# Sirnaomics Ltd. [2257.HK]

(Incorporated in the Cayman Islands with limited liability)

## 2022 Interim Result Presentation

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# Presenters

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**20+ years** of experience

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tgen · ThermoFisher SCIENTIFIC · Frederick National Laboratory for Cancer Research

**25+ years** of experience

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CTO

RXi Pharmaceuticals Next Generation in RNAi · RIBOBIO 锐博生物 · SILENCE THERAPEUTICS

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# Agenda

01 - Company Overview

02 - Pipeline Updates

03 - Future Milestones and Catalysts

04 - Financial Highlights

sirnaomics
Advancing RNAi Therapeutics

sirnaomics
Advancing RNAi Therapeutics

Part 1

# Company Overview

# Sirnaomics: A RNA Therapeutic Innovator on a Global Stage

## Proprietary Delivery Technology Platforms

**Polypeptide nanoparticle (PNP) Platform:** First to achieve positive Phase IIa human clinical data in oncology using RNAi technology

**GalNAc Technology Platform:** GalAhead™ and PdoV™ delivery systems

**Global rights for multiple delivery systems**

## Expanding Clinical Pipelines

Clinical assets STP705 and STP707 for treatment of

- **NMSC:** (facial) isSCC, BCC
- **Fibrosis**: Keloid, PSC, HTS
- **Other oncology:** Liver cancer (basket) and solid tumors
- **Others:** fat sculpting

## Broad therapeutic utility

Oncology, fibrosis, medical aesthetics, anti-viral, cardiovascular and cardiometabolic diseases, etc.

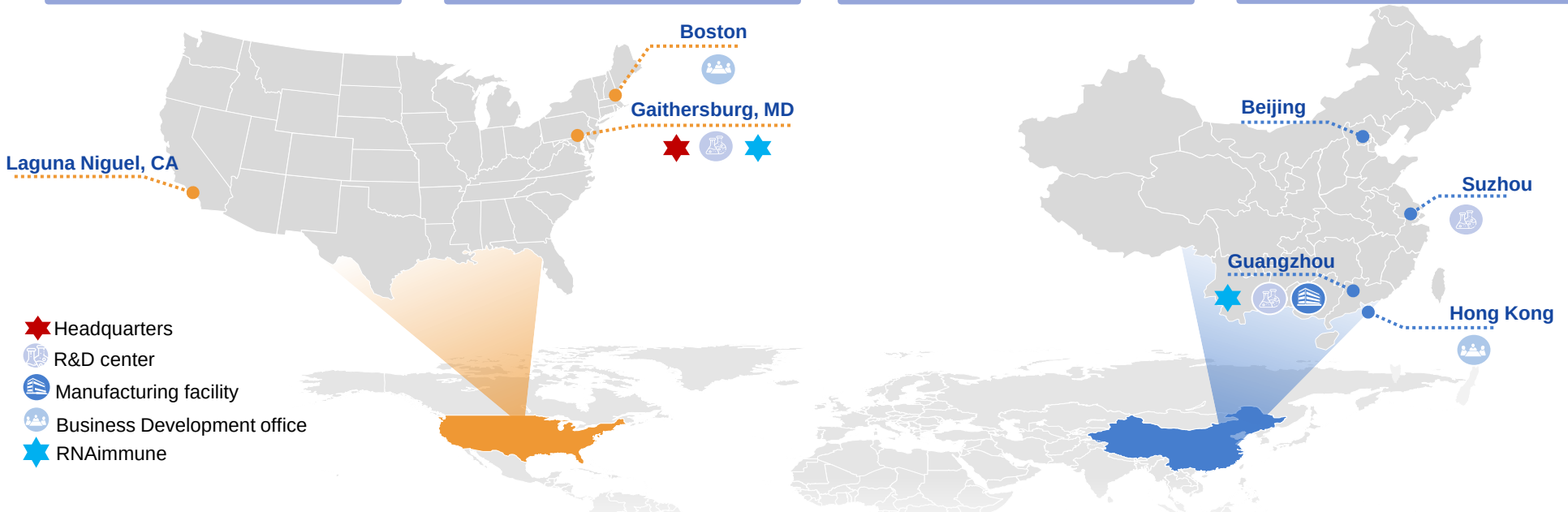
Key preclinical candidates at **IND-enabling stage:** STP355, STP122G, STP125G, STP144G and RIM730

## Established Manufacturing Facilities

Large-scale **GMP-compliant Manufacturing Capabilities**, commenced operation in 1H 2022

Next generation **microfluidic techniques**

An anticipated annual capacity of producing **around 50,000 vials** of lyophilized human injectables



# Major Accomplishments Year to Date

| Jan 22 | Feb 22 | Mar 22 | Apr 22 | May 22 | Jun 22 | Jul 22 | Aug 22 |
|---|---|---|---|---|---|---|---|

**Interim data** from **STP705** Phase II clinical trial for the treatment of **BCC**

Launched **STP707 Phase I clinical trial** for the treatment of **solid tumor** in the U.S.

RNAimmune, our subsidiary, announced a **c.US$ 27 million Series A round fundraising**

**First patient in** for **STP707 Phase I clinical trial** for the liver fibrosis in **PSC** in the U.S.

Launched **STP705 Phase I clinical trial** for submental **fat reduction in the U.S.**

**STP122G** showed therapeutic effect with NHP model for longer than 28 weeks

Received **regulatory clearance** from the Taiwan Ministry of Health and Welfare (TMHW) of **IND application** to commence a Phase I trial of **STP705** for the treatment of advanced **liver tumors**

Become a constituent of **Hang Seng family of indexes**

**First patient in** for **Phase I/II clinical** study of **STP705** for the treatment of **facial isSCC**

**BCC interim data:** 100% complete response in the 180 μg dose level

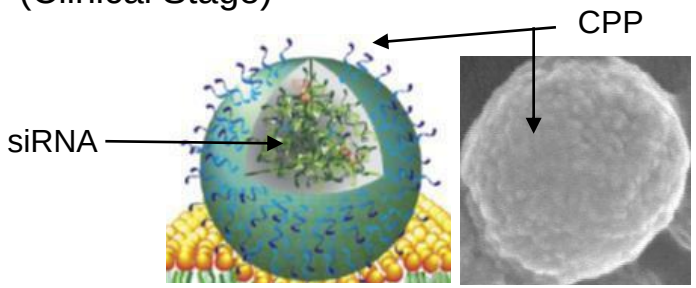
Advances the **GalAhead™ program** for treatment of **complement-related diseases** and develops **Peptide Docking Vehicle (PDoV™)** designed for an enhanced GalNAc delivery platform

