BAYWIND
BIOVENTURES
BUSINESS INVESTMENT ADVISORY
SubQ BIOLOGICS™
NANO / MICRO-PARTICLE TECHNOLOGY PLATFORM
www.baywindbio.com

INTRODUCING SubQ BIOLOGICS™

BAYWIND BIOVENTURES

Nano / Micro-Particle Formulation Technology

- Modulate solubility & dissolution properties of biologics
- Extended-release injectables for long-lasting PK profiles
- Improved bioavailability and injection site tolerability
- Improved biologics stability

Formulation Composition and Process

- GRAS excipients with varying physicochemical properties
- Formulation with 35 to 70% active drug (remainder GRAS)
- Efficient manufacturing process with >80% yield

Applications

- Peptide, protein, antibody, oligonucleotide (RNAi, siRNA, DNA, mRNA), and mucopolysaccharide

COMMERCIAL PRECEDENTS

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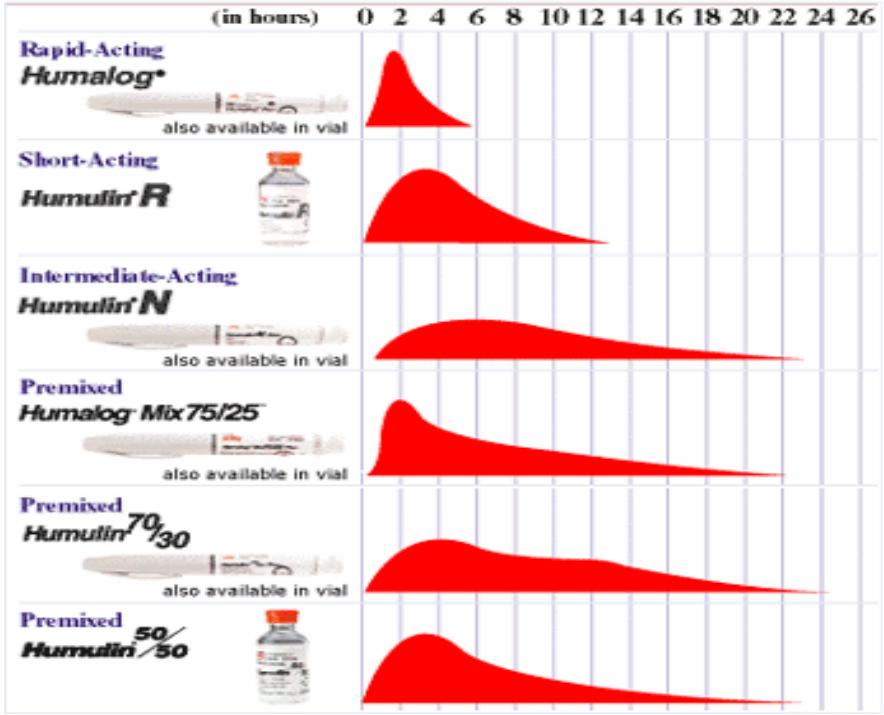
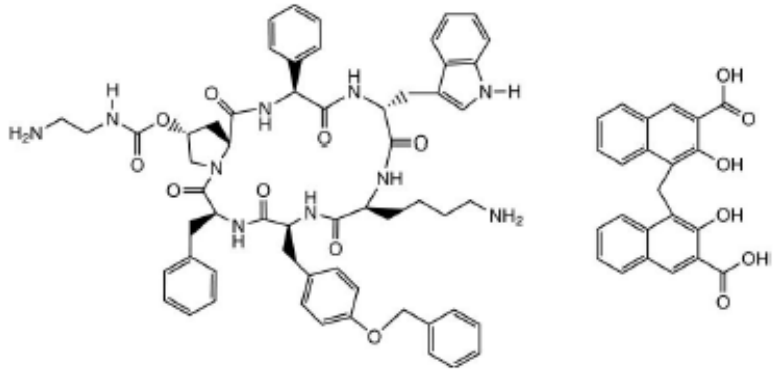
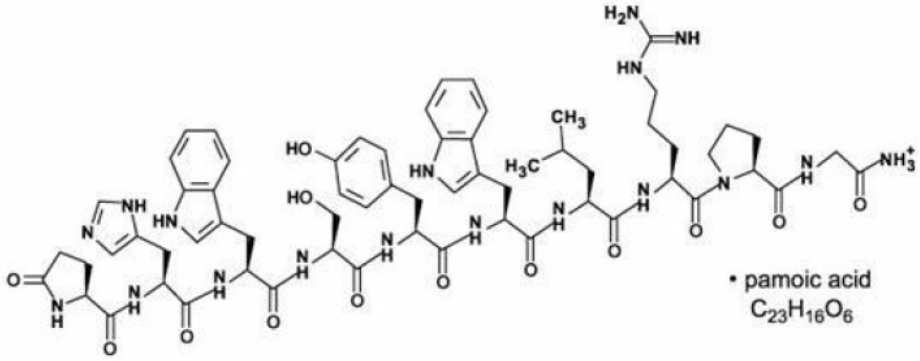
Mixes of Zinc Insulin Suspended in Insulin Solution



