



Multi-jet injection.

James Mckeage. Updated 2024.09.26

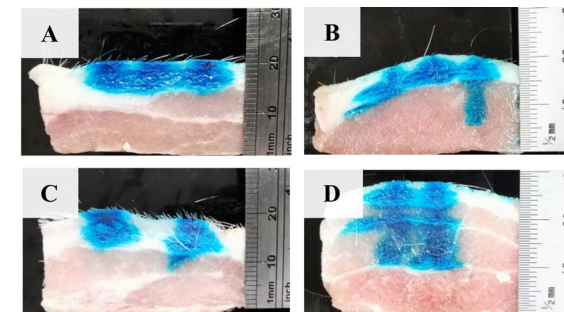
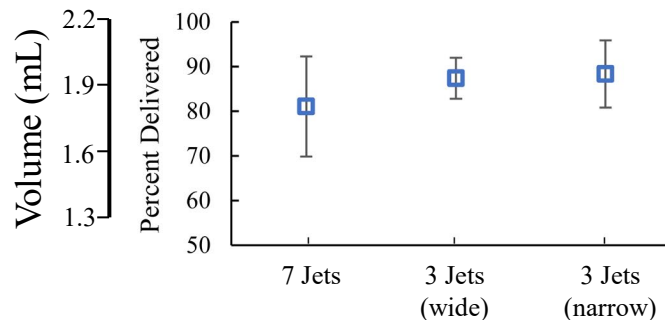
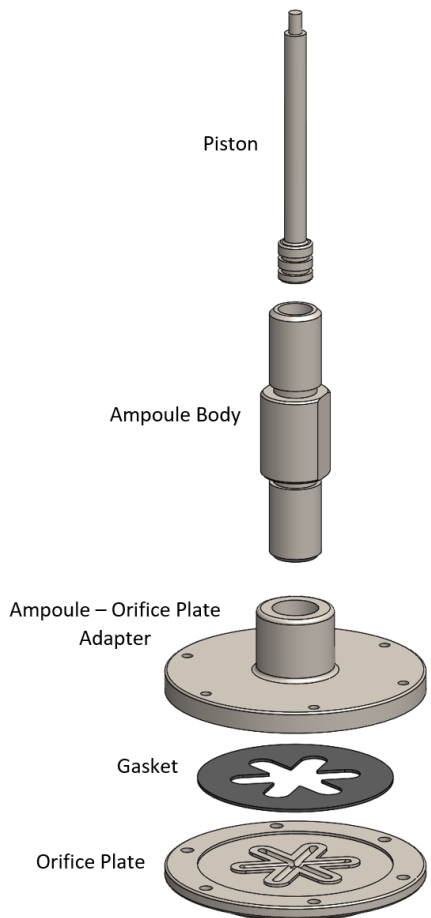