Part 2

# Pipeline Updates

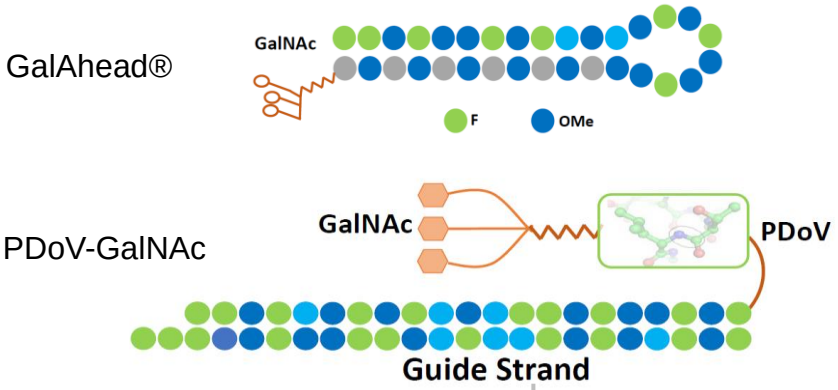
# Delivery Technology Platforms and Therapeutic Areas

**PNP Platform:**
(Clinical Stage)



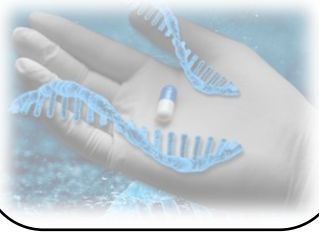

HKP and HKP(+H) are well suited for siRNA Therapeutics or mRNA Therapeutics and Vaccine Deliveries

**GalNAc Platform:**
(Clinical Candidate)



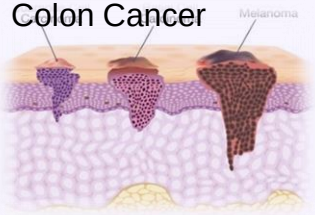

**mRNA**

Vaccine
Neoantigen Vaccine
Protein Replacement
mRNA Antibody



**Cancer**

NMSC (isSCC, BCC)
Liver Cancer
Lung Cancer
Pancreatic Cancer
Colon Cancer



**Fibrosis Diseases**

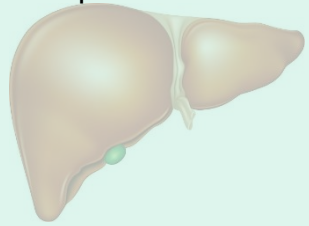
Skin Scar, Keloid
Liver Fibrosis
Lung Fibrosis
Kidney Fibrosis

**Viral Infections**

Influenza
SARS-CoV2
HBV,
HPV

**Liver Metabolic Diseases**

Anti-Coagulant
LDL Deregulation
High Blood Pressure
Compliment Disease



**RNAi**

# Broad and Deep Product Pipeline

| | Candidate | Gene Targets | Indications | Delivery Platform | Pre-clinical | IND Enabling | IND | Phase I | Phase II | Phase III | Rights |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Oncology | STP705* | TGF-β1/COX-2 | isSCC | PNP-IT | | | | | US; China (MRCT)[2] | | Global |
| | | | BCC | | | | | | US | | Global |
| | | | Liver Cancer[1] (Basket) ** | | | | | | US; China (MRCT)[3] | | Global |
| | | | Liver Cancer, combo with anti-PD-(L)1[5] | | | | | | US | | Global |
| | STP707 | TGF-β1/COX-2 | Multiple solid tumors | PNP-IV | | | | | US; China (MRCT)[4] | | Global |
| | | | cSCC | | | | | | US | | Global |
| | | | NSCLC | | | | | | US | | Global |
| | | | Liver Cancer, cSCC, NSCLC, combo with anti-PD-(L)1[5] | | | | | | US | | Global |
| | STP355 | TGF-β1/VEGFR2 | Pan Cancer | | | | | | US | | Global |
| | STP369 | BCL-xL/MCL-1 | Head & Neck Cancer / Bladder Cancer | PNP-IT | | | | | US | | Global |
| | STP779 | TGF-β1/Sulf-2 | Liver Cancer/ Lung Cancer/Pancreatic Cancer | PNP-IV | | | | | US | | Global |
| Fibrosis | STP705* | TGF-β1/COX-2 | Keloid Scarless Healing | PNP-ID | | | | | US | | Global |
| | | | Hypertrophic Scarring | | | | | | US; China (MRCT); China | | Global |
| | STP707 | TGF-β1/COX-2 | Liver Fibrosis (PSC) | PNP-IV | | | | | US; China（MRCT） | | Global |
| | | | Lung Fibrosis | | | | | | US | | Global |
| Medical Aesthetics | STP705* | TGF-β1/COX-2 | Fat sculpting | PNP-ID | | | | | US | | Global |
| Antiviral | STP702 | M1/PA | Influenza | Airway / PNP-IV | | | | | US | | OL China |
| | RIM730[6] | SARS-CoV-2 | Covid-19 vaccine | LNP Intramuscular | | | | | US | | Global |
| GalAhead™ | STP122G | Factor XI | Anticoagulation/Thrombosis | GalAhead™ subcutaneous | | | | | US | | Global |
| | STP125G | ApoC3 | Hypertriglyceridemia | | | | | | US | | Global |
| | STP144G | Complement Factor B | Complement-mediated diseases | | | | | | US | | Global |
| | STP145G | Complement C5 | Complement-mediated diseases | | | | | | US | | Global |
| | STP146G | Complement C3 | Complement-mediated diseases | | | | | | US | | Global |
| | STP247G | Complement CFB/C5 | Complement-mediated diseases | | | | | | US | | Global |
| | STP251G | ApoC3/TMPRSS6 | Hemochromatosis & Hypercholesterolemia | | | | | | US | | Global |
| | STP152G | Non-disclosed | Rare disease | | | | | | US | | Global |
| | STP136G | Non-disclosed | Hypertension | | | | | | US | | Global |
| | STP237G | Non-disclosed | Hypertension & Hypercholesterolemia | | | | | | US | | Global |
| PDoV-GalNAc | STP135G | Non-disclosed | Hypercholesterolemia | PDoV-GalNAc subcutaneous | | | | | | | Global |
| | STP155G | HBV sequences | HBV | | | | | | | | Global |

