

Dealdoc

Licensing and manufacturing agreement for ACP-01

Hemostemix Aspire Health Science

Feb 23 2018

Licensing and manufacturing agreement for ACP-01

Hemostemix Companies:

Aspire Health Science

Announcement date: Feb 23 2018

Deal value, US\$m: n/d

- **Details**
- **Financials**
- Termsheet
- Press Release
- Filing Data
- Contract

Details

Feb 23 2018 **Announcement date:** Industry sectors: **Biotech** Compound name: ACP-01 **Exclusivity:** Exclusive Asset type: Compound

Cardiovascular

Cardiovascular » Congestive heart failure Therapy areas: Cardiovascular » Coronary artery disease

Cardiovascular » Peripheral arterial disease

Technology types: Small molecules Deal components: Licensing Stages of development: Phase II

North America » Mexico

North America » United States Central America » Costa rica Central America » Panama

South America » Dominican Republic

Financials

Deal value, US\$m: n/d

Geographic focus:

Royalty rates, %: 15 : double digit on net sales

Semi-quant royalties: Double digit

Termsheet

February 2020

Aspire Health Sciences initiated a legal proceeding against Hemostemix regarding Hemostemix's purported rescission of the Amended and Restated License Agreement between Aspire and Hemostemix dated September 30, 2019, which Hemostemix announced in a press release dated December 11, 2019.

December 2019

Hemostemix has rescinded the Amended and Restated License Agreement granted to Aspire Health Science dated September 30, 2019, primarily due to Aspire's failure to meet the Condition Precedent of paying USD\$1,000,000 within 30 business days of September 30, 2019, as noted in the Company's Subsequent Events Note as prepared by previous management for the period ended September 30, 2019. No funds were received by the Company.

The notice of rescission was dated, emailed and couriered to Aspire on December 5, 2019.

Under the terms of Amended and Restated License Agreement of September 30, 2019, if Hemostemix rescinds the Agreement, Hemostemix and Aspire are released and discharged from all obligations of the agreement, except the obligation of confidentiality.

The prior agreement, the License Agreement dated February 15, 2018, is continued following Rescission, providing Aspire with a limited license to ACP-01 for Approved Medical Indications in a defined Territory.

Under the terms of the February 15, 2018 License Agreement, the approved medical indications and the territory are defined as follows: "Approved Medical Indications mean Coronary Artery Disease (CAD), Peripheral Arterial Disease (PAD), Critical Limb Ischemia (CLI).

The Territory means the State of Florida, as well as the Commonwealth of The Bahamas, the Republic of Costa Rica, The Dominican Republic, the United Mexican States and the Republic of Panama."

The Company would like to clarify that previous management allowed the Contract Manufacturing Services Agreement between it and Aspire dated February 15, 2018 to expire on July 31, 2019.

The Company has notified Aspire that it intends to work to mutual benefit on a month-to-month basis to complete the clinical trial and negotiate in good faith to come to terms on a new manufacturing agreement.

February 2018

Hemostemix has finalized the terms of a license agreement with Aspire Health Science for the Company's lead therapeutic product technology, ACP-01.

ACP-01 is currently the subject of a U.S. Food and Drug Administration (FDA) and Health Canada approved Phase II clinical trial for patients with critical limb ischemia (CLI).

The Company also recently finalized the terms of a contract manufacturing services agreement with Aspire, formalizing the transition of the Company's stem cell manufacturing operations from Company owned facilities in Israel to Aspire's Orlando, Florida facilities.

Aspire has the exclusive rights to use, sell and import ACP-01 in The Bahamas, Costa Rica, the Dominican Republic, Mexico, Panama and the State of Florida for the treatment of certain approved medical indications, namely Coronary Artery Disease (CAD), Peripheral Artery Disease (PAD), CLI, Congestive Heart Failure (CHF) and such other indications as may be designated by Hemostemix from time to time.

Aspire will have related rights to manufacture ACP-01 at its Orlando, Florida facilities for such purposes.

Hemostemix will receive double digit on net sales from all revenue generated from ACP-01 in the assigned territories.

The License Agreement has an initial three (3) year term, with options for Hemostemix to renew for additional two (2) year extensions.

Commercialization of ACP-01 for the approved medical indications in the assigned territories, shall be the responsibility of Aspire, and is be conducted in accordance with marketing plans developed or to be developed by Aspire in consultation with Hemostemix.

The marketing plans are to set out a description of the strategies and business plan, including sales forecasts (including quarterly revenue targets), and budgets for promotional investment in ACP-01 with respect to commercialization.

The failure to achieve such minimum revenue targets are related to Hemostemix having a consequential right to terminate the license(s) granted for the assigned territories (or as applicable, in any one or more particular state, provincial, national or similar jurisdiction within the assigned territories on a separate basis).