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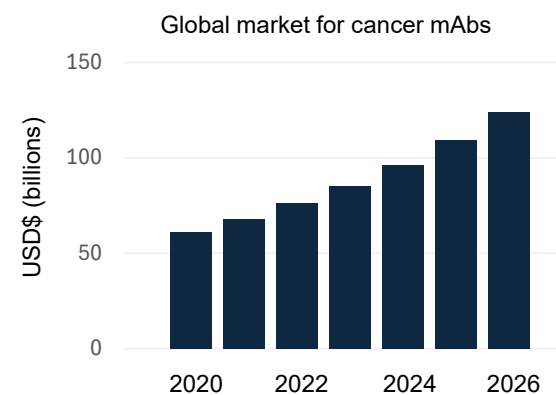
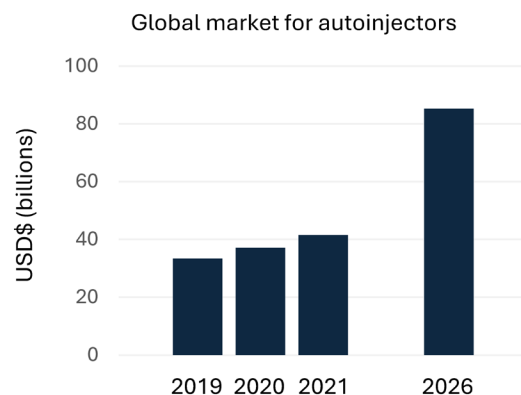
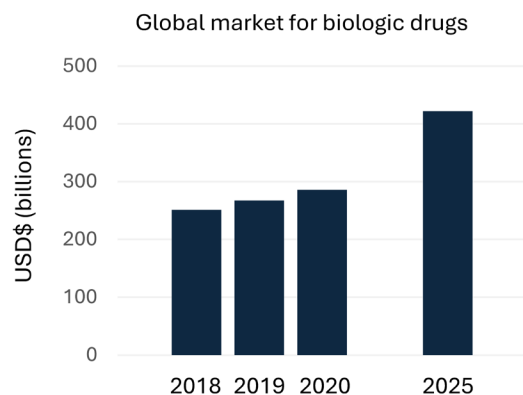
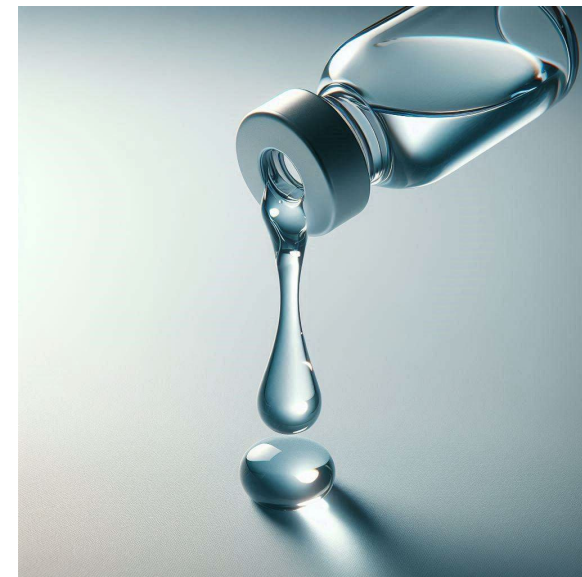
Platform technology for the rapid subcutaneous administration of large volumes.

- Hand-held device for rapid administration of up to >7 mL of liquid in <1 second
- This device will enable subcutaneous delivery of monoclonal antibody based treatments for improved patient experience and potentially enable home based self-delivery
 - Could also allow for extended patent life on current therapies through novel formulation and delivery mechanisms
- Current data pack includes *ex vivo* models of injection through pig skin
 - We can control the depth and spread of the injection by varying the speed, number, and size of the jets
- IP has been filed with a PCT application, priority date 1 September 2023



Biologic drugs – The problem with IV administration

- Biologic drugs count for 7 of the 10 top drugs (by sales)
 - US\$286 billion market (in 2020) growing at 8.1% CAGR
- Administration is one of the biggest problems in the field
 - Unable to be dosed orally
 - Often too high-volume/viscous for injection -> must be delivered IV
 - IV administration is responsible for 50% of the total treatment cost
 - Self administration is not feasible with IV



Alternative routes - Subcutaneous

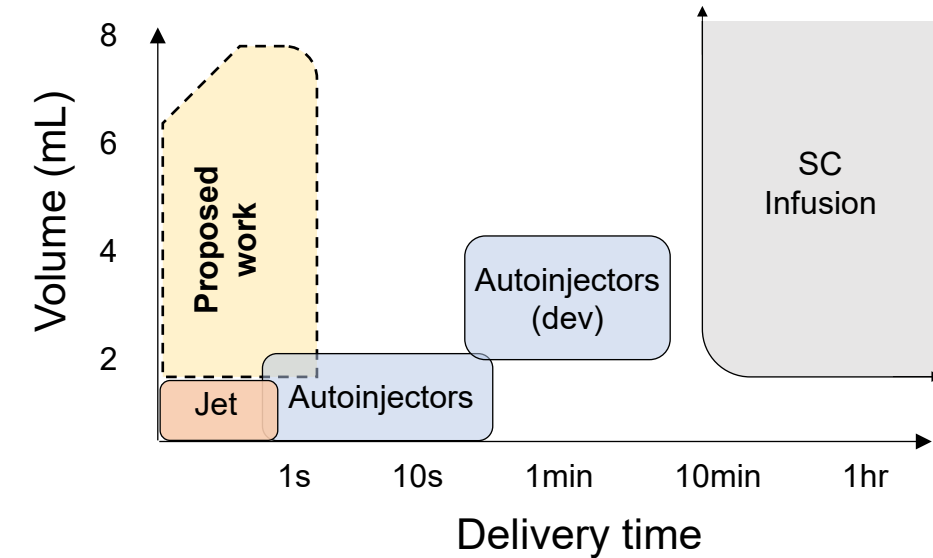
Subcutaneous can offer several advantages over intravenous