*Notes：* * *denotes our core product* ** *denotes orphan drug*

*1. Liver cancer (basket) includes cholangiocarcinoma, hepatocellular carcinoma, liver metastases etc. 2. We filed our IND in China in June 2021, which is currently awaiting approval from NMPA, for study sites in China. The study sites will be part of a global multicenter clinical trials for our Phase IIb clinical trial for isSCC. 3. We expect to file the IND in Greater China as part of the global multicenter clinical trials. 4. We expect to file the IND solely for HCC in China as part of the global multicenter clinical trials. 5. Studies in combination with anti-PD-(L)1 inhibitors conducted pursuant to collaborations with Innovent and Shanghai Junshi. 6. Research and development conducted by our subsidiary RNAimmune.*

# Significant Market Potential & Commercialisation Opportunity

**Large Unmet Medical Need**

- **NMSC:** BCC and SCC account for majority of NMSCs with more than five million newly diagnosed cases in the U.S. every year
  - isSCC (US): 1.3mn / 3.4mn new cases in 2020 / 2030[1]
  - BCC (US): 2.4mn / 4.2mn new cases in 2020 / 2030[1]
- **Liver Cancer:** in the case of China: 510k / 630k new cases in 2020 / 2030; in the case of the U.S.: 42k / 49k in 2020 / 2030
- **HTS and Keloids**[2] **:** in the case of the U.S.: 8mn / 10mn new cases in 2020 / 2030; in the case of China: 7mn / 11mn in 2020 / 2030
- **PSC:** 45k (US) and 194k (China) in 2020

**Market Drivers**

- **NMSCs:** (1) demand for better cosmetic appearance (especially with lesion on head and neck); (2) change in lifestyle and increased outdoor activities; and (3) increase in diagnosis rate
- **Liver Cancer:** (1) primarily attributable to HBV infection, less so by diabetes, NASH and excessive alcohol consumption; and (2) improvements in liver cancer early screening and diagnosis
- **HTS and Keloids:** (1) positively correlated to number of various surgical procedures; (2) increasing awareness regarding post-op wound management

**Opportunity**

- Well established efficacy and safety profile
- Potential to become a first-in-class drug in the case of NMSC and HTS/Keloid, and set the gold standard

Sources

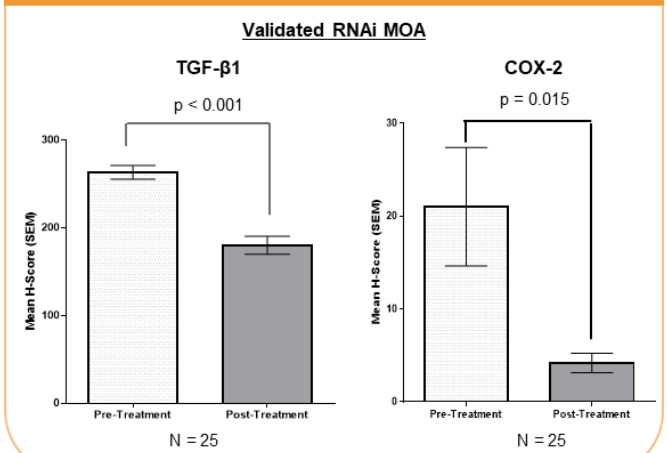
1. *Incidence Estimate of Nonmelanoma Skin Cancer (Keratinocyte Carcinomas) in the US Population, 2012*
2. *Formation of Hypertrophic Scars: Evolution and Susceptibility*

# STP705 - isSCC

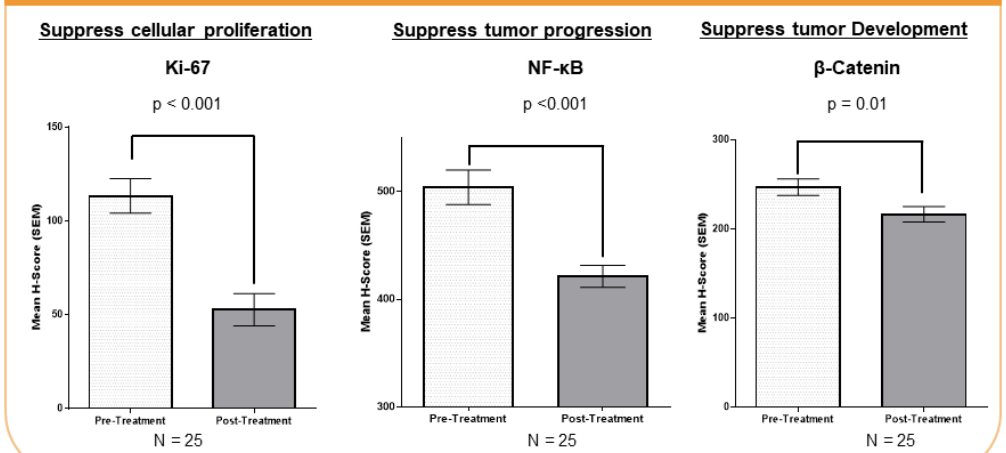
- Positive Phase IIa Clinical Readouts for isSCC treatment:
  - Overall, 76% of subjects across all groups (25 subjects) achieved Complete Histological Clearance
  - Within the 2 higher dosing groups (9/10 subjects), 90% of them have achieved Complete Histological Clearance
  - No significant cutaneous skin reactions and no treatment related AE's or SAE's, Skin Response Scores improved in 4/5 dosing cohorts and there were no dose limited toxicities noted in the study population

**Efficacy Data**

**Silencing of TGF-ß1 and COX-2 Expression by STP705**




**Suppression of multiple cancer related factors**




- Phase IIb clinical trials, in progress, will further evaluate the two most efficacious dosing regimens identified in our Phase IIa clinical trial in a randomized, double blind, placebo-controlled study in up to 100 adult patients with isSCC
- The primary endpoint for the trial is proportion of participants with histological clearance of treated isSCC lesion at the end of treatment

**Status: Phase IIb interim data readout is expected in 2H 2022**

# STP705 - Facial isSCC

**Phase I/II in Progress**

**Protocol, study design and endpoints**

- In August 2022, we have dosed our **first patient in** the clinical trial.
- Expansion into facial isSCC is evidence of the **excellent safety profile** of STP705, demonstrated in our Phase IIa clinical study for the treatment of isSCC, to **ensure good cosmetic results**.
- **Protocol**: open label, dose escalation study is designed to evaluate the safety, tolerability, and efficacy of various doses of STP705 administered by intralesional injection and to determine the recommended dose. The study will also analyze biomarkers common to isSCC formation pathways, including TGF-β1 and COX-2.
- **Study Design:** intralesional injection, once per week for six weeks, a total of **30 patients** divided into 3 cohorts of 10 patients each(Cohort 1: 30 µg, Cohort 2: 60 µg, Cohort 3: 90 µg).
- **Primary Endpoints:** to determine the number of patients with histological clearance of facial isSCC lesions at the end of treatment with STP705.

