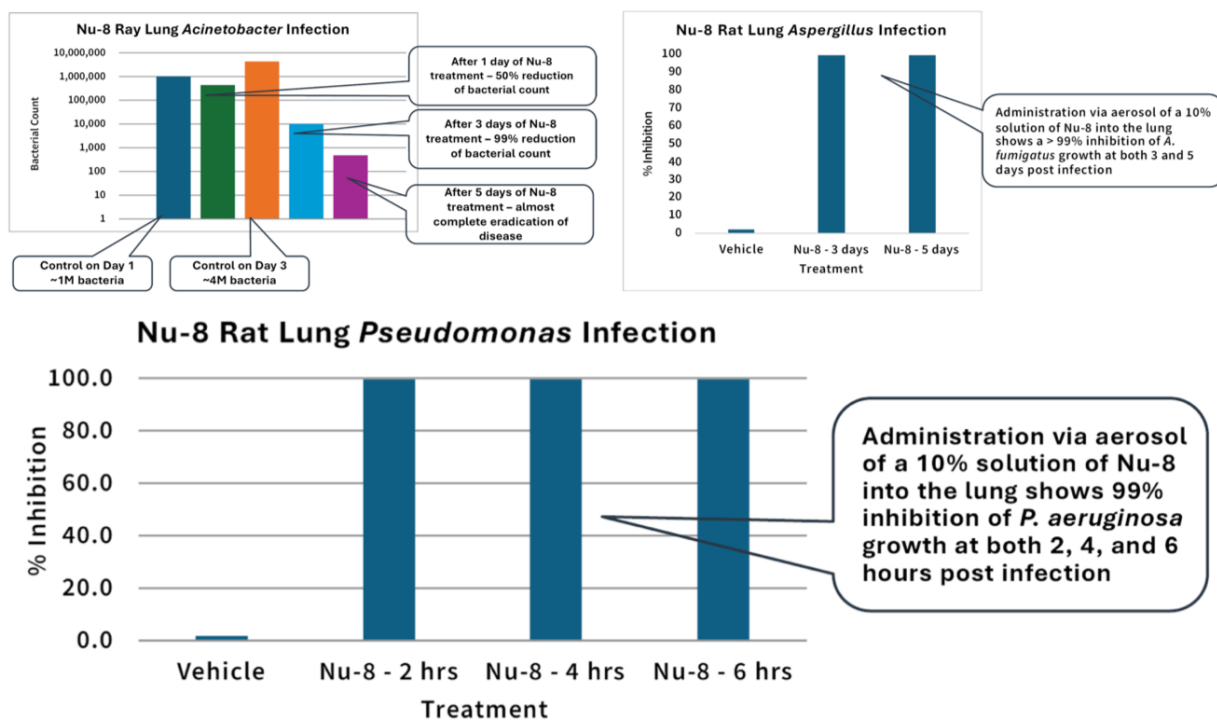


Source: Lakewood-Amedex Biotherapeutics, Inc.

Pulmonary

Lakewood-Amedex is also exploring development opportunities in pulmonary infections, including community-acquired pneumonia (CABP), hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), and chronic pulmonary infections associated with cystic fibrosis (CF). These indications are frequently complicated by multidrug-resistant pathogens such as *P. aeruginosa* and Enterobacteriales species such as *K. pneumoniae* and *E. coli* (Zilderberg et al., 2022). Historical AHRQ analyses estimated approximately \$10 billion in annual hospital costs associated with pneumonia, while more recent claims-based studies continue to demonstrate substantial healthcare utilization and hospitalization expenses associated with the disease (OHS).

The company has conducted early-stage preclinical testing with Nu-8 in an aerosolized formulation that allows for direct administration to the lungs. For these experiments, mice were infected intranasally with either *Acinetobacter*, *Aspergillus*, or *Pseudomonas* and 24 hours post-infection were treated intranasally with Nu-8 (10% nebulized for twenty minutes, twice). For the *Pseudomonas* model, animals were terminated at 2-, 4-, and 6-hours post treatment and the lungs were collected to determine the bacterial load. For the *Acinetobacter* and *Aspergillus* models, the animals were terminated on Day 3 and Day 5 post-treatment to examine bacterial loads in the lungs. The results show that Nu-8 successfully inhibited the growth of all three bacterial species tested in the lungs. The company is continuing to evaluate Nu-8 and other Bisphosphocin compounds in preclinical studies in order to select the most appropriate candidate to take forward into IND-enabling testing.