Signifor LAR (approved 2012)
pasireotide pamoate in PLGA microspheres



Trelstar (approved 2000)
triptorelin pamoate in PLGA microspheres



SubQ BIOLOGICS™ FORMULATION

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Drug Substance

Nano / Micro-Particle Process

Hydrophobic or hydrophilic ligands and/or metal counterions

Simple water based precipitation process with particle size control

Nano/ Micro-particle

Analysis

- Purity and drug content
- In vitro dissolution
- GRAS excipient content
- Solids characterization

Nano / Micro-Particles

- Composition based on properties of the biologic
- Excipients from handbook of pharmaceutical excipients and GRAS list

CHARGED AND HYDROPHILIC COUNTERIONS
Glutamate
Glycinate
Lysinate
Citrate
Succinate
Tartrate

HYDROPHOBIC COUNTERIONS
Deoxycholate
Oleate
Stearate
Nicotinate
Palmitate
Octanoate

+

COMPLEXING AGENTS
Bivalent Metal ions (Zn^{2+}, Ca^{2+}, etc…)

EXTENDED RELEASE PROJECTS

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Compound Type	MW (kDa)	Injection Frequency	Liposome	Salt	Gel	Microsphere
Peptide	1,1.2	Weekly to Monthly		✔	✔	✔
Peptide	2	>4 Months		✔	✔	
Peptide	3,4	Daily		✔		
Peptide	4, 5	Weekly to Monthly		✔	✔	✔
Peptide	4	Weekly to Monthly		✔	✔	
Insulin	6	Daily to Weekly	✔	✔		
Oligonucleotide (nano to micro particle)	8	Weekly		✔		
Oligonucleotide (3 in combination)	10	Weekly				✔
Protein	15	Weekly		✔	✔	
Protein	50	Weekly	✔		✔	
Antibody	150	Weekly		✔		

Salt = SubQ Biologics proprietary nano/micro partlcle technology

SubQ BIOLOGICS™ PROGRAMS

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Peptides

- Numerous partnerships
- 1 to 6 weeks PK (rat and dog)