- Convenience, self-administration
- Improved patient experience
- Reduced dependency on hospital infrastructure, doctor/nurse time
- Lower healthcare costs

The problem:

Subcutaneous delivery via manual needle or autoinjector cannot handle:

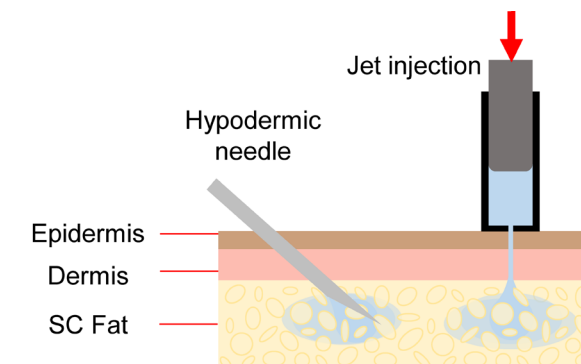
- volumes >2 mL
- highly viscous formulations



IV

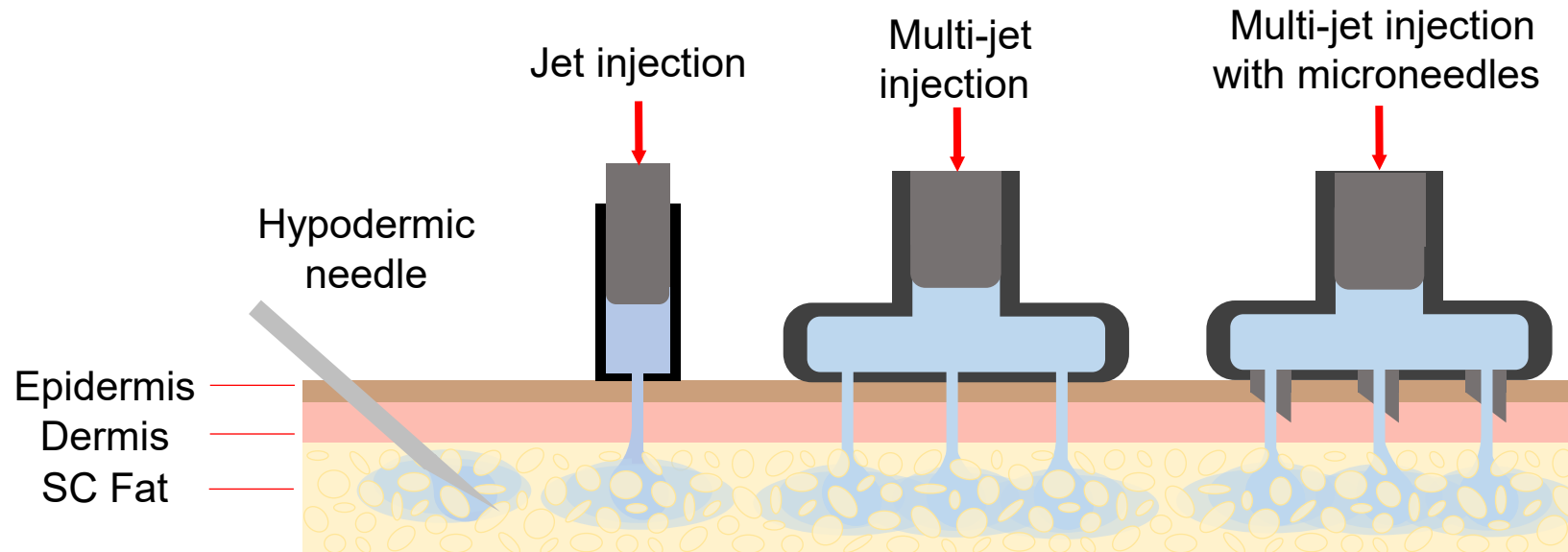


SC



Solution – Multi-jet injectors

- >7mL is able to be delivered through our multi-jet device
 - Avoids the volume limits of SC and Intramuscular by breaking the injection into many smaller injections
- Uses needle-free and/or microneedle technology to improve patient comfort
- Injections are over very quickly (<1 sec) (unlike other high-volume devices in development)