Source: Lakewood-Amedex Biotherapeutics, Inc.

Intellectual Property

Lakewood-Amedex has built a substantial intellectual property estate around its Bisphosphocin platform, which management believes provides protection for both its lead clinical candidate, Nu-3, and its broader pipeline of next-generation compounds. As of the January 2026 S-1 filing, the company reported a portfolio consisting of 97 patents and patent applications, including 68 issued patents and 29 pending applications, spanning major pharmaceutical markets worldwide. Recent patent issuances have increased the portfolio to 99 patents comprising 71 issued patents and 28 pending applications.

Importantly, Lakewood's patent portfolio extends beyond a single product and covers multiple layers of protection. The estate includes composition-of-matter patents directed to Bisphosphocin compounds, formulation patents covering Nu-3 gel, method-of-use patents, and manufacturing process patents. This multi-pronged approach is designed to provide protection not only for specific compounds but also for their formulations, therapeutic applications, and methods of production.

The company's lead asset, Nu-3, is protected by a U.S. patent covering Bisphosphocin gel formulations and their therapeutic uses, with an anticipated expiration date of June 2038. Additional pending applications covering Nu-3 formulations have been filed across multiple international jurisdictions.

Beyond Nu-3, Lakewood-Amedex has established a broad global patent position around its next-generation Bisphosphocin compounds, including Nu-8, Nu-10, and Nu-11. Issued patents covering antimicrobial compounds, compositions, and uses thereof have been granted in numerous jurisdictions, including the United States, Europe, China, Japan, India, Brazil, Australia, South Korea, Mexico, and New Zealand, generally providing protection through at least 2038.

The company has continued to expand its estate through newer filings directed at manufacturing methods, antiviral applications, and additional compound classes. Notably, patent applications covering synthesis methods for Nu-3 and Nu-8 and antiviral uses of Bisphosphocin compounds could extend protection into 2043, while management states that its most recent patent applications have the potential to provide exclusivity through 2044 if ultimately granted.

We view the intellectual property portfolio as one of Lakewood-Amedex's more attractive assets. Anti-infective companies frequently struggle to establish durable competitive advantages because generic competition can emerge rapidly following patent expiration. In contrast, Lakewood's portfolio combines composition-of-matter, formulation, use, and process claims across multiple generations of compounds and across major commercial markets. Assuming successful prosecution of pending applications, the company appears positioned to maintain meaningful intellectual property protection for its core Bisphosphocin platform for at least the next decade and potentially substantially longer.

Patent Family / Technology	Coverage	Key Assets	Geographic Scope	Expected Expiration*
Bisphosphocin® Antimicrobial Compounds	Composition-of-matter patents covering core Bisphosphocin molecules and derivatives	Nu-8, Nu-10, Nu-11 and related compounds	U.S., Europe, China, Japan, India, Brazil, Australia, South Korea, Mexico, New Zealand and other jurisdictions	Through 2038+
Nu-3 Gel Formulation	Formulations and therapeutic use of Bisphosphocin gels for topical administration	Nu-3	U.S. and international filings	June 2038
Methods of Use	Treatment of bacterial, fungal and other infectious diseases using Bisphosphocin compounds	Multiple Bisphosphocin candidates	Global patent portfolio	Through 2038+
Manufacturing & Synthesis Processes	Proprietary methods for producing Bisphosphocin compounds	Nu-3, Nu-8 and related compounds	Pending international applications	Potential protection through 2043
Antiviral Applications	Use of Bisphosphocin compounds against viral pathogens	Platform-wide applications	Pending applications	Potential protection through 2043
Next-Generation Platform Expansion	Additional compounds, formulations and therapeutic applications under development	Future Bisphosphocin candidates	Pending applications in major markets	Potential protection through 2044

*Expiration dates are based on issued patents and management's estimates for pending applications as disclosed in the S-1
Sources: Lakewood-Amedex Biotherapeutics, Inc.; Zacks SCR

Financials and Capital Structure

In May 2026, Lakewood-Amedex filed form 10-Q with financial results for the first quarter of 2026. As expected, the company did not report any revenues for the first quarter of 2026. R&D expenses for the three months ending March 31, 2026 were \$182,000 compared to \$170,000 for the three months ending March 31, 2025. The increase was primarily due to increased workforce-related expenses partially offset decreased stock-based compensation and lower clinical expenses. G&A expenses for the first quarter of 2026 were approximately \$703,000 compared to \$372,000 for the first quarter of 2025. The increase was primarily due to increased professional fees and investor relations expenses.