Proteins

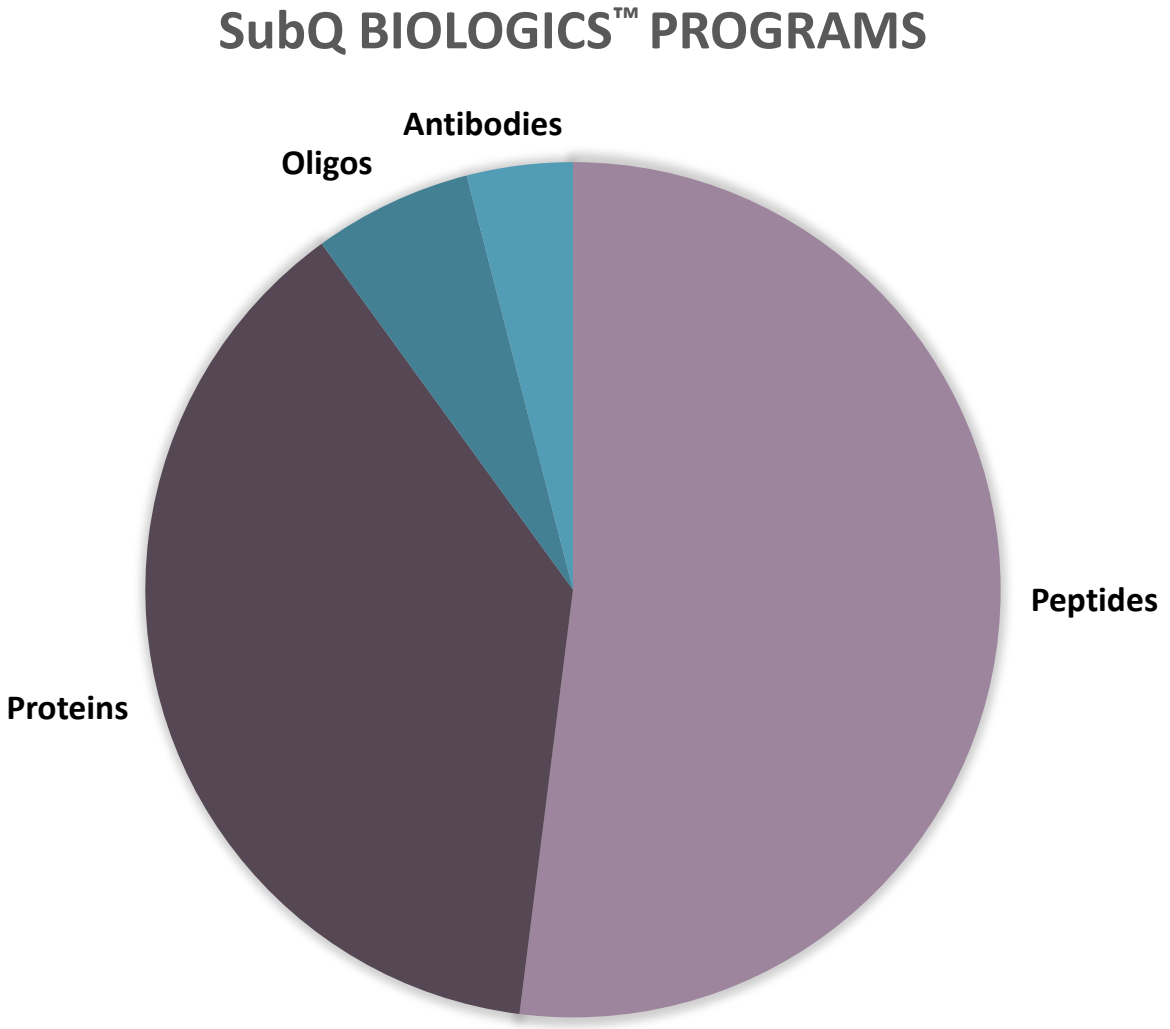
- Up to 1 week PK (rat and mouse)
- Improved injection site reaction