Multi-jet injectors can deliver higher volumes to a tunable depth

We have demonstrated (published or in-press):

- >2 mL needle-free
- >3.9 mL through microneedles

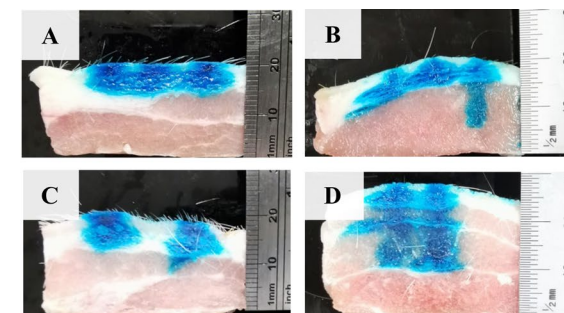
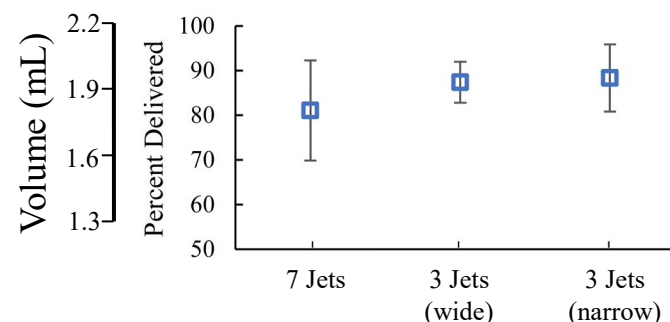
Unpublished results:

- >4 mL needle-free
- >7 mL through microneedles

Injection time less than 0.5 s in all cases

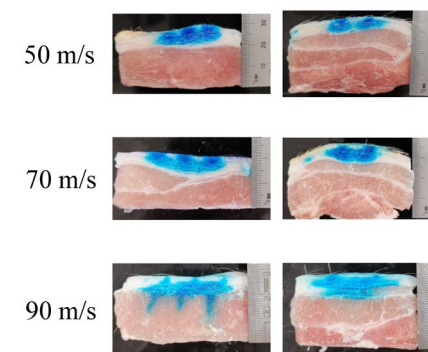
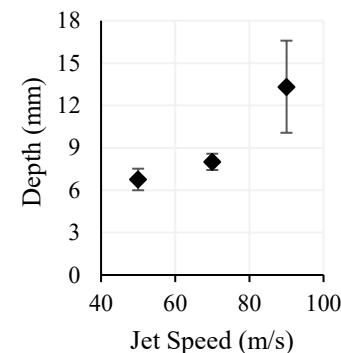
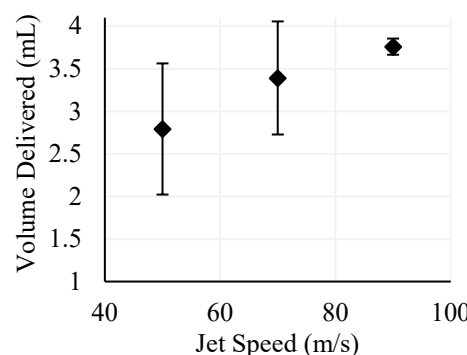
We can control the depth and spread of the injection by varying the speed, number, and size of the jets.