**Status: First Patient In August 2022**

# STP705 - BCC

**Phase II in Progress**

| | Cohort A: 30 µg (N=5) | Cohort B: 60 µg (N=5) | Cohort C: 90 µg (N=5) | Cohort D: 120 µg (N=5) | Cohort E: 180 µg (N=5) |
|---|---|---|---|---|---|
| Histological Clearance | 1/5<br>**20%** | 3/5<br>**60%** | 3/5<br>**60%** | 2/5<br>**40%** | 5/5<br>**100%** |
| **Average Skin Response Scores** | | | | | |
| Pre-treatment | 3.2 | 2.8 | 2.6 | Scores not reported until final report | |
| Post-treatment | 2.4 | 2.6 | 2.6 | | |

- Phase II, open label dose escalation study designed to evaluate the safety, tolerability and efficacy of various doses of STP705 administered as localized injection in patients with BCC. Total of 25 subjects which is divided equally among 5 cohorts (30, 60, 90, 120 and 180 µg dose level)
- Interim data achieves **100% response rate** in the 180 µg dose level. The data showed improved or stable cosmetic result with an excellent safety profile (**no adverse events**) **and no significant cutaneous skin reactions**.
- Looking forward to **mirror the promising data** - the potential to be an alternative to patients with BCC and other non-melanoma skin cancers who have an urgent need for new treatments

**Escalate dosing to evaluate the ideal dosing; final report anticipated in Q1 2023**

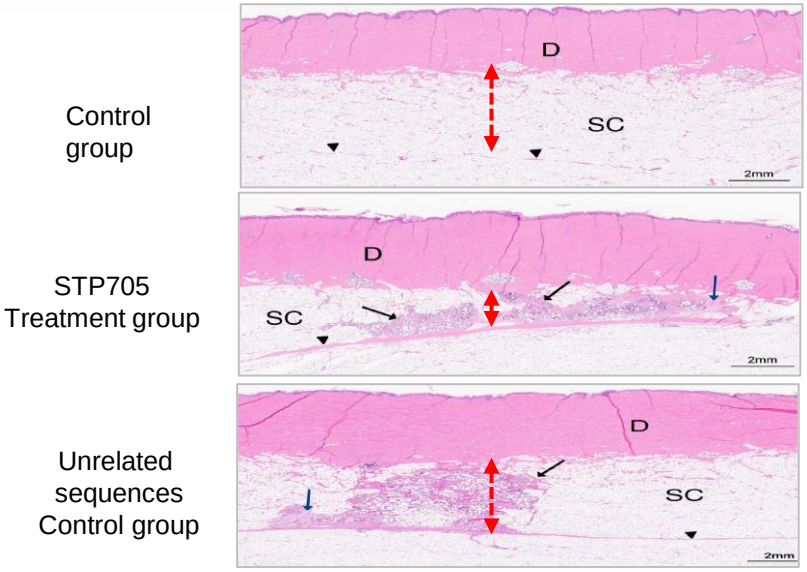
# STP705 – Fat Reduction

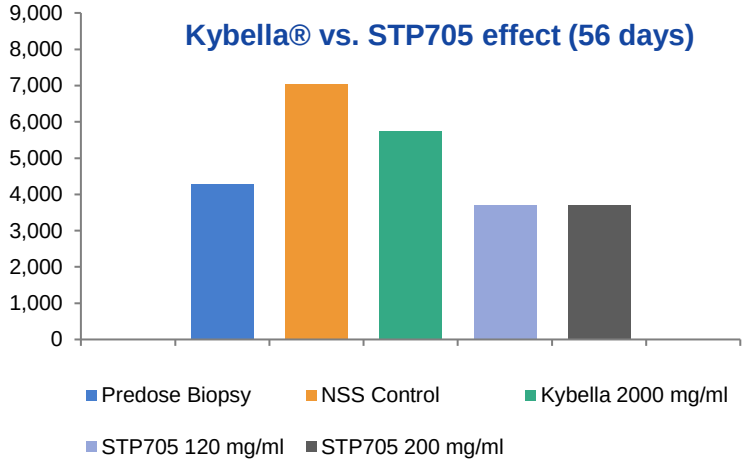
**Phase I in Progress**

**Protocol, study design and endpoints**

- In May 2022, we have launched a Phase I clinical trial of STP705 in adults undergoing abdominoplasty for submental fat reduction.
- **Protocol:** The dose-ranging, randomized, double-blind, vehicle-controlled study to evaluate the safety and tolerability of STP705, delivered via subcutaneous injection.
- **Study Design:** subcutaneous injection, a total of 10 patients
- **Primary Endpoints:** To assess injection comfort, characterize local and systemic safety, and evaluate histological changes of subcutaneous doses of STP705, and to compare the safety and tolerability of three different concentrations of STP705 to select dosages for future studies.