Hemostemix will continue to maintain control of all aspects of the product(s) subject to the License Agreement (including in particular ACP-01), including manufacturing protocols, intellectual property rights, all improvements in the related technology, as well as the use of the technology and products in terms of specific applications.

In addition to the royalties expected to be received from the ACP-01 trial at the PSCC, in accordance with the License Agreement, Hemostemix will also receive all the pertinent data collected during the trial.

The data collected from the heart patients in particular will be of significant value to Hemostemix as it builds the necessary safety and efficacy data for ACP-01 that will allow the Company to expand into future phased clinical trials in Canada and the United States focused on Congestive Heart Failure (CHF).

Press Release

February 2020

Aspire Health Science files lawsuit against Hemostemix Inc. relating to cancellation of amended and restated licensing agreement

ORLANDO, FL, Feb. 7, 2020 /CNW/ - Aspire Health Sciences, LLC ("Aspire") announces that on January 28, 2020, it initiated a legal proceeding against Hemostemix Inc. ("Hemostemix") regarding Hemostemix's purported rescission of the Amended and Restated License Agreement between Aspire and Hemostemix dated September 30, 2019 (the "Amended License Agreement"), which Hemostemix announced in a press release dated December 11, 2019.

The public filings in the Circuit Court of the Ninth Judicial Circuit (the "Florida Court") in Orange County Florida, including Aspire's complaint alleging breach of the Amended License Agreement and seeking specific performance of same, may be obtained at the following link:

https://myeclerk.myorangeclerk.com/CaseDetails?caseId=11269680&caseIdEnc=mTpDuxwS3GjyQVskVvFNDGxZ8uuh20P%2BEX0F1daPYWMnEimKJef0Vff9n

About Aspire Health Sciences, LLC

Aspire is a private company with an FDA registered manufacturing facility specializing in contract manufacturing and development of Cellular Therapies Under cGMP guidelines.

December 2019

Hemostemix Announces Corporate Update

CALGARY, Alberta, December 11, 2019 — Hemostemix Inc. ("Hemostemix" or the "Company") (TSX VENTURE: HEM; OTC: HMTXF) is pleased to announce the appointment of David Wood to the position of Chairman, Bryson Goodwin to the position of Chief Executive Officer, Thomas Smeenk to the position of President, and Natasha Sever to the position of Chief Financial Officer. Yari Nieken will replace Angus Jenkins, who recently resigned from the Company. Mr. Nieken is an independent director. The Directors appointed the Audit Committee and the Compensation Committee.

Mr. Wood is an independent director of the Company and has a wide range of public company experience. Most recently Mr. Wood sat on the board of directors from 1997 until the completion of its change of business transaction in October 2019 of Black Bull Resources Inc., a former mining company, which is now listed on the TSXV under the name Magnetic North Acquisitions Corp. From 1999 to 2013, Mr. Wood served as a director of Iplayco Corporation Ltd. (TSXV:IPC), a playground equipment designing and manufacturing company, for which he also served as Chairman of the Board from 2008 until 2011. Mr. Wood was a director and former CEO and CFO of DataMiners Capital Corp., a NEX listed company, which completed the reverse take of ZoomD Ltd. in August 2019. Mr. Goodwin is a practiced international executive with extensive experience in finance, management, investor relations and operations with both private and public companies. Bryson's experience has demonstrated an operational, market and banking track record in the technology, biotechnology and resource sectors. Over the course of Mr. Goodwin's career, he has fostered an extensive high profile international association of contacts and close relationships through networking and proficient communication skills building performance driven teams. Mr. Smeenk was the Founder, a Director, President and Vice-President, Business Development for TheraVitae Inc., which was taken over by Hemostemix Inc. as its Qualifying Transaction, Mr. Smeenk is a project finance and business development executive with a proven track record of bringing new discoveries to market. He has been a public company executive since 1996, serving most recently as President & CEO of Broadway Gold Mining Ltd, where he completed a \$30 million agreement with Rio Tinto. He served as Vice-President Business Development for Memex Inc. (TSXV:MEM), a company he took public, President & CEO of e-Manufacturing Networks Inc. (TSXV:OEE), President and CEO of Tyranex Gold Inc. and President and CEO of IBI Corporation, where he made a world class vermiculite discovery, which was subsequently sold to Rio Tinto for \$2,000,000. Ms. Sever is a CPA designated in both Canada and Australia with a BCom from Edith Cowan University. She joins the Company with more than 10 years experience in senior finance roles over a wide range of industries including mining, retail and technology. Ms. Sever has held officer positions at a number of publicly listed companies in both Canada and Australia and has a proven record of working in alignment with, and to the benefit of the Board and associated stakeholders. Her extensive experience with company financings as well as TSX & ASX regulatory compliance will serve to ensure the Company manages its affairs in a transparent and proper fashion. Mr. Nieken has a wide range of public company and capital market experience. He founded Foremost Capital Inc., an exempt market dealer and continues to consult for numerous issuers in the healthcare, mineral extraction and wellness sectors. He has served on the boards of several public and private issuers and has raised substantial capital in his career. He was formerly an investment adviser at Union Securities Corp. Mr. Nieken holds an MBA from the Sydney Graduate School of Management and a BA from the University of British Columbia. The Company announces it has rescinded the Amended and Restated License Agreement granted to Aspire Health Science, LLC ("Aspire") dated September 30, 2019, primarily due to Aspire's failure to meet the Condition Precedent of paying USD\$1,000,000 within 30 business days of September 30, 2019, as noted in the Company's Subsequent Events Note as prepared by previous management for the period ended September 30, 2019. No funds were received by the Company. The notice of rescission was dated, emailed and couriered to Aspire on December 5, 2019. Under the terms of Amended and Restated License Agreement of September 30, 2019, if Hemostemix rescinds the Agreement, Hemostemix and Aspire are released and discharged from all obligations of the agreement, except the obligation of confidentiality. The prior agreement, the License Agreement dated February 15, 2018, is continued following Rescission, providing Aspire with a limited license to ACP-01 for Approved Medical Indications in a defined Territory. Under the terms of the February 15, 2018 License Agreement, the approved medical indications and the territory are defined as follows: "Approved Medical Indications mean Coronary Artery Disease (CAD), Peripheral Arterial Disease (PAD), Critical Limb Ischemia (CLI). The Territory means the State of Florida, as well as the Commonwealth of The Bahamas, the Republic of Costa Rica, The Dominican Republic, the United Mexican States and the Republic of Panama." The Company would like to clarify that previous management allowed the Contract Manufacturing Services Agreement between it and