Oligonucleotides

- ASOs for T1DM reversal and CNS
- Mouse tox study data

Antibodies

- Immediate release microparticles
- Extended release to > 1 week



PEPTIDE WEEKLY+ FORMULATIONS

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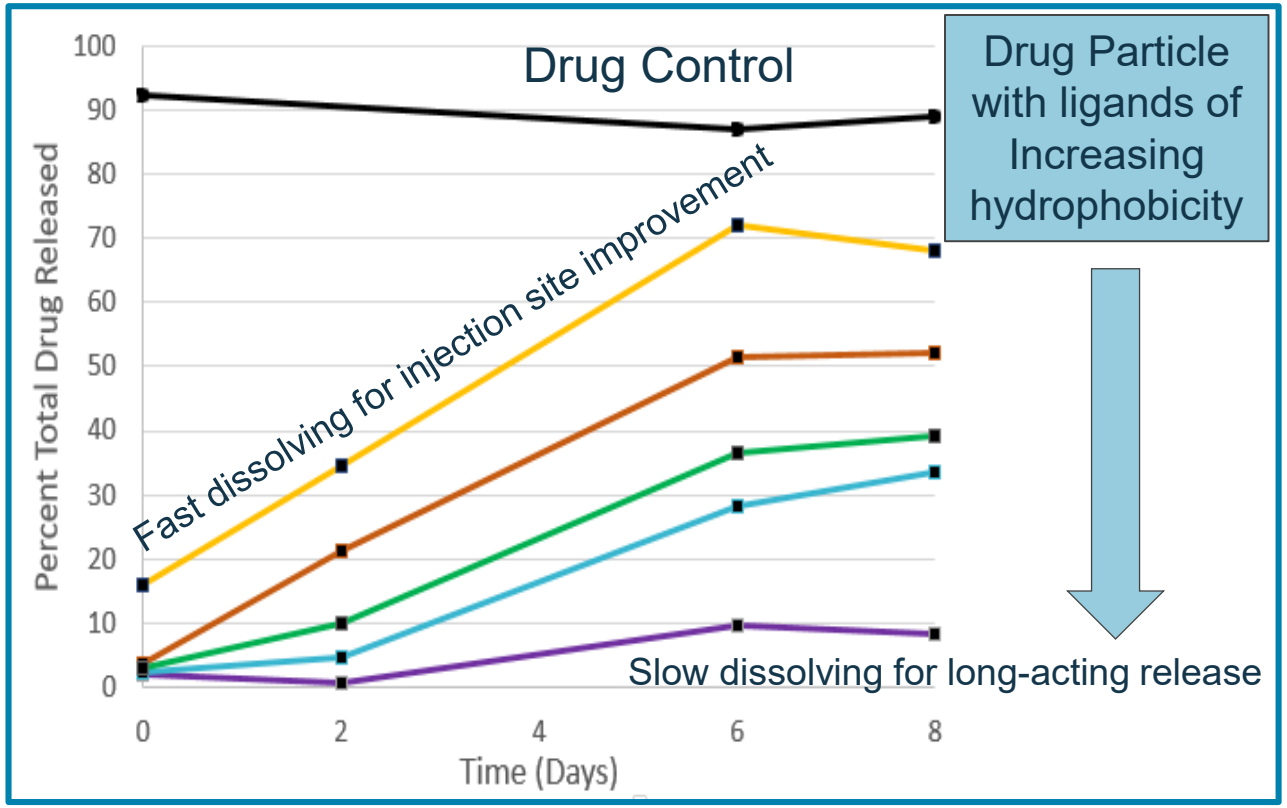
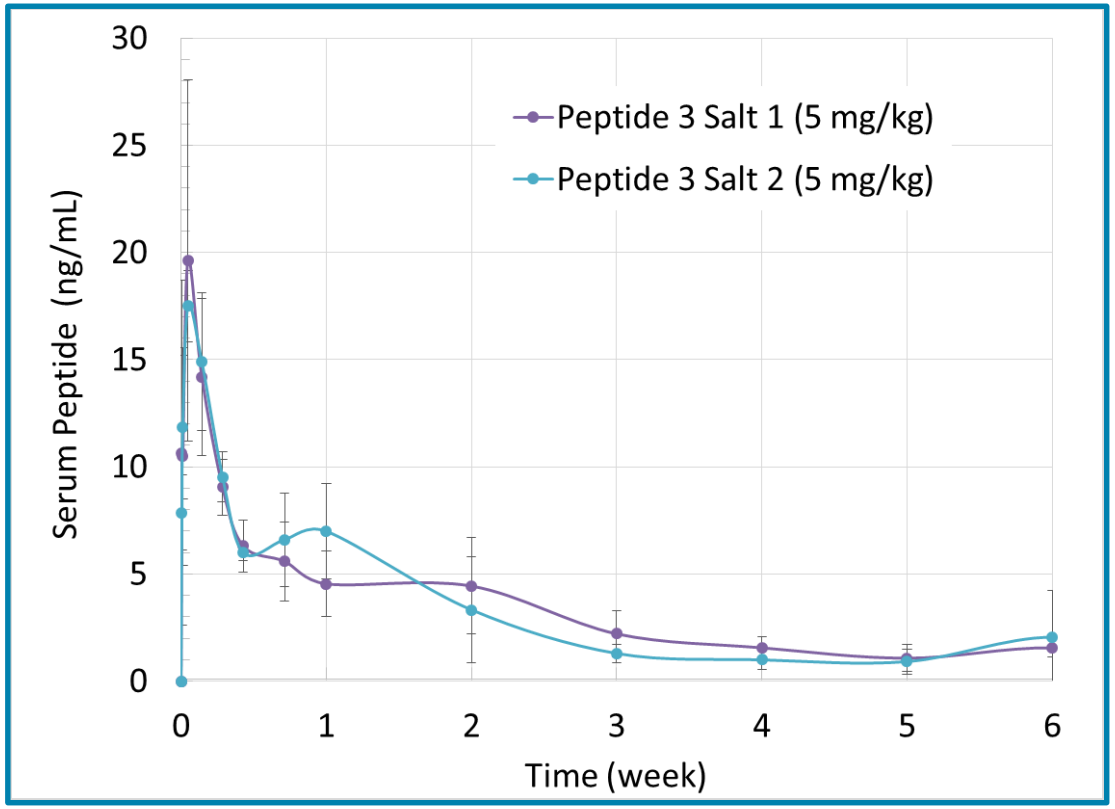
In Vitro Dissolution PBS 37°C