Needle-free



Left: Percent of 2.2 mL delivered into tissue samples with 7 jets, 3 jets (widely spaced), and 3 jets (narrowly spaced). Right: Injected samples that have been cut through the injection sites to visualize delivery

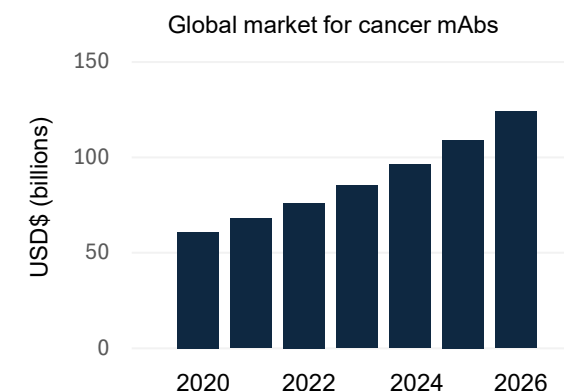
Microneedles



Left: Volume delivered (of 3.9 mL target) into tissue samples vs jet speed. Middle: Maximum depth of penetration into tissue samples vs jet speed. Right: Injected samples that have been cut through the injection sites to visualize delivery

Human health application: Initial product target

- Monoclonal antibodies for cancer therapy typically require 30min-90min infusions every 1-6weeks often for periods of >1year
- IV is standard but SC as an emerging route of administration has been shown to be safe and effective. Where available, SC formulations are large volumes (>5 mL) delivered very slowly (>7 minutes)
- Case study: Trastuzumab (approved 5 mL/600mg SC formulation)
 - A 2019 study estimated a direct cost saving of NZD\$1.1 million and a quantifiable economic benefit of NZD\$6.4 million when just 178 cancer patients were given SC Trastuzumab instead of the typical IV delivery
 - Current standard of care is IV. 900 patients received IV Trastuzumab in NZ in 2022, suggesting our device could facilitate \$5.5 million in direct cost savings and add NZD\$32 million in economic benefits to NZ per year from Trastuzumab alone
 - This device could transform the patient journey, empowering those patients to be able to administer treatment at home, saving both time and money
- Multi-jet injection could further improve delivery
 - Reducing SC delivery time to <1s
 - Improving patient/HCP experience of SC delivery. Facilitate SC becoming best practice
 - Remove need for hyaluronidase co-formulation



Value proposition - Stakeholders/Partners

Patients and health care professionals (HCPs)

- Improved patient adherence, satisfaction, and health outcomes through SC delivery and self-administration. SC delivery also reduces the time demanded from HCPs in administration and self-administration can avoid time lost to travel and wait times at hospitals
- Provides additional route of administration for hard to treat individuals (Patients with damaged veins)

Hospitals and Payors

- Significantly reduce treatment costs compared to traditional IV administration
 - IV administration is estimated to be responsible for 50% of the total treatment cost
- Increased availability of nursing staff and space to enable better patient care of high risk patients
- Reduced wait times at hospitals

Pharma/drug company (Exit)

Our proposed exit is to partner with or license to a pharma company to enable SC delivery of their mAb

- Competitive advantage to enable SC delivery of the therapeutic and the associated cost savings to both patients and HCPs
- Provide additional patent life to mAb therapies through novel formulation and delivery
- Remove need to co-formulate with hyaluronidase
- Developing/enabling SC administration is recognised as an area of interest by pharma companies
 - <https://www.roche.co.nz/innovation/subcutaneous-therapy-roche>
- We anticipate this is will be a class 2 medical device under the FDA guidance document for pen, jet, and related injectors, but it will also fall under the NDA as the delivery vehicle of the new formulation

