PRODUCT PIPELINE | INHIBITORS (FEBRUARY 22, 2018)

NAME	COMPANY	TYPE	CLINICAL TRIALS	DESCRIPTION
Obizur	Baxalta (In January 2013, Inspiration Biopharmaceuticals/Ipsen sold the OBI-1 technology and Ipsen manufacturing facilities to Baxalta, now part of Shire. The sale was approved in March 2013.)	Porcine recombinant factor VIII	In October 2015 Health Canada approved Baxalta's biologics license application for Obizur to treat acquired hemophilia. The submission was based on a global, prospective, multi-centre Phase II/III open label clinical trial, which assessed the efficacy and safety of Obizur in the treatment of serious bleeds in adults with acquired hemophilia A. Obizur is also approved in the U.S.	This is a treatment for patients with acquired hemophilia A. Unfortunately, despite Health Canada approval and the unmet need, it has not yet been approved for funding in Canada.
CSL689 rVIIa-FP	CSL Behring	Recombinant factor VIIa	A Phase I trial was completed in 2013. The product was granted Orphan Drug Designation (ODD) by the European Commission. This could entitle CSL Behring to exclusively market in Europe for a period of 10 years if the product at the stage of license application fulfils the orphan drug requirements. In August 2015, the first of 54 patients was enrolled in a Phase II/III trial	This is a recombinant fusion protein linking coagulation factor VIIa with albumin for the treatment of inhibitors in hemophilia A and B. A greater than 8-fold increase in half-life was observed in Phase I clinical studies.
LR769	rEVO Biologics and LFB SA	rFVIIa	LFB SA and its subsidary rEVO announced in March 2015 that it will start its global Phase III trials of LR769, Persept 2 and 3, in the second half of 2015. The first part of the study will evaluate two dosing regimens in adolescents and adults with inhibitors to FVIII and FIX.	This is a novel recombinant form of human factor VIIa (rhFVIIa) for patients with congenital hemophilia A or B and inhibitors.
Factor VIIa-CTP	OPKO Health	Recombinant factor VIIa	OPKO Health has submitted an investigational new drug (IND) application to the U.S. FDA seeking approval to conduct a Phase IIa trial of its long-acting version of coagulation factor VIIa to treat bleeding episodes in hemophilia A or B patients with inhibitors to factor VIII or IX. Factor VIIa-CTP has been granted orphan drug designation in both the U.S. and Europe. As of November 2015, Opko was recruiting subjects for a Phase I/II trial.	Factor VIIa-CTP is a new, long-acting recombinant factor VIIa using the company's proprietary technology to extend its circulatory half-life without the use of polymers, encapsulation techniques or nanoparticles. The technology is based on a naturally occurring peptide, the C-terminal peptide (CTP) of the beta chain of human chorionic gonadotropin.