Aspire dated February 15, 2018 to expire on July 31, 2019. The Company has notified Aspire that it intends to work to mutual benefit on a month-to-month basis to complete the clinical trial and negotiate in good faith to come to terms on a new manufacturing agreement. ABOUT HEMOSTEMIX INC. Hemostemix is a publicly traded clinical-stage biotechnology company that develops and commercializes innovative blood-derived cell therapies for medical conditions not adequately addressed by current treatments. It is one of the first clinical- stage biotech companies 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. The Company's intellectual property portfolio includes over 50 patents issued or pending throughout the world. The Company is continuing research and development of its lead product, ACP-01 with other applications, including cardiovascular, neurological and vascular indications. For more information, please visit www.hemostemix.com. Contact: Bryson Goodwin or Thomas Smeenk, Director, Hemostemix Inc. Suite 1150, 707 – 7th Avenue S.W. Calgary, Alberta T2P 3H6 BG: 604-341-1531 or TS: 905-580-4170 Neither the TSX Venture Exchange nor its Regulation Service Provider (as that term is defined under the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.

February 2018

Hemostemix Signs License Agreement with Aspire Health Science

CALGARY, Alberta, Feb. 23, 2018 (GLOBE NEWSWIRE) -- Hemostemix Inc. ("Hemostemix" or the "Company") (TSX VENTURE:HEM) is pleased to announce it has finalized the terms of a license agreement (the "License Agreement") with Aspire Health Science, LLC ("Aspire") for the Company's lead therapeutic product technology, ACP-01. ACP-01 is currently the subject of a U.S. Food and Drug Administration (FDA) and Health Canada approved Phase II clinical trial for patients with critical limb ischemia (CLI). Aspire is an Orlando, Florida based private company focused on the field of stem cell manufacturing as well as related research and development utilizing state-of-the-art FDA cGMP (Current Good Manufacturing Practices) certified laboratory facilities in Orlando, Florida. As previously announced, the Company also recently finalized the terms of a contract manufacturing services agreement (the "Manufacturing Agreement") with Aspire, formalizing the transition of the Company's stem cell manufacturing operations from Company owned facilities in Israel to Aspire's Orlando, Florida facilities.

Under the terms of the License Agreement, Aspire has the exclusive rights to use, sell and import ACP-01 in The Bahamas, Costa Rica, the Dominican Republic, Mexico, Panama and the State of Florida for the treatment of certain approved medical indications, namely Coronary Artery Disease (CAD), Peripheral Artery Disease (PAD), CLI, Congestive Heart Failure (CHF) and such other indications as may be designated by Hemostemix from time to time. Aspire will have related rights to manufacture ACP-01 at its Orlando, Florida facilities for such purposes. Hemostemix will receive double digit on net sales from all revenue generated from ACP-01 in the assigned territories. The License Agreement has an initial three (3) year term, with options for Hemostemix to renew for additional two (2) year extensions.