As of March 31, 2026, Lakewood had approximately \$11,700 in cash and cash equivalents. In April 2026, the company received net proceeds of approximately \$6.8 million from a private placement of Series C Convertible Preferred Stock. We estimate the company's current cash position will be sufficient to fund operation through the end of 2026. Following the reverse stock split on June 22, 2026, Lakewood-Amedex has approximately 1.7 million shares outstanding and, when factoring in stock options, warrants, and the Series C Convertible Preferred Stock, a fully diluted share count of 2.8 million.

Risks to Consider

In addition to the risk factors listed below, investors are encouraged to read the company's most recent S-1 and 10-Q filing that discusses additional risk factors.

Development Risk: Lakewood-Amedex remains an early-stage biotechnology company with no approved products and limited clinical development experience. While the company has generated encouraging preclinical data across multiple Bisphosphocin candidates, its lead asset, Nu-3, has not yet demonstrated efficacy in a controlled Phase 2 or Phase 3 clinical trial. As a result, investors must recognize that the majority of the value proposition remains dependent on the successful translation of preclinical findings into meaningful clinical outcomes. In addition, the Bisphosphocin platform is a novel class of antimicrobial compounds. Although management believes the compounds possess broad-spectrum activity, anti-biofilm properties, and a low propensity for resistance development, these characteristics have not yet been validated in large clinical studies. The company's broader pipeline opportunities, including CAUTI and pulmonary infections, remain at an even earlier stage of development and will require additional candidate selection, formulation optimization, IND-enabling studies, and regulatory review before entering human trials. Failure to demonstrate sufficient efficacy, safety, or manufacturability could materially impair the value of both Nu-3 and the broader Bisphosphocin platform.

Clinical Risk: Clinical development represents the most significant near-term risk for Lakewood-Amedex. The company's investment thesis is heavily dependent upon the successful advancement of Nu-3 for iDFUs, an indication that presents several unique clinical development challenges. Patients with diabetic foot infections frequently exhibit significant variability in wound size, infection severity, glycemic control, vascular status, and standard-of-care treatment practices. These variables can complicate clinical trial design and introduce substantial variability into efficacy outcomes. Demonstrating statistically significant improvements over standard wound care and systemic antibiotic therapy may therefore prove more challenging than preclinical data would suggest. Additionally, while topical administration may reduce systemic toxicity concerns, regulators and clinicians will closely evaluate local tolerability, wound healing outcomes, and any evidence of delayed tissue repair. Because Nu-3 is intended for use in infected wounds, even modest safety concerns could negatively impact physician adoption and regulatory review. The company also faces execution risk associated with patient enrollment, site selection, trial management, and endpoint achievement. Delays in enrollment or unexpected clinical outcomes could significantly extend development timelines and increase capital requirements.

Regulatory Risk: Lakewood-Amedex operates within one of the most heavily regulated sectors of the healthcare industry. The company must obtain regulatory approval from the U.S. Food and Drug Administration (FDA) and potentially other global regulatory agencies before commercializing any Bisphosphocin-based therapy. Although infected diabetic foot ulcers represent a significant unmet

medical need, the regulatory pathway for novel anti-infective products can be complex. The FDA may require additional toxicology studies, manufacturing validation work, or clinical trials beyond those currently anticipated by management. Regulatory agencies could also require longer follow-up periods, larger patient populations, or additional safety monitoring, all of which could increase development costs and delay commercialization. Since Bisphosphocins represent a novel antimicrobial class, regulators may scrutinize manufacturing consistency, resistance development potential, and long-term safety data more extensively than would be required for well-established drug classes. Any regulatory setback, complete response letter, clinical hold, or delay in approval could materially impact the company's valuation.