**Pre-Clinical Minipig Model Efficacy Validation**



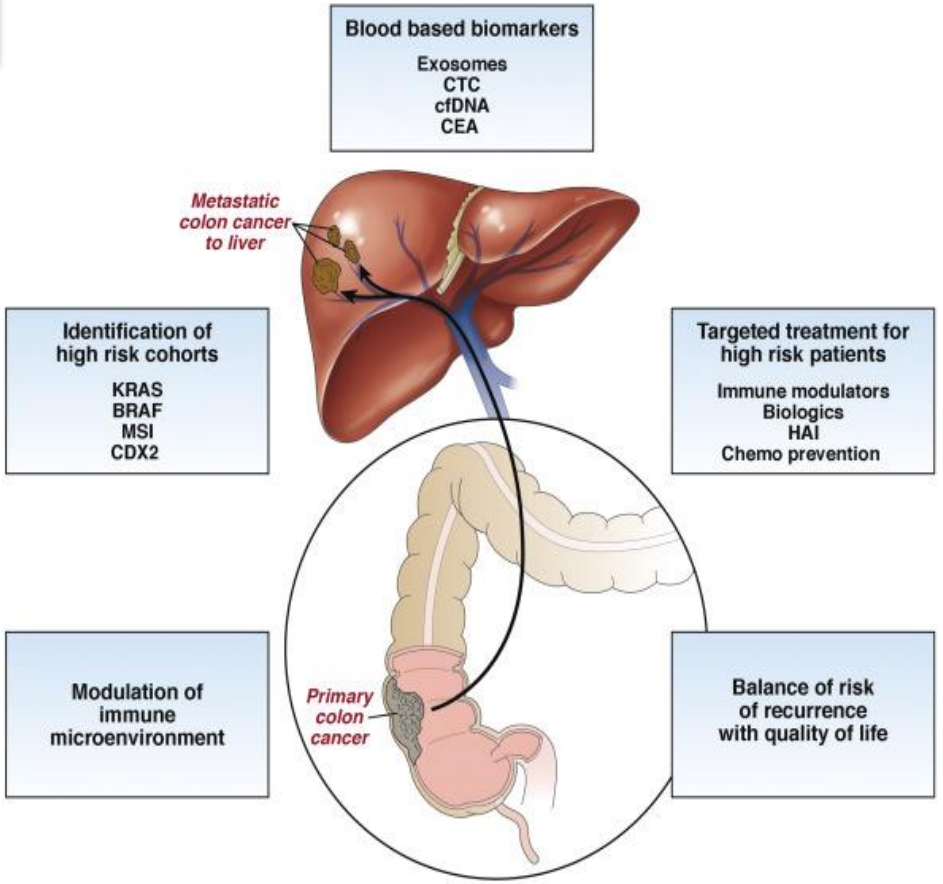

**Status: Expected first patient in Q3 2022**

# STP707 - Solid Tumors

## In Situ or Metastatic Liver Cancer

**Phase I in Progress**

- In November 2011, we initiated a Phase I clinical trial for solid tumors in the U.S.
- **Protocol:** multi-center open label, dose escalation and dose expansion study to evaluate the safety, tolerability, and anti-tumor activity of STP707 with IV administration in subjects with advanced solid tumors who are refractory to standard therapy
- **Study Design:** intravenous systemic administration, a 28-day cycle, administered on day 1, 8, 15, and 22, 5 cohorts (Cohort 1: 3 mg, Cohort 2: 6 mg, Cohort 3: 12 mg, Cohort 4: 24 mg, Cohort 5: 48 mg)
- **Primary Endpoints:**
  - To determine maximum tolerated dose (MTD)
  - To establish dosage recommendations for future Phase II studies
- **Secondary Endpoints:**
  - To determine pharmacokinetics (PK)
  - To assess tumor-infiltrating lymphocytes
  - To observe preliminary anti-tumor activities



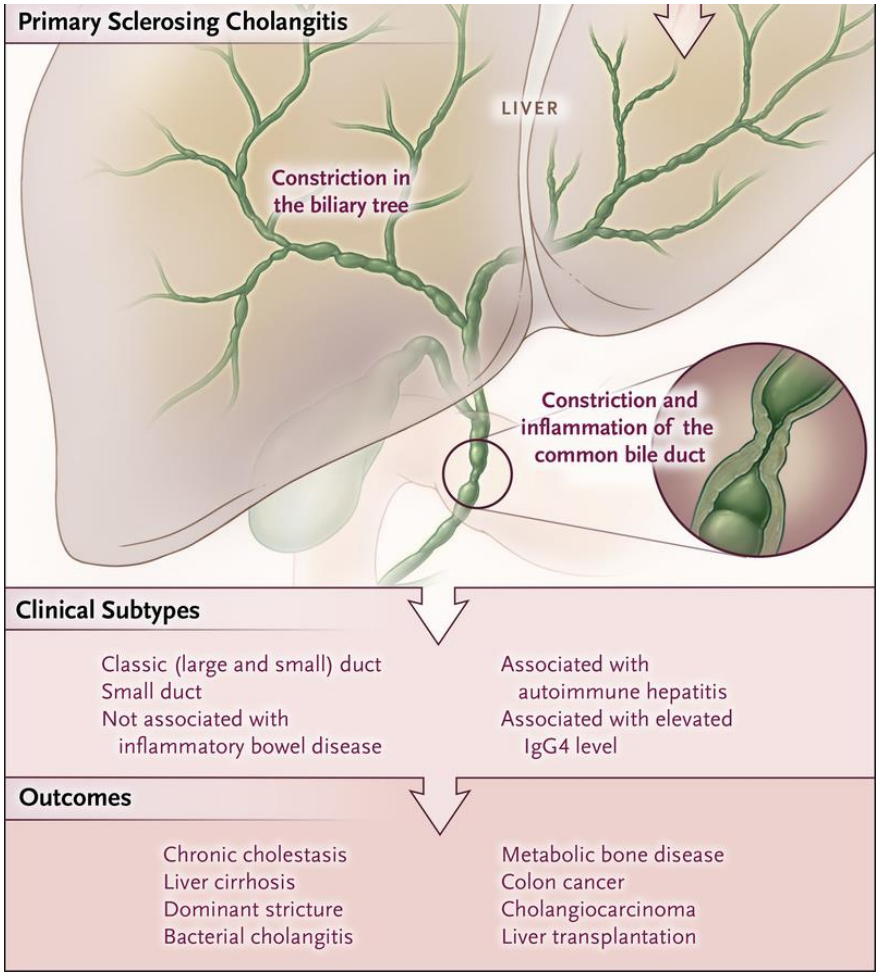

**Status: Safety data readout is expected in Q4 2022**

# STP707 - Liver Fibrosis

## Primary Sclerosing Cholangitis (PSC)

**Phase I in Progress**

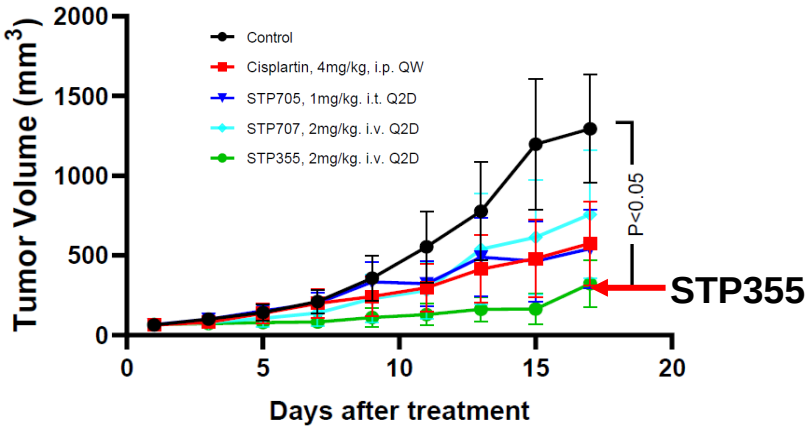
- Obtained US FDA approval of IND application for Phase I clinical trail of STP707 in treatment of PSC by intravenous administration
- Clinical trial for PSC launched in 1Q22, with interim data expected in 1H 2023
- **Protocol:** Single-center, randomized, dose-escalation, sequential cohort study to evaluate safety, tolerability, and pharmacokinetics of single ascending dose of STP707 when administered by IV infusion in healthy subjects
- **Study Design:** intravenous systemic administration, 4 cohorts (Cohort 1: 3 mg, Cohort 2: 6 mg, Cohort 3: 12 mg, Cohort 4: 24 mg)
- **Primary Endpoints:** To evaluate the safety and tolerability of STP707 when administered intravenously in healthy subjects
- **Secondary Endpoints:** To evaluate the pharmacokinetics (PK) of STP707 when administered IV in healthy subjects



