

**REPORT/RECOMMENDATION TO THE BOARD OF SUPERVISORS
OF SAN BERNARDINO COUNTY
AND RECORD OF ACTION**

September 23, 2025

FROM

ANDREW GOLDFRACH, ARMC Chief Executive Officer, Arrowhead Regional Medical Center

SUBJECT

Revenue Clinical Trial Agreement with Aveera Medical, Inc. for a Study

RECOMMENDATION(S)

Approve a Revenue Clinical Trial **Agreement No. 25-753** with Aveera Medical, Inc., including non-standard terms, for participation in the Pivotal Multi-center Trial of the Boomerang Catheter for Percutaneous Deep Vein Arterialization study, effective upon execution and continuing until completion of study-related activities.

(Presenter: Andrew Goldfrach, ARMC Chief Executive Officer, 580-6150)

COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

Provide for the Safety, Health and Social Service Needs of County Residents.

FINANCIAL IMPACT

Approval of this item will not result in the use of Discretionary General Funding (Net County Cost) as this Clinical Trial Agreement (Agreement) with Aveera Medical, Inc. (Aveera) is a revenue-generating agreement. Depending on the number of participants and the durations of each visit, Arrowhead Regional Medical Center (ARMC) will receive revenue ranging from \$300-\$650 and up to \$7,000 for initiating the study and International Review Board (IRB). ARMC is expected to receive sponsor payments over the term of the study, based on anticipated patient enrollment.

BACKGROUND INFORMATION

The Agreement with the Aveera will enable ARMC to participate as the 17th U.S. site in a multicenter clinical trial for “Assessing the Safety and Efficacy of the Chronic Limb-Threatening Ischemia (CLTI) Treatment Using the Boomerang™ Catheter”. CLTI is a severe vascular condition caused by inadequate blood flow to the legs and feet, often leading to rest pain, non-healing ulcers, gangrene, and ultimately limb amputation.

The purpose of the clinical trial is to evaluate the safety and effectiveness of the Investigational Boomerang™ Catheter System for a new vascular use in the leg, specifically targeting blockages in arteries behind and below the knee down to small arteries at the joint of the leg and foot. ARMC’s clinical team will perform percutaneous Deep Venous Arterialization (pDVA) for patients with CLTI whose only remaining treatment option is below- or above-knee amputation.

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National enrollment for the study is capped at 120 patients and ARMC expects to have 39 applications. Participation positions ARMC as a key research partner in an innovative therapy, offering County residents opportunity to receive a treatment option that might offer significant benefit when other options are limited.

Approval of the Agreement supports the County's goals by helping ARMC offer a new treatment to patients who have no other viable treatment options. This clinical trial brings advanced medical technology to the hospital and helps improve patient care. The study is paid for by the sponsor, so it does not use County funds, which supports responsible spending. It also helps ARMC work with other medical and research groups, showing the County's commitment to partnerships that benefit public health and government services.

The Agreement with Aveera was negotiated by the parties and deviates from the standard County contract terms as follows:

1. Aveera limits its indemnity obligations to claims arising out of (1) the proper use and administration of the study device in accordance with the study protocol, (2) the negligence, recklessness, or intentional wrongful acts or omissions of Aveera, (3) intellectual property infringement claims from use of the study device, or (4) Aveera's failure to follow applicable laws, but will not extend to claims that arise from the County's conduct.
 - The County standard contract general indemnity provision requires the contractor to indemnify, defend, and hold County harmless from third-party claims arising out of the acts, errors or omissions of any person.
 - Potential Impact: Aveera's indemnity obligation is more limited compared to the standard County general indemnity obligation. In the event a claim arises that falls outside the scope of Aveera's limited indemnity obligation, the County could be financially responsible for the defense of the claim and any resulting judgment/settlement.
2. The Agreement requires the County to maintain a policy or program of self-insurance to insure its activities under the Agreement with a limit of at least \$1 million per occurrence and \$3 million annual aggregate.
 - The County standard contract does not impose any insurance requirements on the County.
 - Potential Impact: The County will need to be mindful of these contractual insurance requirements to ensure compliance to avoid breaching the County's obligations.
3. The County may terminate this Agreement without cause with at least 90 days written notice.
 - The County standard contract gives the County the right to terminate the contract, for any reason, with a 30-day written notice of termination without any obligation other than to pay amounts for services rendered and expenses reasonably incurred prior to the effective date of termination.
 - Potential Impact: The County will need to be mindful of the extended notice period in the event the County seeks to terminate the Agreement without cause.
4. Venue is in the state or federal courts of California.
 - County Policy 11-05 requires venue for disputes in Superior Court of California, County of San Bernardino, San Bernardino District.

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- Potential Impact: Aveera is located in Orange County, California. In the event that Aveera files a lawsuit in Orange County, the County could incur expenses it may not have had to incur if the lawsuit was venued in the San Bernardino County Superior Court.

ARMC recommends approval of the Agreement, including the non-standard terms, as participation in this clinical trial provides significant patient benefits and advances the health and safety of County residents.

PROCUREMENT

Not applicable.

REVIEW BY OTHERS

This item has been reviewed by County Counsel (Charles Phan, Supervising Deputy County Counsel, 387-5455) on August 14, 2025; Risk Management (Stephanie Pacheco, Staff Analyst II, 386-9039) on August 27, 2025; ARMC Finance (Chen Wu, Budget and Finance Officer, 580-3165) on August 29, 2025; and County Finance and Administration (Jenny Yang, Administrative Analyst, 387-4884) on September 8, 2025.

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Record of Action of the Board of Supervisors
San Bernardino County

APPROVED (CONSENT CALENDAR)

Moved: Joe Baca, Jr. Seconded: Curt Hagman
Ayes: Col. Paul Cook (Ret.), Jesse Armendarez, Dawn Rowe, Curt Hagman, Joe Baca, Jr.

Lynna Monell, CLERK OF THE BOARD

BY 
DATED: September 23, 2025



cc: ARMC - Goldfrach w/agree
Contractor - c/o ARMC w/agree
File - w/agree
CCM 09/25/2025