Commercial Risk: Even if Nu-3 ultimately receives regulatory approval, commercial success is far from guaranteed. The diabetic foot ulcer treatment market is highly competitive and includes established standards of care involving wound debridement, off-loading, advanced wound dressings, and systemic antibiotics. Physicians may be slow to adopt a novel therapy unless compelling clinical data demonstrate superior outcomes, reduced amputations, improved healing rates, or meaningful cost savings. Reimbursement represents another important consideration. Healthcare payors will likely require evidence that Nu-3 provides economic benefits relative to existing treatment approaches. Failure to secure favorable reimbursement could limit adoption regardless of clinical efficacy. The company also faces potential competition from existing wound-care products, topical anti-infectives, advanced biologics, and future therapies currently in development. Larger competitors may possess greater commercial resources, broader sales infrastructure, and stronger relationships with physicians and healthcare systems. More broadly, antimicrobial products have historically faced commercialization challenges due to stewardship programs designed to limit unnecessary antimicrobial use. While Nu-3's localized delivery approach may partially mitigate this risk, commercial adoption remains uncertain until robust clinical and pharmacoeconomic data become available.

Financing Risk: Lakewood-Amedex has historically generated operating losses and is expected to continue incurring significant expenses as it advances Nu-3 through clinical development. The company has not yet generated meaningful product revenue and remains dependent upon external financing to support operations. Clinical development, regulatory submissions, manufacturing scale-up, and potential commercialization activities will require substantial capital. Management expects that additional equity offerings, debt financings, strategic partnerships, grant funding, or other sources of capital may be necessary to support future operations. There can be no assurance that additional financing will be available on favorable terms, or at all. Future equity financings could result in significant shareholder dilution, while debt financing could introduce additional financial obligations and restrictions. Should capital markets become less receptive to early-stage biotechnology companies, Lakewood-Amedex could be forced to delay development programs, reduce operating activities, or pursue strategic alternatives.

MANAGEMENT PROFILES

Kelvin Cooper, PhD – Chief Executive Officer, Director

Dr. Cooper is a seasoned pharmaceutical scientist and executive with more than 45 years of experience in all aspects of drug discovery and development across several therapeutic areas including infectious disease, cancer, respiratory, immunology, and inflammation. Before joining Lakewood-Amedex, Kelvin filled several roles at Pfizer from 1981 to 2011, including Senior Vice President for Portfolio Development in their Established Pharmaceutical Sciences Business Unit from 2009 to 2011; Senior Vice President of Worldwide Pharmaceutical Sciences with responsibility for both small molecules and biologics in the areas of drug substance, drug product, and device development from 2000 to 2008; Executive Director of drug development for cancer, respiratory, allergy, immunology, and infectious disease from 1998 to 2000; and Director of Drug Discovery in those same therapeutic areas 1994-1997. Dr. Cooper earned a Ph.D. in Organic Chemistry from the University of Nottingham and is a past recipient of the Captain Black Award for Science. He has also authored 50 publications and holds 36 patents.

Thomas Balzer, MD, PhD – Chief Medical Officer

Dr. Balzer is an accomplished international healthcare professional with extensive experience in Clinical Drug Development and Medical Affairs. In his most recent position, Dr. Balzer was Head of Clinical Development at Thrive Detect, an Exact Sciences Company, and was leading the development of a multi-cancer detection liquid biopsy assay. Dr. Balzer worked for more than 25 years in various positions at Bayer HealthCare and served as Vice President and Global Head of Medical Affairs & Clinical Development Radiology at Bayer U.S. in NJ with responsibility for Bayer's medical imaging business. This included pharmaceuticals (contrast media), medical devices, and informatics/ AI projects. Dr. Balzer also built, developed, and managed teams at different locations worldwide and completed four global clinical development programs/ NDAs as well as several additional indication expansions, which were all successful in achieving approval. Dr. Balzer attended medical school in Berlin, Germany, and conducted his residency at the Benjamin Franklin Hospital of the Free University Berlin. He is board-certified in Germany in Internal Medicine, and he earned his Ph.D. from the Free University for work in neuro-endocrine pharmacology. Dr. Balzer's scientific work has been published in more than 60 peer-reviewed articles and several book chapters.