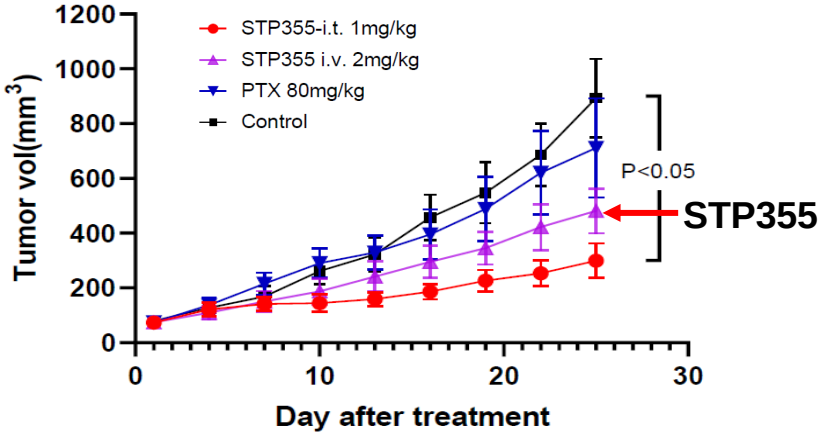

**Status: Interim safety data readout is expected in 1H 2023**

# STP355 - TGF-β1/VEGFR2 RNAi Therapeutics

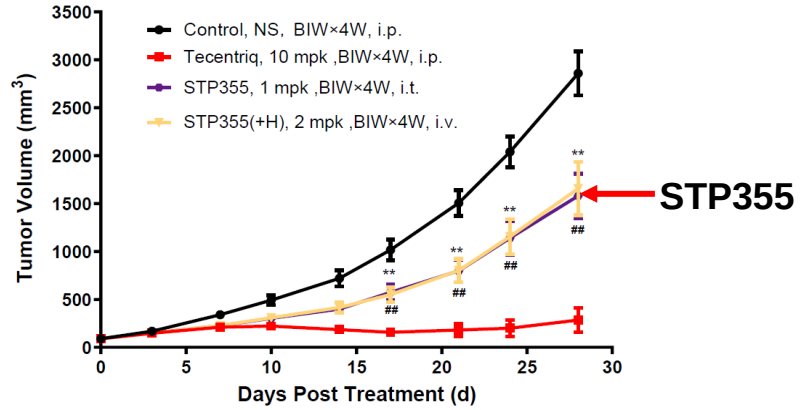
**Antitumor results: C57BL16 melanoma model, N = 6, P<0.05**



