IGEM Grant Report

☐ Progress (due January 1) ☐ Annual (due July 31) **X** Final (due August 31)

IGEM Grant # ___**IGEM25-002**_____ Principal Investigator_____**Tinker**_____

Submission Date_____**8-28-25**_____ Primary Institution_**Boise State University**__

*Instructions: Complete each section of this report directly on this template. Completed reports must be limited to **1 page for Progress Reports and 2 pages for Annual or Final Reports in 12 pt Arial or similar font**, excluding the expenditure report. Simple and concise answers will be appreciated, and even bullet lists of information will be sufficient. Reports that do not follow these requirements will be returned for revision. Submit reports by the appropriate due date to HERC@edu.idaho.gov.*

Section 1: Summary of project accomplishments for the reporting period

Objective 1: Determine the stability and antigen-delivery capacity of *S. aureus IsdA+ClfA-CTA2/B* dissolvable microneedles.

- Silk and sugar microneedles (MN) containing vaccine were successfully constructed and assessed for structure using electron and digital microscopy
- Silk and sugar MN were tested for mechanical stability including force-displacement and puncture testing, and found to be resistant to relevant forces and consistently puncture to 260nm.
- A fluorescent CTA2/B fusion was produced to assess delivery using sugar MN. MN patches were found to successfully deliver this protein into pig skin as determined by confocal microscopy.
- Vaccine deposition into pig skin of was determined using immunohistochemistry. Sugar MN were found to successfully deposit antigen into pig dermal layer. Quantification of deposition was performed using analytical microscopy.

Objective 2: Assess MN *IsdA+ClfA-CTA2/B* immunogenicity in mice.

- A 28 day mouse vaccine immunogenicity study was completed using sugar MN. Analysis of antigen-specific responses in the blood on Day 28 showed no difference between CTA2/B adjuvant control and vaccine-loaded MN. T-cell stimulation assays also indicated no difference between vaccine-loaded and adjuvant only control MN responses in mice.
- Analysis of removed patches from mice using microscopy indicated that only partial insertion and dissolution of sugar microneedles occurred.
- The challenge study (Objective 2A) was not performed as a result of immunogenicity outcomes.
- A modified immunogenicity study was performed. Outcomes using fluorescent dye indicated improved placement with good MN dissolution after 20 min. Skin cells were isolated and assessed for type recruited to MN site after 48 hrs. Results showed no significant increase in infiltration of immune cells in MN patch, however sample size was small (n=2).

Section 2: High-level summary of budget expenditures for the period. A re-budget was performed on 9/30/24 due to the loss of hired Research Technician to another position, and a need to hire multiple students to complete objectives. This resulted in a decrease in salary costs including a substantial decrease in Fringe that was directed instead to student costs (OE). Animal studies (Objective 2) were performed in the spring

of 2025 and occurred with the help of multiple students and the Co-PI, resulting in expenditure of all but 8.87% of original budget.

Section 3: Demonstration of economic development/impact.
Industry involvement/private sector engagement. Dr. Tinker is a co-founder of Pentamer Biologics, LLC. (CEO, B. Allinson), a start-up company that has a cooperative agreement with Boise State for use of a family of related patents (*Cholera toxin and its use as a staph vaccine, U.S. #8,834,898 Tinker*). This start-up has been successful obtaining a Phase I USDA STTR for development of a bovine vaccine. Pilot IGEM-HERC funding supported Pentamer Biologics through the acquisition of essential preliminary data for a human vaccine to pursue NIH and DoD small business funding.
Economic development via jobs created. In addition to jobs for undergraduate students created directly, funding supported two temporary research technicians and indirectly supported a post-doctoral fellow (E. Overgaard) employed by Pentamer Biologics.
Grants: This funding was synergistic with an NSF TRANSFORM seed grant (current), and provided preliminary data for a Rocky Mountain REACH application (submitted June 2025). A USDA STTR Phase II and NIH STTR Phase I will be submitted in collaboration with Pentamer Biologics (Sept 23, 2025, and planned Jan 5, 2026).
Technology transfer: An invention disclosure for methods related to dissolvable silk/sugar microneedles, and a related disclosure for a third antigen (NSF TRANSFORM) are planned for the fall 2025.