Peter F. Ceccacci – Chief Financial Officer

Mr. Ceccacci joined Lakewood-Amedex in 2009, bringing a wealth of financial management leadership expertise with him. Before joining Lakewood-Amedex, Mr. Ceccacci had an extensive career in public accounting with nearly 20 years spent as a Partner at several firms. He has also served as the CFO of a technology company and has more than 15 years of experience in both the life sciences and technology sectors. Mr. Ceccacci is an accomplished senior executive with comprehensive experience in accounting, finance, information systems, strategy, compliance, and management. Skilled in analytics, financial reporting, budgeting, and projection modeling, Mr. Ceccacci brings a strategically astute and results-driven business acumen to the company's executive leadership team. Mr. Ceccacci earned a Bachelor of Science degree in Accounting from Susquehanna University.

VALUATION

We are initiating coverage of Lakewood-Amedex Biotherapeutics, Inc. (LABT) with a valuation of \$12.00. Lakewood-Amedex is a clinical-stage biopharmaceutical company developing a novel class of antimicrobial compounds known as Bisphosphocins[®], a proprietary platform designed to address one of the largest and fastest-growing challenges in modern healthcare: antimicrobial resistance (AMR). The company's lead clinical candidate, Nu-3, is being developed for the treatment of infected diabetic foot ulcers (iDFU), an indication affecting millions of patients worldwide and one that continues to suffer from limited treatment innovation despite significant clinical and economic burden. If clinical efficacy is demonstrated, Nu-3 has the potential to offer a differentiated approach through direct local delivery of a broad-spectrum antimicrobial agent capable of targeting both susceptible and resistant pathogens while minimizing systemic exposure.

Nu-3 in DFU

Rather than targeting bacterial DNA replication, protein synthesis, cell wall biosynthesis, or other classical intracellular pathways, Bisphosphocins were developed to exert antimicrobial activity primarily through rapid disruption of bacterial membrane integrity, producing bactericidal effects through a mechanism fundamentally distinct from many traditional antibiotic classes.

Lakewood-Amedex's lead compound, Nu-3, is being developed as a gel formulation for the treatment of iDFU. The company has aligned with the FDA on a protocol for a Phase 2b study, however a smaller Phase 2a study will be conducted first to establish initial proof-of-concept in patients before moving on to the larger Phase 2b study. We anticipate the Phase 2a trial initiating in the second half of 2026. The company has amassed a wealth of preclinical data supporting the use of Nu-3 in DFUs, including:

- Broad Activity Against DFU Pathogens
Preclinical studies show that Nu-3 exhibits broad activity against a wide range of bacterial pathogens that can cause infection in DFUs. Of note is that the MIC for the top 10 bacterial isolates from DFU infections is 8 to 50 times below one of the clinical doses to be tested (10% gel – 100 mg/mL).
- Single-Dose Murine Skin Infection Model
A MRSA infection was introduced to skin abrasions on mice and allowed to establish for four hours before applying placebo, 10% Nu-3 solution, or 10% Nu-3 gel. The results showed that the Nu-3 10% gel inhibited bacterial growth up to 8 hours, while the Nu-3 10% solution only inhibited growth for the first two hours, thus showcasing the advantage of the gel formulation.
- Porcine Toxicology Model
A porcine toxicology study was conducted to evaluate the effects of Nu-3 gel (up to 20%) on normal wound healing. Treatment was conducted for up to two weeks at concentrations well in excess of what will be evaluated in the clinic. There were no adverse effects on normal wound healing and no skin sensitization was seen.

Valuation

We value Lakewood-Amedex using a probability-adjusted discounted cash flow (DCF) model that takes into account potential future revenues for Nu-3 in iDFU, which represents the most advanced asset in the pipeline, along with a modest value assigned to the broader Bisphosphocin platform to reflect the optionality associated with the company's preclinical CAUTI and pulmonary infection programs.

Diabetes continues to be one of the fastest-growing chronic diseases worldwide, with approximately 590 million adults globally currently living the disease, including approximately 38 million in the U.S. and over

60 million across the five largest E.U. pharmaceutical markets (France, Germany, Italy, Spain, and the U.K.) (International Diabetes Federation). A substantial proportion of diabetic patients develop foot ulcers and published reports indicate that up to 50% of those ultimately end up becoming infected. Thus, we estimate that there are approximately one million infected diabetic foot ulcers in the U.S. each year with a significantly larger opportunity globally.