Pharmacokinetics in Rat



PROTEIN IMMEDIATE AND EXTENDED RELEASE FORMULATIONS

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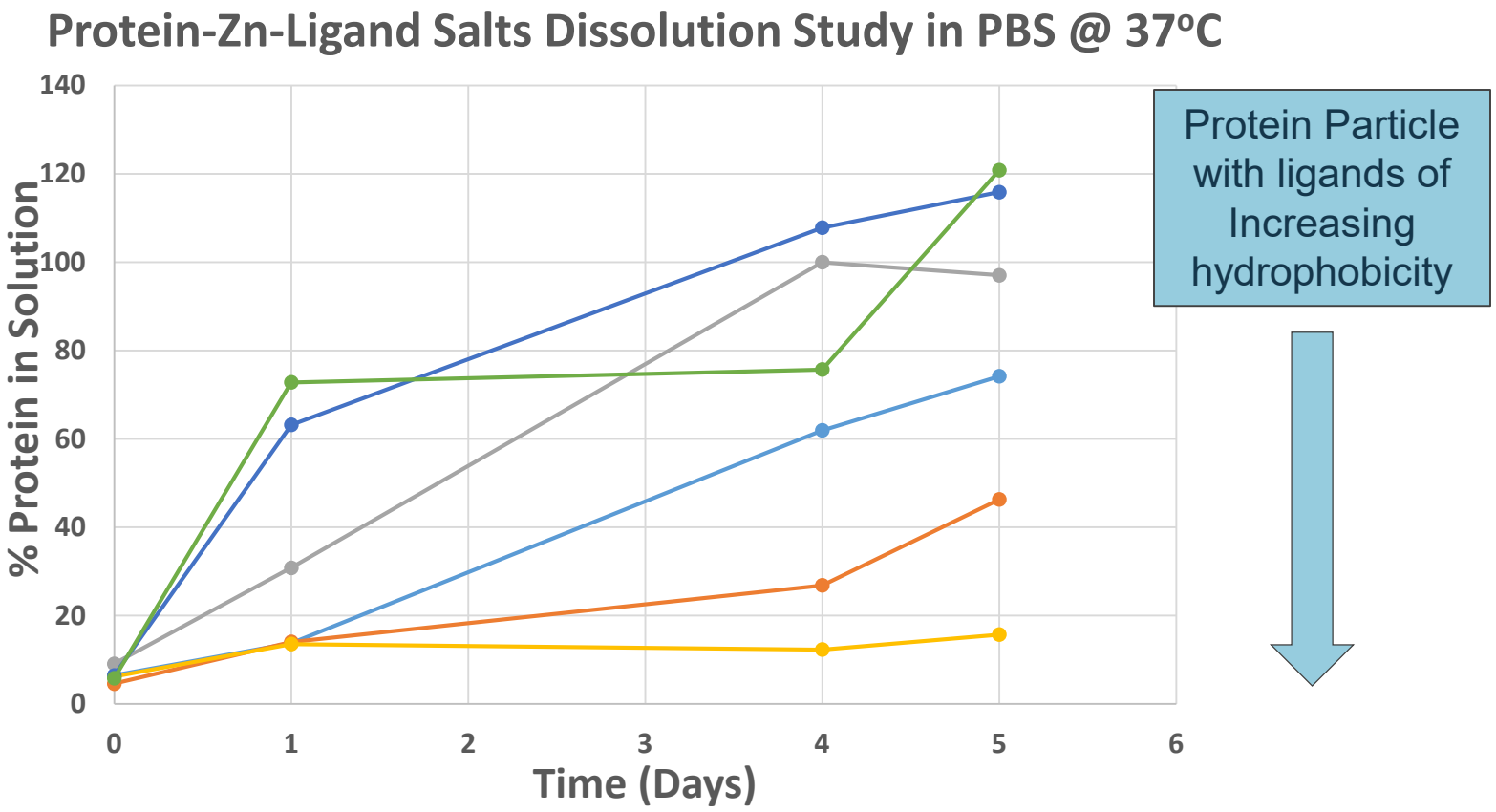
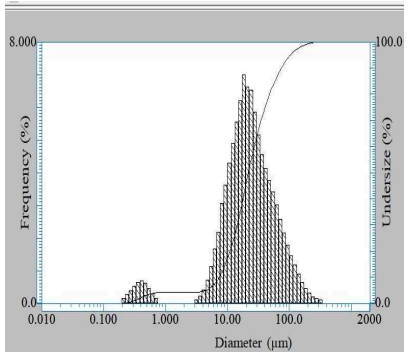