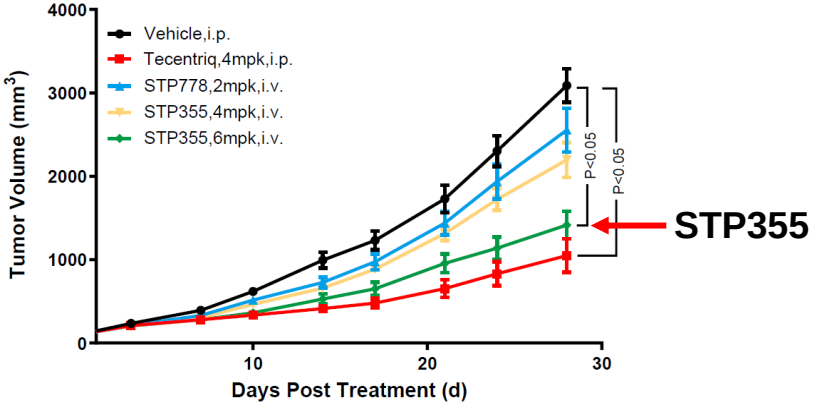

**Antitumor results: MDA-MB-231 xenograft breast cancer model, N = 6, P<0.05**




**Antitumor results: C57BL16 mouse colon cancer model with MC38-hPDL1 tumor。N =8， P< 0.05**




**Antitumor results: C57BL16 mouse colon cancer model with C38-hPDL1 tumor, N = 6, P<0.05**




**Status: IV dosing for treatment of solid tumors; expect to file IND in 2023**

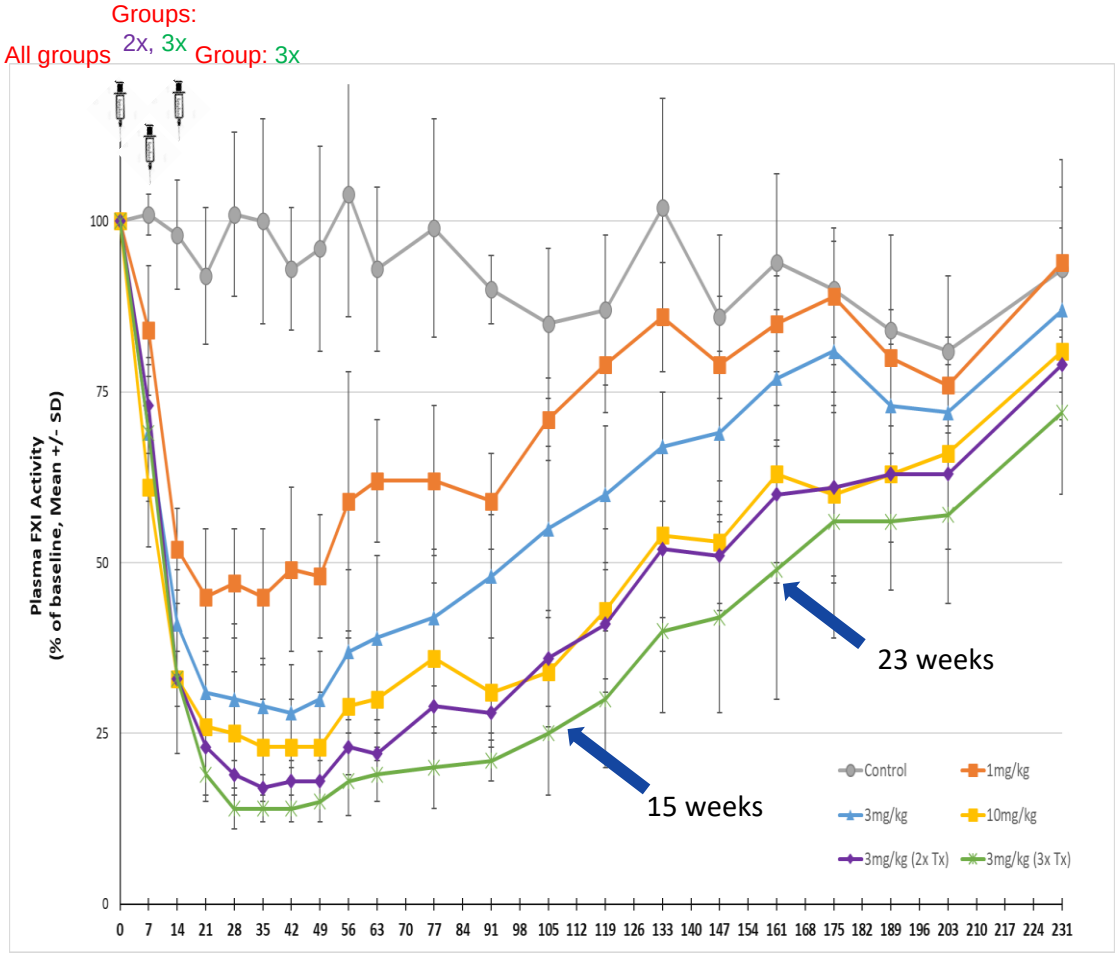
# GalAhead™ Pipeline

| Drug | Technology | Target | Indication | Discovery | Candidate Nomination | IND Enabling | IND |
|---|---|---|---|---|---|---|---|
| STP122G | mxRNA | Factor XI | Anticoagulation/Thrombosis | | | | |
| STP125G | mxRNA | APOC3 | Hypertriglyceridemia | | | | |
| STP144G | mxRNA | Complement Factor B | Complement-mediated diseases | | | | |
| STP145G | mxRNA | Complement C5 | Complement-mediated diseases | | | | |
| STP146G | mxRNA | Complement C3 | Complement-mediated diseases | | | | |
| STP247G | muRNA | Complement CFB/C5 | Complement-mediated diseases | | | | |
| STP251G | muRNA | APOC3/TMPRSS6 | Hemochromatosis & Hypertriglyceridemia | | | | |
| STP152G | mxRNA | Non-disclosed | Rare disease | | | | |
| STP136G | mxRNA | Non-disclosed | Hypertension | | | | |
| STP237G | muRNA | Non-disclosed | Hypertension & Hypertriglyceridemia | | | | |

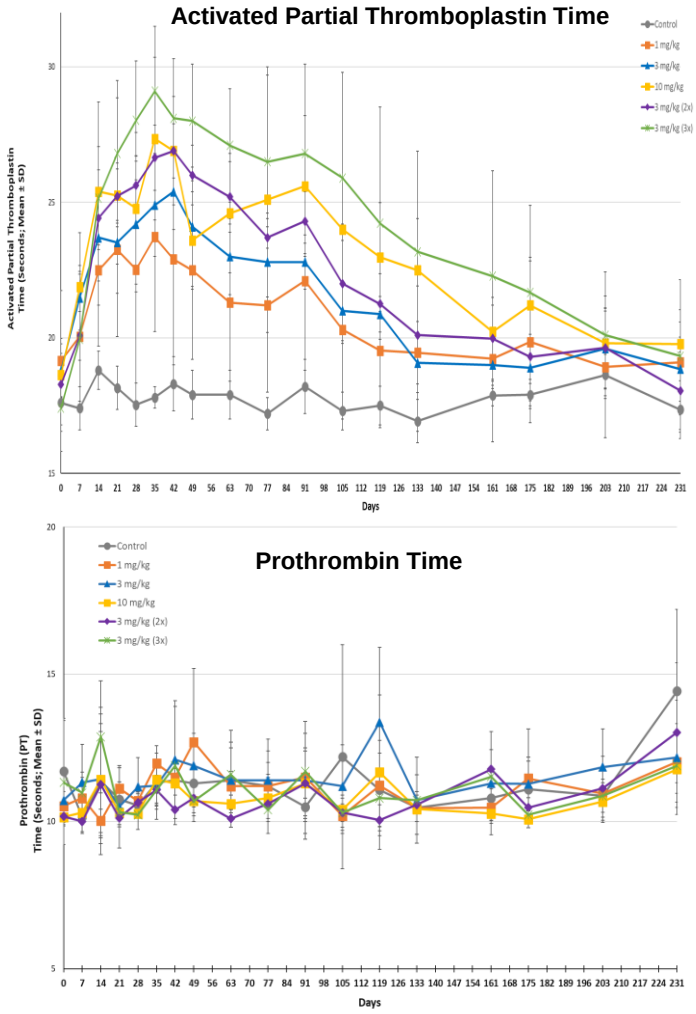
# STP122G: Factor XI knockdown in non-human primates (33 wks)