Section 4: Number of faculty and student participants as a result of funding, and brief description of student efforts.
Faculty/staff participation: Funding supported the salaries of the PI (J. Tinker, 0.75 mth) and Co-PI (S. Theodossiou, 0.75 mth), as well as a Research Technician (D. Pica, 1 mth).
Student participation: Two PhD students, one MS student and three undergraduate students were directly supported. Major accomplishments included a successful Ph.D. dissertation defense (H. Bridgewater, Dec'24), a successful MS thesis defense (H. Hedelius, June'25), and submission of manuscript during this project period (*Dissolvable microneedles to deliver cholera toxin B-adjuvanted protein subunits to the skin, Science Advances, submitted Dec 7, 2024, rejected Dec 24, 2024, to be resubmitted, Oct 2025*). A student in the Co-PIs laboratory was also indirectly supported on this project as a major component of an ME thesis (B. Penney, expected graduation Dec'25).

Section 5 : Updated details and/or progress on the long-term sustainability plan for the project and description of future plans for project continuation or expansion. Sugar and silk microneedles containing *Staphylococcus* vaccine antigens were found to be stable, reproducible and effective to deliver vaccine to pig skin, as determined by microscopy. Despite these outcomes, sugar microneedles did not successfully stimulate antigen-specific responses in mice. Reasons for this may include: incomplete insertion into skin and antigen instability in the skin. Funding was pivotal however as key methods were developed and areas for improvement identified, including: vaccine incorporation into microneedles, animal vaccination protocols and skin cell isolation. Data obtained will support the resubmission of a well-scored NIH STTR Phase I proposal and technology transfer to Pentamer Biologics.

Section 6: Expenditure Report – Attach an expenditure report as a separate document showing expenses toward the original budget submitted for this project.

(see attached)

Reporting period:7/1/24-6/30/25

Category	Original budget	Budgeted (re-budget)	Spent	+/-	%remaining
Salary	$97,700.00	$113,675.60	$100,297.54	$13,378.06	11.77
Fringe	$37,300.00	$8075.00	$8632.34	($557.34)	-6.90
Travel	$3500.00	$0.0	$0.0	$0.0	-
OE (including student costs, capital)	$27,100.00	$43,849.40	$41,980.04	$1869.36	4.26
Totals		**$165,600.00**	**$150,909.92**	**$14,690.08**	**8.87**

Title:	A Microneedle-based Transcutaneous Staphylococcus Aureus	**Start Date:**	7/1/2024	**Projection as of:**	7/25/2025
Award #	3941021	**End Date:**	6/30/2025	**Updated by:**	Brittany Archuleta
Fund		**Budget Period:**	6/30/2025		
Dept		**OSP #**	11613	**PI:**	Juliette Tinker
Cost Center		**Sponsor #**		**Sponsor:**	Idaho State Board of Education (HERC)
Project				**F&A Type and Rate:**	No F&A 0.00%

	Original Budget	PPM Budget	Pending Rebudgets	Life to Date Expenses	Balance	Encumbrance	Available Budget	% Remaining	Burn Rate
Salary	$ 97,700.00	$ 113,675.60		$ -	$ 113,675.60	$ -	**$ 113,675.60**	100.00%	0.00%
Fringe	$ 37,300.00	$ 8,075.00		$ -	$ 8,075.00	$ -	**$ 8,075.00**	100.00%	0.00%
OE	$ 27,100.00	$ 42,849.40		$ (40,980.04)	$ 1,869.36	$ -	**$ 1,869.36**	4.36%	95.64%
Travel	$ 3,500.00	$ -		$ -	$ -	$ -	**$ -**	-	#DIV/0!
Capital	$ -	$ 1,000.00		$ (1,000.00)	$ -		**$ -**	-	100.00%
Subcontracts >25k	$ -	$ -			$ -		**$ -**	-	#DIV/0!
Subcontracts <25k	$ -	$ -			$ -		**$ -**	-	#DIV/0!
Student Costs (OE)	$ -	$ -			$ -		**$ -**	-	#DIV/0!
Total Direct	$ 165,600.00	$ 165,600.00	$ -	$ (41,980.04)	$ 123,619.96	$ -	**$ 123,619.96**		
F&A	$ -	$ -			$ -	$ -	**$ -**		-
			$ -						
Totals	$ 165,600.00	$ 165,600.00		$ (41,980.04)	$ 123,619.96		**$ 123,619.96**		
			AAR Amount	$ 150,909.92					
			Variance	$ 108,929.88					

Timeline Burn Rate:	116.21%
Current Burn Rate:	25.35%