



## Current Agreements

### Dealdoc

**Contract service agreement for clinical research monitoring services, project management, regulatory document management, and related services**

Hemostemix  
Topstone Research

Sep 26 2017

# Contract service agreement for clinical research monitoring services, project management, regulatory document management, and related services

<b>Companies:</b>	<a href="#">Hemostemix</a> <a href="#">Topstone Research</a>
<b>Announcement date:</b>	Sep 26 2017
<b>Deal value, US\$m:</b>	n/d

- [Details](#)
- [Financials](#)
- [Termsheet](#)
- [Press Release](#)
- [Filing Data](#)
- [Contract](#)

## Details

<b>Announcement date:</b>	Sep 26 2017
<b>Industry sectors:</b>	Biotech Services
<b>Asset type:</b>	Business
<b>Therapy areas:</b>	Cardiovascular » Limb ischemia
<b>Technology types:</b>	Clinical testing
<b>Deal components:</b>	Contract service
<b>Stages of development:</b>	Phase II

## Financials

<b>Deal value, US\$m:</b>	n/d
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## Termsheet

Hemostemix has engaged Topstone Research to provide clinical research monitoring services, project management, regulatory document management, and related services to advance the Company's international, multicenter, Phase II clinical trial for patients with critical limb ischemia (CLI).

## Press Release

Hemostemix Announces Agreement With CRO Service Provider Topstone Research

BLACKFALDS, Alberta, Sept. 26, 2017 (GLOBE NEWSWIRE) -- Hemostemix Inc. ("Hemostemix" or the "Company") (TSX VENTURE:HEM) is pleased to announce it has engaged Topstone Research Inc. ("Topstone") to provide clinical research monitoring services, project management, regulatory document management, and related services to advance the Company's international, multicenter, Phase II clinical trial for patients with critical limb ischemia (CLI). Topstone, is a Toronto, Ontario based global full-service contract research organization ("CRO") service provider.

Spanning across multiple therapeutic areas of experience, Topstone develops inventive approaches designed to continually improve clinical research and meet the specific study needs of its clients. Putting the patient at the forefront, Topstone takes a patient-centered approach to recruitment and conduct of clinical trials and has developed efficient ways to identify, target, recruit and retain participants.

Beginning with its engagement of Drive Capital, management of the Company has been actively reviewing and evaluating proposals from various CROs with the goal of being prepared to re-start the Company's CLI trial. With the engagement of Topstone, the Company now expects to be able to do so in an effective and efficient manner.

The CLI trial will continue to be a randomized, placebo-controlled, double blind phase 2 clinical trial to confirm the safety and efficacy of the Company's lead product, ACP-01, a proprietary stem-cell therapy derived from a patient's own blood.

Under the current approved protocols of the Food and Drug Administration of the United States Department of Health and Human Services (the "FDA") and Health Canada, the study is designed to assess the efficacy of ACP-01, particularly with respect to the study's placebo arm. It is anticipated that an interim analysis will reinforce the safety record of the therapy, as shown in previous Phase I trials, and provide a clear view of the effectiveness of the therapy. In advance of completing the Phase II trial, the ACP-01 therapy may be made available through partnerships via the "right-to-try" law enacted recently in Texas, USA.

In the USA and Europe combined, it is estimated that 5-6 million people suffer from critical limb ischemia (CLI) associated with peripheral artery diseases (PAD). CLI is the most severe and deadliest form of PAD. In 2015, almost 20 million citizens of the United States suffered from PAD. CLI is characterized by narrowing and hardening of the arteries in the patient's limb(s) caused and/or aggravated by diabetes, Buerger's Disease, other diseases and smoking. With decreased blood flow to the affected extremity, patients can suffer a host of complications including nerve and tissue damage. In advanced stages, limb ischemia can lead to gangrene, which often requires treatment with amputation. The disease is associated with a high rate of mortality and the need for frequent hospitalization from surgical complications.

Kyle Makofka, Chief Restructuring Officer commented, "We are very excited about being in a position to work with Topstone and to re-start the Company's CLI trial. We considered a wide range of potential partners for this project and Topstone demonstrated the capability not only to ensure the highest standards of quality, but also an ongoing commitment to ensure the most efficient methods are consistently used and to understand our product, needs and timelines. CLI is a debilitating disease which frequently results in loss of limbs and lives. Our therapy aims to save patients from amputation and provide a better quality of life."

#### ABOUT HEMOSTEMIX INC.

Hemostemix is a public clinical-stage biotechnology company that develops and commercializes innovative blood-derived cell therapies for medical conditions not adequately addressed by current treatments. It is the first clinical-stage biotech company to test a stem-cell therapy in an international, multicenter, Phase II clinical trial for patients with critical limb ischemia (CLI), a severe form of peripheral artery disease (PAD) caused by reduced blood flow to the legs. The Phase II trial targets a participant's diseased tissue with proprietary cells grown from his or her blood that can support the formation of new blood vessels.

#### **Filing Data**

*Not available.*

#### **Contract**

*Not available.*