Infected DFUs represent a significant unmet medical need due to the combination of bacterial infection, impaired wound healing, recurrent disease, hospitalization risk, and the potential risk of amputation. We believe these characteristics support a premium-priced product capable of delivering both antimicrobial activity and improved clinical outcomes.

We anticipate the Phase 2a trial of Nu-3 being conducted in 2026 followed by a larger Phase 2b trial in 2027. Assuming successful clinical development, we model a partner-sponsored Phase 3 program beginning in 2029 and extending into 2030 with the potential for regulatory approval in 2031. We believe a \$1,500 treatment-course price is reasonable when compared with advanced wound-care products currently used in DFUs. Importantly, unlike wound-healing products such as Regranex®, Nu-3 is being developed specifically for infected DFUs, potentially positioning the product to address both infection management and wound healing within a patient population at elevated risk of hospitalization and amputation.

We currently model for direct commercialization in the U.S. and partnership-based commercialization internationally. We estimate peak revenues of approximately \$500 million and \$300 million seven years after launch in the U.S. and E.U., respectively. Using a 25% probability of success and a 12% discount rate leads to a net present value for Nu-3 in iDFU of \$97 million.

While Nu-3 represents the primary driver of value today, we believe the Bisphosphocin platform possesses strategic importance beyond the lead compound. The company has generated encouraging preclinical data in catheter-associated urinary tract infections (CAUTI), pulmonary infections, and additional localized infections disease settings. While we do not assign indication-specific valuations, we assign the platform a value of \$25 million to reflect future development optionality.

Combining the net present value for Nu-3 in iDFU, the platform, and the company's current cash position leads to a net present value for Lakewood-Amedex of \$130 million. Dividing by the fully diluted share count (approximately 2.8 million) plus an additional 8 million shares to account for additional financings leads to a valuation of \$12 per share.

PROJECTED FINANCIALS

Lakewood-Amedex Biotherapeutics	2025 A	Q1 A	Q2 E	Q3 E	Q4 E	2026 E	2027 E	2028 E
Nu-3	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Bisphosphocin Candidate	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
License and other revenues	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Total Revenues	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Cost of revenues	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Research & development	\$1.3	\$0.2	\$0.3	\$0.3	\$0.3	\$1.1	\$3.0	\$4.0
General & administrative	\$2.5	\$0.7	\$0.8	\$0.8	\$0.9	\$3.2	\$3.5	\$4.0
Depreciation	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Operating Income	(\$3.8)	(\$0.9)	(\$1.1)	(\$1.1)	(\$1.2)	(\$4.3)	(\$6.5)	(\$8.0)
Non-Operating Expenses (Net)	(\$0.1)	(\$0.0)	(\$0.0)	(\$0.0)	(\$0.0)	(\$0.1)	(\$0.1)	(\$0.1)
Pre-Tax Income	(\$3.8)	(\$0.9)	(\$1.1)	(\$1.1)	(\$1.2)	(\$4.4)	(\$6.6)	(\$8.1)
Income Taxes	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Net Income	(\$3.8)	(\$0.9)	(\$1.1)	(\$1.1)	(\$1.2)	(\$4.4)	(\$6.6)	(\$8.1)
Reported EPS	(\$5.53)	(\$1.32)	(\$0.65)	(\$0.56)	(\$0.48)	(\$2.52)	(\$1.32)	(\$1.16)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Basic Shares Outstanding	0.7	0.7	1.7	2.0	2.5	1.7	5.0	7.0

Source: Zacks Investment Research, Inc.

David Bautz, PhD

HISTORICAL STOCK PRICE

Lakewood-Amedex Biotherapeutics Inc (LABT)

3.6500 +3.2639 (+845.35%) 06/22/26 [NASDAQ]

3.6500 x 300 4.0000 x 100 PRE-MARKET 3.7800 +0.1300 (+3.56%) 07:52 ET

CHART for Mon, Jun 22nd, 2026

Full Screen Chart ↗

Notes My Charts Alerts Watch Actions Help

Symbol... Daily 6-Month Indicators Compare f(x) 1x1

Extended Hrs Real-Time Templates



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