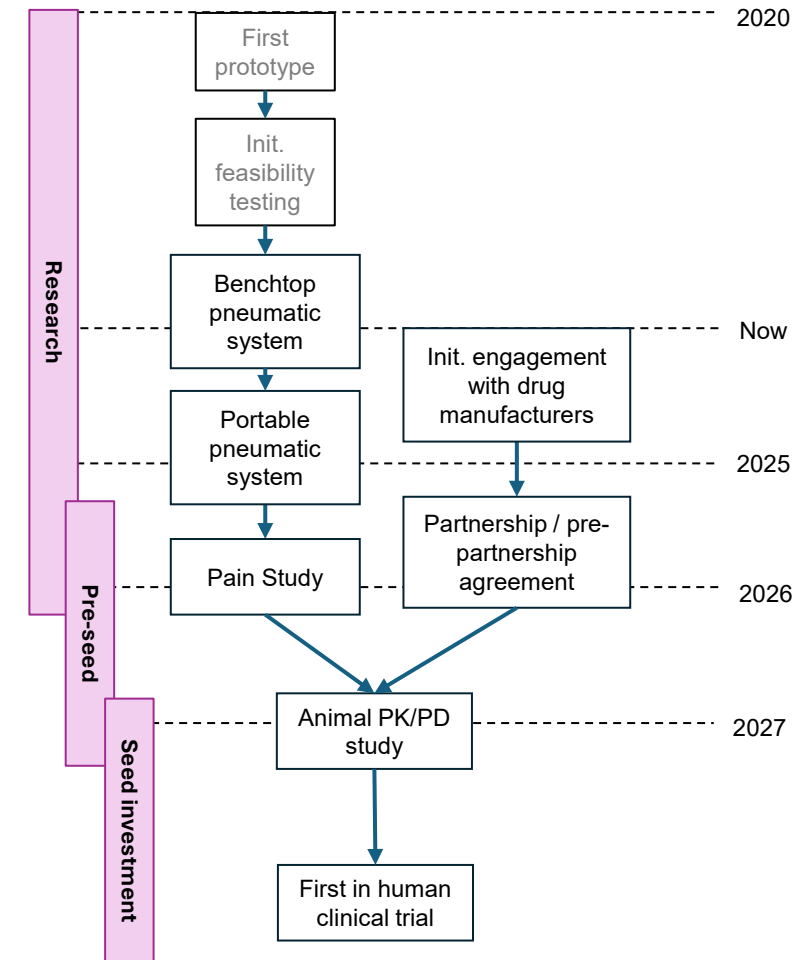
Short-medium term strategy: Gather evidence of patient and clinician acceptance of our device, and multi-jet injection generally, in one or more initial applications

Long term strategy: Partner with a drug company to improve delivery of a current marketed drug OR enable a bespoke delivery system for a novel drug as a key value add

Regulatory strategy: We will target drugs needing to go through regulatory path anyway for development of drug-device combination product (e.g. new drug, or new formulation to extend patent life)

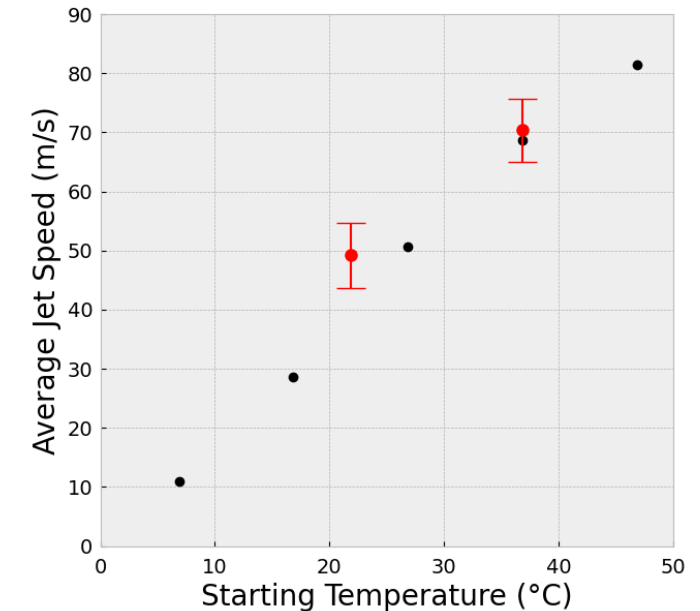
Key milestones

1. Develop a clinically suitable prototype
2. Perform pain/acceptance study injecting saline into volunteers
3. Animal PK/PD study
4. Perform proof-of-concept clinical trial(s)
 - What type of proof-of-concept evidence would future drug development partners find convincing?



Additional development – Warming function

- Warming a very viscous liquid can make it much less viscous.
- Has potential to introduce stability issues for therapeutics if sustained too long OR heated too rapidly OR too high temperature.
- “Just-in-time” heating of jet injection will allow drugs of 10x-100x greater viscosity to be injected subcutaneously, thus avoiding the need to dilute these compounds into volumes requiring IV administration.
- Being able to accurately bring an injectable to body temperature just before injection will not only increase injectability, but also increase patient comfort



99% glycerol has a viscosity of ~1000 cP at room temperature. 10x-100x more viscous than what is currently injected

Contact us

If you wish to know more, please
get in touch

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