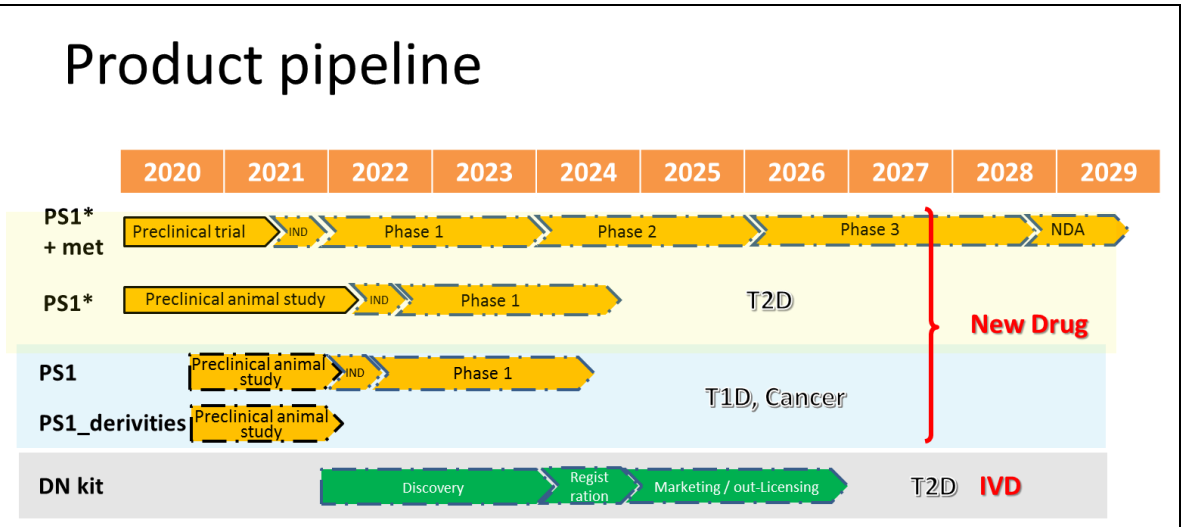
2020 第三梯次團隊手冊	
單位中文/ 單位英文簡稱(大寫)	中央研究院 (Academia Sinica)
計畫主持人姓名中文	楊文欽/研究員兼副主任
計畫主持人姓名英文	Wen-Chin Yang
公司名稱	藥祇生醫
	Pharmasaga Pharmaceutical Inc.
中文	糖尿病市場首見藥 PS1 開發
英文	Development of the first-in-class diabetes drug, PS1
募資成果	團隊目前估值為新台幣一億元，預計在執行價創計畫後，估值將達新台幣四億元
	Current pre-money valuation is calculated NT$100M. Upon execution of Trust-U project, the post-money valuation is expected to hit NT$220M.
募資計畫	團隊正尋求天使輪募資，預計將募新台幣 1.2 億，以完成 IND 與臨床一期
	We are looking to raise NTD 120M in Angle round to cover IND application and phase I clinical trials.
Diabetes, PX inhibitor, First-in-class	
中文	團隊發現胰島 β 細胞會特定表現伴隨蛋白 PX，PX 表達會隨著糖尿病增加。PX 基因剔除會減少模式鼠糖尿病，其基因轉殖鼠促進糖尿病。PX 小分子抑制劑 PS1 可治療和逆轉糖尿病。其機制是透過減少高糖環境下誘導的 ROS，減少β細胞死亡和改善其功能。因此，PX 可作為糖尿病診斷和治療標的。 PS1 的臨床前試驗已完成 PD、CMC、PK、配方和 PS1 在動物之最大容忍劑量(MTD)，有效劑量 100 倍仍不具毒性。正在完成所剩下毒理試驗，包括基因毒、(非)GLP 毒性試驗和安全藥理學。預計價創計畫結束時(2021 年 6 月)完成臨床前試驗、CTD 撰寫和 IND 申請，並成立藥祇生醫。2022 年 6 月開始臨床一期試驗(2 年內完成) ，2024 年 6 月開始臨床二期試驗(2 年內完成)。國外授權發生在臨床一期或二期結束後，授權金額分別為 3-6 億和 9-18 億台幣。此外，完成 IND 後將開發 PX 做為糖尿病診斷試劑，為公司創造短期營收，並打造成為台灣診療糖尿病最具代表性之公司。

	
英文	We discover a chaperone protein, PX, which is specifically expressed in β cells. This expression is further up-regulated in response to excess nutrients. Moreover, PX deficiency reduces diabetes development in db/db mice, a model of type 2 diabetes (T2D). Its transgenic mice show opposite outcomes. In summary, PX protein is a target of diagnosis and therapy against T2D. Using molecular docking, chemical modification and lead optimization, PS1 is developed as a small-molecule drug candidate. We have proved that PS1 suppresses β cell dysfunction and loss via reduction of high glucose-mediated reactive oxygen species (ROS). Furthermore, PS1 alone and in combination can treat and reverse T2D. In pre-clinical study, the pharmacodynamics data, chemistry, manufacturing and control (CMC), pharmacokinetics (PK) data, formulation, and maximum tolerated dose (MTD) of PS1 were completed. Currently, study of PS1 genotoxicity, (non)-GLP toxicity, and safety pharmacology will be completed before mid-2021. Common technical document (CTD) and investigational drug (IND) application of PS1 as well as establishment of the start-up, Pharmasaga, will be finished by mid-2021. We expect to perform clinical trial phase 1, from 2022 to 2023, and clinical trial phase 2, from 2024 to 2025. International out-licensing of PS1 is planned by the completion of trial phase 1 or 2. The licensing fee for PS1 at the end of trial phase 1 or 2 is 10M-20M and 30M-60M, respectively. Besides, PX can be developed as a in vitro diagnostic devices (IVD) fro T2D. This IVD development will contribute to the revenue of company, making our company one of the most leading companies that excel in diagnosing and treating diabetes in Taiwan.