## Long-Lasting Target Knockdown Effect and Strong Therapeutic Benefit

### STP122G therapeutic effect at 33 weeks



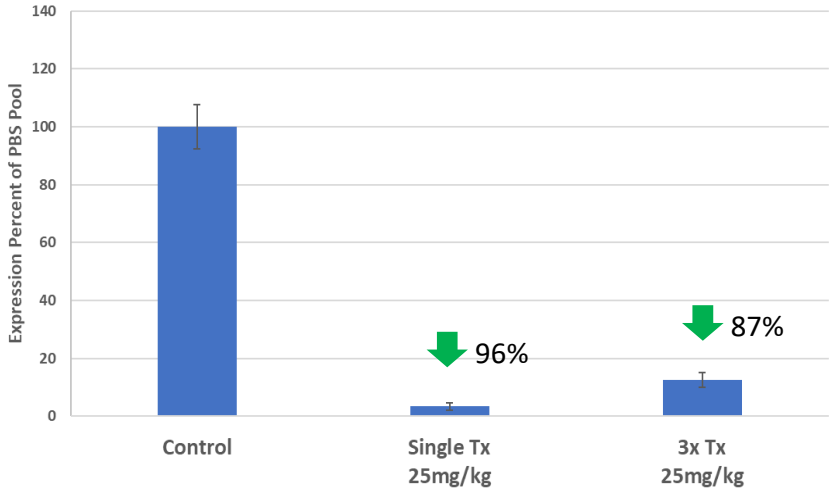

### Strong Therapeutic Benefit



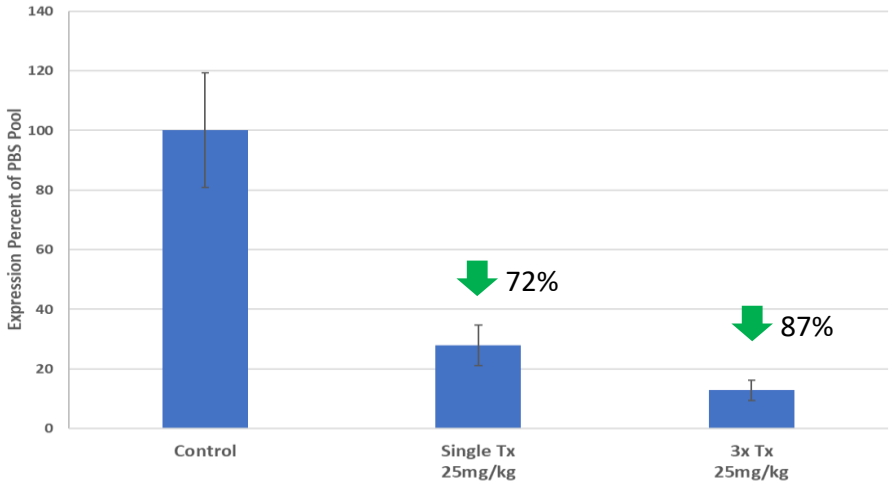

**IND enabling; expect to file IND in Q4 2022**

# STP251G: APOC3 & TMPRSS6 mRNA Knockdown *In Vivo*

## **APOC3:** mRNA in Liver Tissues




## **TMPRSS6:** mRNA in Liver Tissues




**High Potency**

- Comparable KD between single and multiple treatments
- Successful KD of two hepatocyte-specific targets with both single and multiple treatments

Animal model: humanized mice

Timepoint: 2 weeks

molecule is nominated as the Candidate for the STP251G program

# Well-Established Clinical Manufacturing Capabilities

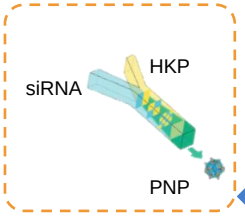

## Guangzhou Pilot Plant Facility

- Pilot Plant fully operational since 2022.
- Formulation F&F of PNP & GalNAc products.
- ~50,000 human injectables vials annually.
- 8 batches drug product produced to date.
- QMS GMP regulatory compliant.
- **CMC Process  CPP Verifications Success.**

# Global Mfg. Collaboration & Supply Chain Establishment

**Well established /verified cGMP process**

**Future commercial manufacturing sites**





- **PNP manufacturing process - microfluidic technology - continuously improving to support pipeline expansion.**
- **Well established cGMP process for manufacturing, verified thru our own pilot plant scale.**

- **Plan in place assessing feasibility of future site to establish commercial mfg. capacity for product launch.**

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Part 3

# Future Milestones and Catalysts

# Anticipated Milestones and Catalysts

| Candidates | | 1H 2022 | 2H 2022 | 2023 |
|---|---|---|---|---|
| STP705 | isSCC | | Interim data readout | |
| | BCC | Interim data readout | 100% complete response in Cohort 5 | Interim data readout; Final data readout |
| | Liver Cancer (Basket) | | Initiate Phase I trial in Taiwan | |
| | Fat sculpting | Initiate Phase I trial | First Patient In | |
| | Facial isSCC | | First Patient In | |
| STP707 | Multiple solid tumors | Initiate Phase I trial | Safety data / IND filing in Taiwan | |
| | PSC | Initiate Phase I trial | | Interim safety data |
| STP355 | Pan Cancer | | | IND filing |
| RIM730 | Covid-19 vaccine | | IND filing | |
| STP122G | Thrombotic disorders | | IND filing | |
| STP125G | Hypertriglyceridemia | | | IND filing |
| STP144G | Complement-mediated diseases | | | IND filing |

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Part 4

# Financial Overview

# Profit and Loss

| Ref | | Jun 30 2022 US$ (m) | Jun 30 2021 US$ (m) |
|---|---|---|---|
| | Other income, other gains and losses | 0.4 | 0.0 |
| 1 | Changes in fair value of financial liabilities at fair value through profit or loss ("FVTPL") | (2.9) | (12.4) |
| 2 | Administrative expenses | (11.1) | (5.2) |
| 3 | Research and development expenses | (32.1) | (12.3) |
| | Listing expenses | 0.0 | (3.5) |
| | Finance costs | (0.4) | (0.1) |
| | **Loss for the period** | **(46.1)** | **(33.5)** |

1. **Changes in fair value of financial liabilities at FVTPL:** decreased to US$2.9m from US$12.4m (US$9.5m or 77% decrease) primarily due to conversion of the Company's preferred shares to ordinary shares upon IPO on December 30, 2021.

2. **Admin Expense:** increased significantly from US$5.2m to US$11.1m (US$5.9m or 113% increase) due to expansion of business and increase in professional and consultancy fee

3. **Expenses:** increased to US$32.1m from US$12.3m (US$19.8m, or 160% increase) due to:
   - Our acceleration of R&D execution:
     - Chemistry, manufacturing and control expenses increased from US$2.4m to US$8.7m
     - Clinical trials expense increased from US$1.8m to US$3.5m
     - Preclinical test expense increased from US$1.8m to US$6.0m
     - Material consumed increased from US$1.3m to US$4.2m

# Cash flow

| Ref | cash flow | For six months ended Jun 30, 2022 US$ (m) | | For six months ended Jun 30, 2021 US$ (m) | |
|---|---|---|---|---|---|
| | Cash and cash equivalents on Jan 1 | | 212.0 | | 103.2 |
| 1 | Net cash used in operating activities | (45.4) | | (19.4) | |
| 2 | Net cash (used in) from investing activities | (9.1) | | (1.2) | |
| 3 | Net cash from financing activities | 12.9 | | 35.2 | |
| | Net cash change | | (41.6) | | 14.6 |
| | FX impact | | (0.7) | | 1.4 |
| 4 | Cash and cash equivalents on June 30 | | 169.7 | | 119.2 |

1. **Net cash used in operating activities:** increased to US$45.4m from US$19.4m (US$26.0m or 134% increase) primarily due to the expansion of the Group's research and development activities, general corporate and administrative activities

2. **Net cash from investing activities:** increased to US$9.1m from US$1.2m (US$7.9m or 634% increase) due to increase in purchase and deposits paid for property and equipment of US$7.4 million

3. **Net cash from financing activities:** decreased to US$12.9m from US$35.2m (US$22.3m or 63% decrease). The US$12.9m is mainly due to proceeds from the exercise of the over-allotment option of US$8.2m and proceeds from partial issuance of Series A preferred shares of RNAimmune

4. **Closing cash balance:** Healthy cash position of US$169.7m closing cash balance for Jun 30, 2022

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# Q&A