Protein Particle with ligands of Increasing hydrophobicity

Protein-Zn-Ligand Characterization

- **Particle size distribution**
- **Microscopy**
- **HPLC purity and potency**
- **HPLC-SEC**



HIGH CONCENTRATION ANTIBODY

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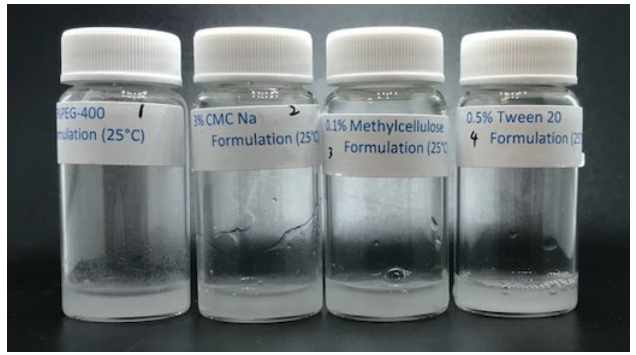
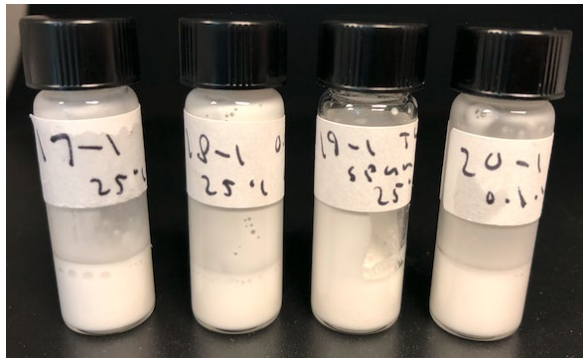
IV to SC Switch Using Nano / micro-Particle Formulation

Injection	Volume Limit	Concentration	Antibody Dose
Subcutaneous	1 mL	300 mg/ml	300 mg
Intramuscular	2 mL	300 mg/ml	600 mg

2 mg/ml suspension



300 mg/ml suspension



SubQ™ BIOLOGICS PARTNERS

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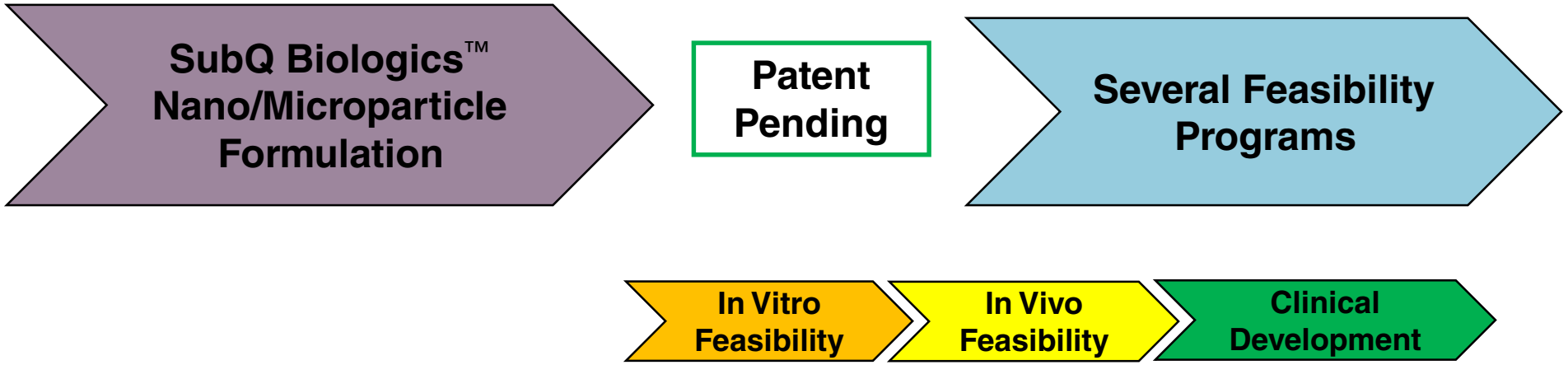