Commercialization of ACP-01 for the approved medical indications in the assigned territories, shall be the responsibility of Aspire, and is be conducted in accordance with marketing plans developed or to be developed by Aspire in consultation with Hemostemix. The marketing plans are to set out a description of the strategies and business plan, including sales forecasts (including quarterly revenue targets), and budgets for promotional investment in ACP-01 with respect to commercialization. The failure to achieve such minimum revenue targets are related to Hemostemix having a consequential right to terminate the license(s) granted for the assigned territories (or as applicable, in any one or more particular state, provincial, national or similar jurisdiction within the assigned territories on a separate basis). Hemostemix will continue to maintain control of all aspects of the product(s) subject to the License Agreement (including in particular ACP-01), including manufacturing protocols, intellectual property rights, all improvements in the related technology, as well as the use of the technology and products in terms of specific applications.

Management expects that the License Agreement will allow Hemostemix to begin generating revenue from its technology while it continues with the Phase II CLI trial in Canada and the United States. As a first step towards commercialization under the License Agreement, Aspire is in late stages of negotiating terms with The Partners Stem Cell Centre ("PSCC") operating within The Medical Pavilion Bahamas ("TMPB"), based in Nassau, Bahamas, to complete a Phase I Open Trial, Non-Randomized, Single Center Study at their Nassau facility. TMPB is the brainchild of Dr. Conville S. Brown (now the Chairman, President and CEO of the related CSB5 Group of Companies), founded in 1990 and focused on a Partnered Care Model intended to share the burden of health care between the private, user and government sectors with the goal of ensuring accessibility to quality treatment to all. It is a private medical facility with more than 50 full-time medical staff and international directors, including world-renowned specialists in multiple disciplines and collaborative centres, including The Bahamas Heart Centre, The Cancer Centre Bahamas, The Institute for Advanced Medical Procedures and the PSCC.

The ACP-01 trial at the PSCC has been approved by the local Ministry of Health and will consist of twenty (20) heart patients and twenty (20) CLI patients for treatment under the same clinical trial protocol applicable to the Hemostemix Phase II clinical trial. Dr. Brown (MD, MBBS, FACC, FESC, PhD), who specializes in Internal Medicine and Cardiology has been personally involved in the development of the ACP-01 trial at the PSCC with Aspire.

Management of the Company understands that the estimated royalties for it generated through the completion of the ACP-01 trial at the PSCC are to be in the range of Cdn \$250,000 to \$350,000.

In addition to the royalties expected to be received from the ACP-01 trial at the PSCC, in accordance with the License Agreement, Hemostemix will also receive all the pertinent data collected during the trial. The data collected from the heart patients in particular will be of significant value

to Hemostemix as it builds the necessary safety and efficacy data for ACP-01 that will allow the Company to expand into future phased clinical trials in Canada and the United States focused on Congestive Heart Failure (CHF).

Angus Jenkins, Chair of the Board of Hemostemix, commented; "This represents another important step in the plan to provide continued evidence of the safety and efficacy of ACP-01 for cardiovascular disease as well as show the need to commercialize Hemostemix's technology. With this licencing arrangement, we not only begin to generate revenue, we also increase our exposure to the medical community and gain valuable data without relinquishing any control over our intellectual property."

ABOUT ASPIRE HEALTH SCIENCE

Aspire is an Orlando, Florida based private company focused on the field of stem cell manufacturing as well as related research and development utilizing state-of-the-art U.S. Food and Drug Administration (FDA) cGMP (Current Good Manufacturing Practices) certified laboratory facilities in Orlando, Florida. As previously disclosed by the Company, Aspire was founded by Drive Capital in January of 2017 and has been organized as a wholly-owned subsidiary of Drive Capital Holdings (USA), Inc., that is itself a wholly-owned subsidiary of R.E.J. Investment Group, LLC.

In accordance with the approach for transactions involving Aspire previously disclosed by the Company, the board of directors of the Company (the "Board") have considered the possible application of Multilateral Instrument 61-101 – Protection of Minority Security Holders in Special Transactions ("MI 61-101") to transactions between the Company and Aspire, on the basis that they could possibly constite one or more "related party transactions" within the meaning of MI 61-101. In addition, the Board also considered relevant corporate law applicable to disclosure by officers in relation to contracts in the same context. The Board has received and considered detailed disclosure from management and others, in relation to Aspire generally and the License Agreement in particular. The Board has concluded that Aspire is not a related party of the Company within the meaning of MI 61-101 and that accordingly, transactions with Aspire will generally not be "related party transactions" within that framework. Notwithstanding this conclusion, the Board has further determined that even if transactions with Aspire were to be considered related party transactions within the meaning of MI 61-101, they would be exempt from the formal valuation and minority approval requirements it provides for.

ABOUT HEMOSTEMIX

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.

Hemostemix Inc. is traded on the TSX Venture Exchange under the trading symbol HEM. To find out more visit hemostemix.com or email office@hemostemix.com.

Filing Data Not available. Contract Not available.