Partner Programs*	Indication	Molecule	Program Status	Partnered
4-Month gel injection	Urology	Peptide		Feasibility Partner
Weekly micro-particle	Rare disease	Protein		Feasibility Partner
Weekly micro-particle	Endocrine	Peptide		Feasibility Partner
Nano-particle project	CNS	Oligo		Feasibility Partner

*Partner programs have not been publicly disclosed

SubQ™ BIOLOGICS INTERNAL R&D

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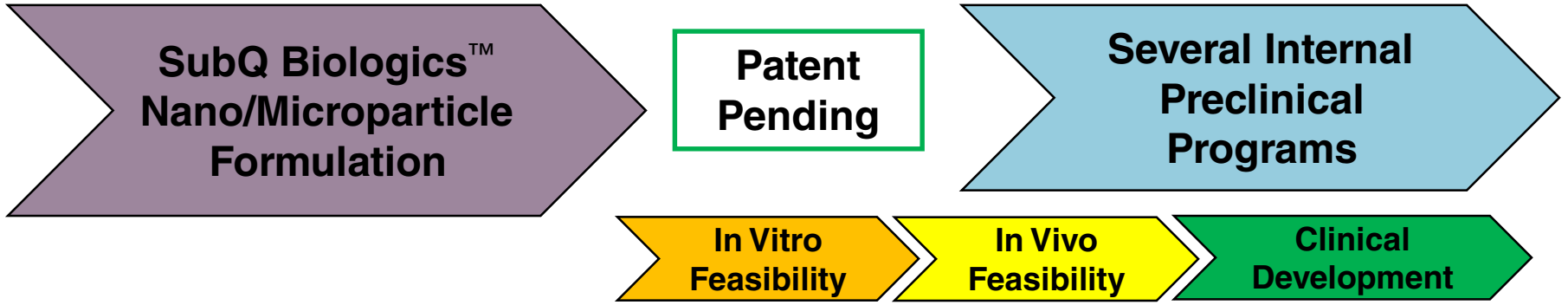

Programs	Indication	Molecule	Program Status	Partner
Weekly GI Peptides: Exen, Pram, Ins, Gluc, GIP	Diabetes	Peptide		TBD
Dual Triple Combo	Diabetes	2-3 Peptide		TBD
IV to SC Switch	Oncology	Protein		TBD
Long-Acting Biologic	Oncology	Protein		TBD
Nanoparticle pH Triggered Release	TBD	Oligo		TBD

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DELIVERY TECHNOLOGY INCUBATOR

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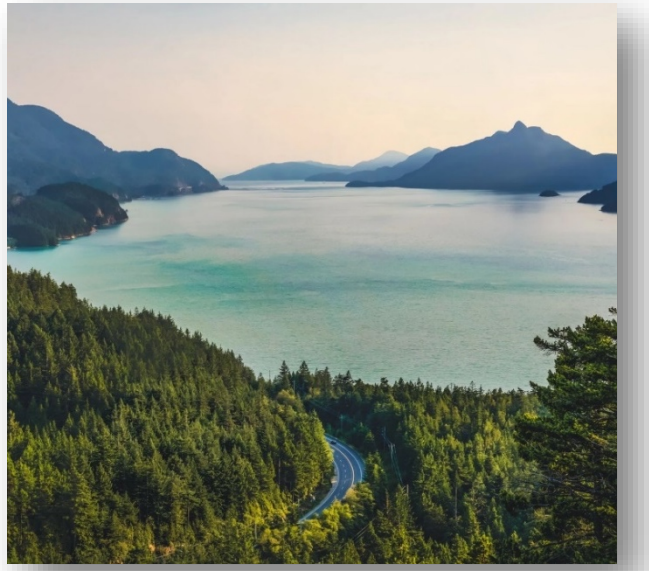
Novel delivery platform technologies

- Novel delivery system R&D
- Delivery enabled products
- Areas with significant unmet need



Funding Strategy

- Internal funding to preclinical proof of concept
- External funding for clinical proof of concept
  - Pharma partners or investors

DDE LABS PARTNERSHIP

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- DDE Labs is a state-of-the-art R&D lab in the heart of San Diego biotech
- Experts in injectables and combination product development
- Baywind Bio leverages DDE's talent and resources as technology incubator
- SubQ Biologics™ patents filed and now in pre-clinical development